Document Coversheet

Study Title: Human Perception of Odors and Odor Blockers

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	1/5/2026
NCT Number:	NCT06191419
IRB Number	43123
Coversheet created:	4/29/2026

IRB Approval
1/5/2026
IRB # 43123
IRB3

IMPORTANT NOTE:

If you accidentally select the wrong IRB type or "Protocol Process Type" while your Initial Review (IR) application is in draft form (unsubmitted), you may change your selections. Please contact the Office of Research Integrity (ORI) at 859-257-9428, IRBsubmission@uky.edu, or request a consult to resolve any questions regarding your selections *prior* to submitting your Initial Review application.

If your **submitted IR application has been returned to you for requested revisions or additional information,** to streamline the review process **do not make changes** to your selections here **unless instructed to do so by the ORI/IRB.**

Changes to this section cannot be made after initial approval has been issued (the option is not available for MR or CR).

For guidance, see:

- Which IRB should review my research?
- Which Protocol Process Type?
- "Getting Started"

Which IRB

(•) Medical ( ) NonMedical

Protocol Process Type

( ) Exemption
(•) Expedited (Must be risk level 1)
( ) Full

The revised Common Rule expanded exemption certification category 4 for certain secondary research with identifiable information or biospecimens. The regulations no longer require the information or biospecimens to be existing. For more information see the Exemption Categories Tool.

EXPEDITED CERTIFICATION

0 unresolved comment(s)

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

A. Research activities that (1) present no more than *minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
B. The categories in this list apply regardless of the age of subjects, except as noted.
C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
D. The expedited review procedure may not be used for classified research involving human subjects.
E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

**"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. 45 CFR 46.102(i)*

Check the appropriate categories that apply to your research project:

☐ Study was originally approved by the full IRB at a convened meeting.

☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

A. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
B. Research on medical devices for which (i) an investigational device exemption application is not required*; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

* Study must meet one of the IDE Exempt categories listed on the Device Form Attachment.
** An approved Device used in research according to its approved labeling is considered Exempt from IDE requirements.
NOTE: Select Category 1 for compassionate use medical device applications or individual patient expanded access investigational drug applications for which FDA has waived the requirement for full review.

☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

A. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
B. From other adults and children* considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

NOTE: Intravenous (IV), Port, Central, or any other lines are NOT eligible under this category even if the research involves "minimal risk".

*In Kentucky, "child/children" refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Informed Consent SOP for discussion of "Emancipated Individuals" under Kentucky state law.) Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., DHHS, FDA, and U.S. Department of Education). Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." If conducting research outside the state of Kentucky, you are responsible for complying with applicable state law.

☐ 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

A. Hair and nail clippings in a nondisfiguring manner;
B. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
C. Permanent teeth if routine patient care indicates a need for extraction;
D. Excreta and external secretions (including sweat);
E. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
F. placenta removed at delivery;
G. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
H. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
I. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
J. Sputum collected after saline mist nebulization.

☑ 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

A. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
B. Weighing or testing sensory acuity;
C. Magnetic resonance imaging;
D. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
E. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ 5) Research involving materials (data, documents, records, or specimens) that have been or will be collected solely for non-research purposes (such as medical treatment or diagnosis) as well as research involving existing information or specimens that were previously collected for research purposes, provided they were not collected for the currently proposed research. (Note: Some research in this category may qualify for Exempt review. This listing refers only to research that is not exempt.)
(Note: If submission includes materials previously collected for either non-research or research purposes in a protocol for which IRB approval expired, you may check Category 5. However, a separate category must also be selected for prospective collection of data/specimens obtained solely for research purposes)

☐ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☑ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

CONTINUATION REVIEW/FINAL REVIEW

0 unresolved comment(s)

In accordance with federal regulations and/or local policies, the IRB conducts periodic review of all currently approved projects. If you need your IRB approval to continue and you do not complete and submit the required materials in a timely manner, IRB approval will expire at the end of your current approval period.

If you have any questions, please contact the Office of Research Integrity at 859-257-9428 or email IRBsubmission@uky.edu.

To initiate your continuation review (CR)/annual administrative review (AAR), or properly close your study, complete this section and update/correct all other sections of your IRB application as applicable.
*****IMPORTANT*** Before leaving this page to update other sections of your application, be sure to SAVE this section first.**

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1. Status of the Research

Check the statement(s) that best describe(s) the current status of your research:

- ☐ No subjects have enrolled to date.
- ☑ Recruitment and/or enrollment of new subjects or review of records/specimens continue.
- ☐ Study is closed to enrollment, but subjects still receive research-related interventions (e.g., treatment, blood draws).
- ☐ Study enrollment is permanently closed; subjects have completed all research-related interventions; and the study remains active only for long-term follow-up of subjects (see Tool Tip above for info on long-term follow-up of subjects).*
- ☐ Research has progressed to the point that it involves 1) Data analysis, including analysis of identifiable private information or identifiable biospecimens; and/or 2) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.*
- ☐ The remaining research activities are limited only to data analysis. There is access to records or specimens either directly or through codes or links to the data.*
- ☐ The remaining research activities are limited only to data analysis. There is no subject/record/specimen identifying codes or links to the data; the researcher or research team cannot readily ascertain the subject's identity.*
- ☐ All study activities are complete. IRB approval can be inactivated.

*Possibility that review will move from Full to Expedited.

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2. If subjects have been enrolled within the last year, and the IRB approved a consent/assent form for your study:

Please attach a complete, signed copy for the last two subjects enrolled with **each** consent/assent form/HIPAA form since the last annual review.
(Example: If 3 different approved consent forms were used since the last annual review, please provide the two most recent signed copies of each version for a total of six.)

Attachments

Attach Type	File Name
Entire Signed Consent Form	Consent 2 Smoker 25.pdf
Entire Signed Consent Form	Consent 1 Smoker 25.pdf
Entire Signed Consent Form	Consent 1 SplitNostril 25.pdf
Entire Signed Consent Form	Consent 2 SplitNostril 25.pdf
Entire Signed Consent Form	Consent 3 smoker stamped.pdf

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3. Informed Consent

If the study is **open to subject enrollment, please go to the Informed Consent section of the E-IRB Application and verify attachment(s) include:**

- One clean copy in PDF (without the IRB Approval stamp) of the currently approved consent/assent document(s), or,
- If requesting changes to the consent/assent document(s), submit one copy with the changes highlighted (and designate Document Type as "Highlighted"), and one clean copy in PDF (without the changes highlighted).

If the study is **open to subject enrollment and the IRB has waived the requirement to document informed consent, please go to the Informed Consent section of the E-IRB Application and verify attachment(s) include:**

- One clean copy in PDF of the currently approved document used for the informed consent process (e.g., cover letter, phone script), or,
- If requesting changes to the consent/assent document(s), submit one copy with the changes highlighted (and designate Document Type as "Highlighted"), and one clean copy in PDF (without the changes highlighted).

If the study is **closed to subject enrollment, please go to the Informed Consent section of the E-IRB Application and remove Informed Consent Documents designated to get an IRB approval stamp to avoid having them appear valid for enrollment.**

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4. Unanticipated Problems Involving Risk to Subjects or Others/Adverse Events Summary & Assessment

Did any **problems/adverse events** occur during the last 12 months?

○ Yes ◉ No

In the space below, provide a written summary of both unanticipated problems* and available information regarding adverse events since the last review (e.g., initial review or annual/continuing review). The amount of detail provided in such a summary will vary depending on the type of research being conducted; in many cases, such a summary could be a brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and investigator's brochure (if applicable). **The summary must include the PI's assessment whether the problems/adverse events warrant changes to the protocol, consent process, or risk/benefit ratio.**

Note: It is the IRB's expectation that all unanticipated problems involving risk to subjects or others or related deaths requiring prompt reporting are submitted in the appropriate time frame (See Policy [PDF]). Your response to this Annual/Continuing Review is considered assurance that all prompt reportable problems/adverse events have been submitted for IRB review.

*For multisite studies, the written summary should describe external events determined to be unanticipated problems involving risk to subjects or others.

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5. Subject Info To-Date

Our records for the previously approved IRB application indicate the **IRB approved estimate** of subjects to be enrolled (or records/specimens reviewed) is:

710

Enter the number of enrolled subjects (or records/specimens reviewed) that **have not been previously reported** to the IRB

107

Our records for the previously approved IRB application indicate the previous total # of subjects enrolled (or records/specimens reviewed) since activation of the study is:

153

The new total number of subjects enrolled (or records/specimens reviewed) since activation of the study:

260

Please review the Project Info section for the IRB approved estimate of subjects to be enrolled (or records/specimens reviewed). If this new total exceeds your approved estimate of subjects to be enrolled (or records/specimens reviewed), please update the number in the field for Number of Human Subjects in the Project Info section.

6. Data and Safety Monitoring Board (DSMB)/Plan (DSMP)

If your study is monitored by a DSMB or under a DSMP, attach all documentation (i.e. summary report; meeting minutes) representing Data and Safety Monitoring activities that have not been previously reported to the IRB.

Attachments

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7. Since the most recent IRB Initial/Continuation Review Approval:

Have there been any **participant complaints** regarding the research?

○ Yes ◉ No

If yes, in the field below, provide a summary describing the complaints.

Have any **subjects withdrawn** from the research voluntarily or by you as the PI for reasons related to safety, welfare, or problems related to the conduct of the research? If a participant does not meet the screening criteria for a study even if they signed a screening consent it is NOT considered a withdrawal.

○ Yes ◉ No

If yes, in the field below, provide a detailed explanation to the withdrawal(s) including if participants were lost to contact.

Has any **new and relevant literature** been published since the last IRB review, especially literature relating to risks associated with the research?

○ Yes ◉ No

If yes, attach a copy of the literature as well as a brief summary of the literature including, if pertinent, the impact of the findings on the protection of human subjects.

Attachments

Have there been any **interim findings?**

◉ Yes ○ No

If yes, attach a copy of **Interim Findings**.

Attachments

Attach Type	File Name
Interim Findings	Interim findings 2025.pdf

Have **subjects experienced any benefits?**

○ Yes ◉ No

If yes, in the field below, provide a description of benefits subjects have experienced.

Have there been any **inspections/audits/quality improvement reviews** of your research protocol resulting in the need for corrective action in order to protect the safety and welfare of subjects?

○ Yes ◉ No

If yes, please attach documentation evidencing the outcome(s) and any corrective action(s) taken as a result.

Attachments

Was an FDA 483 issued as a result of any inspections/audits?

○ Yes ◉ No

If yes, submit documentation using attachment button above.

8. Risk Level:

Our records for the previously approved IRB application show your research is:

Risk Level: 1

Has something during the course of your research changed the level of risk?

○ Yes ◉ No

If yes, go to the Risk Level section, mark the appropriate risk level, and in the field below, describe why the risk level has changed:

9. Funding/Support:

Our records for the **previously approved** IRB application indicate your research is being submitted to, supported by, or conducted in cooperation with the following external or internal agency(ies) or funding program(s):

- ☐ Grant application pending
- ☐ (HHS) Dept. of Health & Human Services
  - ☐ (NIH) National Institutes of Health
  - ☐ (CDC) Centers for Disease Control & Prevention
  - ☐ (HRSA) Health Resources and Services Administration
  - ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☑ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Other:

Please **update the Funding/Support section of your IRB application** if needed, including the following attachments if they contain changes not previously reported to the IRB:

- A current copy of your **protocol if you are conducting industry/pharmaceutical research;**
- A current **Investigator Brochure** (submit a copy with all changes underlined).
- A **new or revised grant application** for this project.

Did your project receive extramural funding?

○ Yes ◉ No

If yes, please review and correct if necessary, the OSPA Account # information under the **Funding/Support section** of your IRB application.

If the project is externally funded, has the sponsor offered any of the research team enrollment incentives or other personal benefit bonuses? (e.g., cash/check, travel reimbursements, gift checks, etc.)

○ Yes ○ No ◉ N/A

Note: It is University of Kentucky policy that personal benefit bonuses are not allowed. If these conditions change during the course of the study, please notify the IRB.

10. Project Information

Our records for the previously approved IRB application indicate your estimated project end date is:

12/31/2026

If you have a new estimated project end date, please go to the Project Info section and change the date in the field for Anticipated Ending Date of Research Project.

11. Study Personnel

Our records for the previously approved IRB application indicate the following individuals are study personnel on this project (if applicable):

Last Name	First Name
Anaya	Paul
Ashford	Kristin
Burris	Jessica
Campbell	Kenneth
Frazier	Abby
Han	Dong
Hawk	Gregory
Isaacs	Jennifer
Kotter	John
Rakesh	Gopalkumar
Schenk	Ashley
Sorrell	Vincent
Stoops	William

Please review the individuals listed above and update your records as needed in the Study Personnel section of the E-IRB application, being sure that each individual listed has completed or is up-to-date on the mandatory human research protection training [see the policy on Mandatory Human Subject Protection Training FAQs (required every three years)].

12. Progress of the Research

To meet federal requirements the IRB is relying on your RESEARCH DESCRIPTION as a protocol summary and their expectation is that it is up-to-date. If the currently approved protocol (or research description) in your E-IRB application is outdated, please make applicable changes, and describe in the field below any substantive changes and explain why they are essential. If none, insert "N/A" in the text field below. If you are closing your study, you may use the space below to summarize the final status of the research.

N/A

Note: No changes in the research procedures should have occurred without previous IRB review. Approval from the IRB must be obtained before implementing any changes.

Provide a brief **summary** of any **modifications that affect subject safety and/or welfare** approved by the IRB since the last initial or continuation review (If none, insert "N/A" in the text field below.):

N/A

Attach one copy of the most recent progress report sent to the FDA, if available. All PI-sponsored IND/IDE studies are required to submit a copy of the FDA progress report.

Attachments

13. Confidentiality/Security

Review your Research Description section and update the Confidentiality portion, if necessary, to describe measures for security of electronic and physical research records (e.g., informed consent document(s), HIPAA Authorization forms, sensitive or private data).

14. Subject Demographics

Our records for the previously approved IRB application indicate the following categories of subjects and controls are included in your research:

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☑ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking
- ☐ International Citizens
- ☑ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☐ Patients
- ☐ Appalachian Population

Please review the Subject Demographics section of your IRB application for accuracy, and note the following:

If during the course of your research 1) any prisoners have been enrolled, OR 2) subjects have been enrolled that became involuntarily confined/detained in a penal institution that have not been previously reported to the IRB, go to Subject Demographic section in your E-IRB application and mark “prisoners” in the categories of subjects to be included in the study, if it is not already marked.

Note: If either 1 or 2 above apply, and you have received funding from the Department of Health and Human Services (HHS), a Certification Letter should have been submitted to the Office for Human Research Protections (OHRP); prisoners and individuals who have become involuntarily confined/detained in a penal institution cannot continue participation in the research until OHRP issues approval. If the Certification has not been submitted, contact the Office of Research Integrity.

Based on the **total # of subjects** who have enrolled, complete the subject demographic section below:

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native				
Asian	10	26		
Black or African American		3		
Latinx	5	17		
Native Hawaiian or Other Pacific Islander				
White	82	113		
American Arab/Middle Eastern/North African	1	2		
Indigenous People Around the World				
More than One Race		1		

Unknown or Not Reported				

If unknown, please explain why:

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15. Research Sites

Our records for the previously approved IRB application indicate that you are conducting research at the following sites:

UK Sites

- [x] UK Classroom(s)/Lab(s)
- [ ] UK Clinics in Lexington
- [ ] UK Clinics outside of Lexington
- [ ] UK Healthcare Good Samaritan Hospital
- [ ] UK Hospital

Schools/Education Institutions Schools/Education Institutions

- [ ] Fayette Co. School Systems *
- [ ] Other State/Regional School Systems
- [ ] Institutions of Higher Education (other than UK)

Other Medical Facilities

- [ ] Bluegrass Regional Mental Health Retardation Board
- [ ] Cardinal Hill Hospital
- [ ] Eastern State Hospital
- [ ] Nursing Homes
- [ ] Shriner's Children's Hospital
- [ ] Other Hospitals and Med. Centers

- [ ] Correctional Facilities
- [ ] Home Health Agencies
- [ ] International Sites

Other:

If the above listed sites are not accurate, go to the Research Sites section of the E-IRB application to update the facilities at which research procedures have been or will be conducted.

If you are adding a new off-site facility, you may also need to update your E-IRB application Research Description, Research Sites, Informed Consent, and other affected sections as well as any documents which will list the off-site facility. Documents needing updating may include, but not limited to:

- Consent forms (attachment under Informed Consent section)
- Brochures (attachment under Additional Info section)
- Advertisements (attachment under Research Description section) ;
- Letter of support (attachment under Research Sites section)).

Please revise applicable sections and attachments as necessary.

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16. Disclosure of Significant Financial Interest

Disclosure of Significant Financial Interest:

Our records for the previously approved IRB application indicate that you, your investigators, and/or key personnel (KP) have a significant financial interest (SFI) related to your/their responsibilities at the University of Kentucky (that requires disclosure per the UK administrative regulation 7:2):

○ Yes ◉ No

If you need to update your records, please go to the PI Contact Information section and/or Details for individuals listed in the Study Personnel section to change your response to the applicable question(s).

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17. Supplementals

To ensure the IRB has the most accurate information for your protocol you are expected to re-visit the E-IRB application sections and make corrections or updates as needed. At a minimum you are being asked to review the following sections for accuracy:

STUDY DRUG INFORMATION—Please review for accuracy.
STUDY DEVICE INFORMATION—Please review for accuracy.
RESEARCH ATTRIBUTES—Please review for accuracy.
OTHER REVIEW COMMITTEES -- Please review for accuracy.

PROJECT INFORMATION

0 unresolved comment(s)

Title of Project: (Use the exact title listed in the grant/contract application, if applicable).
If your research investigates any aspect of COVID-19, please include "COVID19" at the beginning of your Project Title and Short Title

Human perception of odors and odor blockers

Short Title Description
Please use a few key words to easily identify your study - this text will be displayed in the Dashboard listing for your study.

Odor perception

Anticipated Ending Date of Research Project: 12/31/2027

Maximum number of human subjects (or records/specimens to be reviewed) 810

After approval, will the study be open to enrollment of new subjects or new data/specimen collection? ◉ Yes ○ No

Are you requesting that the UK IRB serve as the lead IRB for a multi-site study, **OR** that the UK IRB defer review to another IRB? [Click here for "IRB Reliance" help]
○ Yes ◉ No
If "Yes," before completing your IRB application, fill out the Reliance Request Form and submit it to irbreliance@uky.edu.

PI CONTACT INFORMATION

0 unresolved comment(s)

Principal Investigator (PI) role for E-IRB access
The PI is a UK-affiliated individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*).

Non-UK individuals ("external") are not eligible for the role of Principal Investigator and cannot create a new application, nor will they be listed in the "Change Principal Investigator" search tool.

If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be listed as PI here.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to myUK and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a 'Name Change Form' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the HR Benefits Office for additional information.

The Principal Investigator's (PI) contact information is filled in automatically based on who logged in to create the application.

If you are not the Principal Investigator, do NOT add yourself as study personnel.
To change the PI contact information on an application in Researcher edit status:

- click "Change Principal Investigator";
- search for the PI's name using the search feature;
- click "Select" by the name of the Principal Investigator, then "Save Contact Information".

You will automatically be added as study personnel with editing permissions to continue editing the application.

Change Principal Investigator:

First Name:	Timothy	Room# & Bldg:	B281 BBSRB
Last Name:	McClintock	Speed Sort#:	405360298
Middle Name	S		
Department:	Physiology - 7H750	Dept Code:	7H750
PI's Employee/Student ID#:	00011578	Rank:	Professor
PI's Telephone #:	8593231083	Degree:	Ph.D.
PI's e-mail address:	mcclint@uky.edu	PI's FAX Number:	8593231070
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	11/15/2023
		RCR Trained:	Yes

Do you, the PI/researcher, have a significant financial interest related to your responsibilities at the University of Kentucky (that requires disclosure per the UK administrative regulation 7:2)?

○ Yes ◉ No

RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

- (●) (Risk Level 1) Not greater than minimal risk
- ( ) (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- ( ) (Risk Level 3) Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ( ) (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

*****For Expedited and Exempt Applications, the research activities must be Risk Level 1 (no more than minimal risk to human subjects).*****

Refer to UK's guidance document on assessing the research risk for additional information.

SUBJECT DEMOGRAPHICS **0 unresolved comment(s)**

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 18 yrs to 60 yrs

Study Population:

Describe the characteristics of the subject population, including age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- Justification for the inclusion of vulnerable groups such as children, prisoners, adults with impaired consent capacity, or others who may be vulnerable to coercion or undue influence.

Please consider this FDA Guidance on Enrollment of Participants from Underrepresented Populations in Clinical Studies

Subjects: Non-clinical healthy adults, ages 18 - 60. All gender identities and racial/ethnic groups are eligible to participate. N = 20-30 subjects per experiment.

Exclusions:
1. Persons > 60 years of age are excluded to avoid the complications from the gradual decline in olfactory acuity that often occur at advanced ages.
2. History of an odor-triggered clinical condition, such as migraines. Subjects who experience any sort of adverse reaction after smelling an odor during the study will be discontinued.
3. Persons who claim to have deficiencies in smell or taste. (In most cases, taste perception depends greatly on the odors released from foods or beverages in the mouth).
4. Smokers. Smoking alters sensitivity to odors.
5. Persons who have experienced a fragrance allergy.
6. Persons with diagnosed neurological or psychological conditions that could affect their ability to rate sensory perceptions, and persons taking medications or treatments known to alter the senses of smell or taste.
7. Persons, who by long exposure to odors normally considered foul, may have come to enjoy such odors.
8. Pregnant females
9. Persons suffering from cold or allergies on the day of testing may be excluded or rescheduled.
10. Persons < 18 years of age are excluded from this study

July 2022 Modification: Objective 6. Former smoker survey
Subjects: All genders and ages 18-60.
Exclusions:
1. Current smoker
2. Never smoked

January 2023 Modification: Objective 7. Suppression of desire to smoke
Subjects: Smokers of all genders and ages 18 – 60.
Exclusions:
1. Non-smoker
2. Outside age range
3. Self-reported inability to smell or taste.

July 2024 Modification: Objective 8. Identify new odors that suppress perception of real cigarette smoke odor.
Subjects: Healthy adults of all genders and ages 18 – 60.
Exclusions:
1. Current smoker
2. Pregnant
3. Outside age range
4. Self-reported inability to smell or taste.

October 2025 Modification: Objective 9. Identify neural pathways affected by odors that suppress both perception of real cigarette smoke odor and the urge to smoke.
Subjects: N = 10-20 healthy adults of all genders and ages 18 – 60.
Exclusions:
1. Pregnant
2. Outside age range
3. Self-reported inability to smell or taste.
4. Metal that cannot be removed from body
5. Having suffered a major head injury and/or concussion
6. Having been diagnosed with a neurological disorder (e.g. stroke, seizures)
7. Taking medications that affect the central nervous system (e.g., for depression, schizophrenia, panic disorder), as these medications can interfere with the MRI signal

December 2025 Modification: Objective 10. Determine how odors that effectively block perception of cigarette smoke odor by acting in the olfactory periphery (the nose) alter the perception of cigarette smoke compared to odors that are ineffective blockers.
Subjects: N = up to 100 healthy adults of all genders and ages 18 – 60 who have been participants in one or more of our prior studies/objectives.
Exclusions:
1. Pregnant
2. Outside age range
3. Self-reported inability to smell or taste.
4. Experience migraine headaches
5. Fragrance allergies

Attachments

Attach Type	File Name
StudyPopulation	Odor Pleasantness Research Questionnaire2.pdf

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Kentucky State Census, Kentucky Race/Ethnic Table, Kentucky Population Data.
(Please note: The IRB will expect this information to be reported at Continuation Review time for Pre-2019 FDA-regulated Expedited review and Full review applications):

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native:	1	1		
Asian:	32	80		
Black/African American:	10	30		
Latinx:	20	50		
Native Hawaiian/Pacific Islander:				
White:	261	313		
American Arab/Middle Eastern/North African:	3	9		
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:				

If unknown, please explain why:

Ethnic origin and gender are not part of the exclusionary criteria for this project. All ethnic origins and both genders are equivalent sources of information for this research project. We are therefore able to accept subjects of all genders of all ethnic origins.

Indicate the categories of subjects and controls to be included in the study. You may be required to complete additional forms depending on the subject categories which apply to your research. If the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check populations which the research does not specifically target. For example: a large record review of a diverse population may incidentally include a prisoner or an international citizen, but you should not check those categories if the focus of the study has nothing to do with that status.

Check All That Apply (at least one item must be selected)

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☑ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking (translated long or short form)
- ☐ International Citizens
- ☑ Normal Volunteers
- ☐ Military Personnel and/or DoD

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults
- Economically or Educationally Disadvantaged Persons

Other Resources:

- UKMC Residents or House Officers [see requirement of GME]
- Non-English Speaking [see also the E-IRB Research Description section on this same topic]

Civilian Employees
- Patients
- Appalachian Population

- International Citizens [DoD SOP may apply]
- Military Personnel and/or DoD Civilian Employees

Assessment of the potential recruitment of subjects with impaired consent capacity (or likelihood):

☐ Check this box if your study does NOT involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). If there is no direct intervention/interaction you will not need to answer the impaired consent capacity questions.

Does this study focus on adult subjects with any conditions that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

○ Yes ◉ No

If Yes and you are not filing for exemption certification, go to "Form T", complete the form, and attach it using the button below.

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

For creating your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and edit to match your research project.

Additional Resources:

- Informed Consent/Assent Website
- Waiver of Consent vs. Waiver of Signatures
- Sample Repository/Registry/Bank Consent Template

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- If another site is serving as the IRB for the project, attach the form as a “Reliance Consent Form” so the document will not receive a UK IRB approval stamp; the reviewing IRB will need to stamp the consent forms.
- Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".
- It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.
- Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.
  Document Types that do NOT get an IRB approval stamp are:
  - "Highlighted Changes",
  - "Phone Script", and
  - "Reliance Consent Form",
  - "Sponsor's Sample Consent Form".

How to Get the Section Check Mark

1. You must:

   a) provide a response in the text box below describing how investigators will obtain consent/assent, and
   b) check the box for at least one of the consent items and/or check mark one of the waivers

2. If applicable attach each corresponding document(s) **as a read-only PDF**.
3. If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only select "Stamped Consent Doc(s) Not Needed".
4. After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

Check All That Apply

- [x] Informed Consent Form (and/or Parental Permission Form and/or translated short form)
- [ ] Assent Form
- [ ] Cover Letter (for survey/questionnaire research)
- [ ] Phone Script
- [ ] Informed Consent/HIPAA Combined Form
- [ ] Debriefing and/or Permission to Use Data Form
- [ ] Reliance Consent Form
- [ ] Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- [ ] Stamped Consent Doc(s) Not Needed

Attachments

Attach Type	File Name
Informed Consent/Parental Permission	Informed consent Odors 020724.pdf
Informed Consent/Parental Permission	Informed consent Smokers 020724.pdf
Informed Consent/Parental Permission	Informed consent Bag Odors 121725.pdf
Informed Consent/Parental Permission	Informed consent fMRI odors Oct 2025 v4.pdf
Informed Consent/Parental Permission	Informed consent RATA 2026 v2.pdf

Informed Consent Process:

Using active voice, in the text box below, describe how investigators will obtain consent/assent. Include:

- the circumstances under which consent will be sought and obtained
- the timing of the consent process (including any waiting period between providing information and obtaining consent)
- who will seek consent
- how you will minimize the possibility of coercion or undue influence
- the method used for documenting consent
- if applicable, who is authorized to provide permission or consent on behalf of the subject
- if applicable, specific instruments or techniques to assess and confirm potential subjects' understanding of the information

Will electronic consent form/process be utilized on-site or remotely for this study?

○ Yes ◉ No

If yes, in addition to addressing the above bullet points, describe the e-consent method and platform, including any hyperlinks, videos, or enhancements used to convey information, if applicable. Attach a representation of the e-consent with signature fields. For guidance, see the ORI E-Consent web page.

Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Special considerations may include:

- Obtaining consent/assent for special populations such as children, prisoners, or people with impaired decisional capacity
- *Research Involving Emancipated Individuals*
  If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **prior to submitting this application to the IRB**. Include research legal counsel's recommendations in the "Additional Information" section as a separate document.
- *Research Involving Non-English Speaking Subjects*
  For information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.
- *Research Repositories*
  If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template.

Informed consent will be obtained when subjects first arrive for their sessions. An informed consent form for this study is attached. Signed consent forms for studies in progress are kept locked in a safe in MS535 Medical Sciences, to which only Dr. McClintock and Ms Frazier have the combination. Once a study is completed the signed informed consent forms are transferred to in a safe in Dr. McClintock's office. Only he can open this safe.

December 2019 Modification. This study is completely separate from the one objective already completed, Objective 3. We are not tracking subjects from Objective 3, nor will we contact them individually. It is possible that subjects from Objective 3 may volunteer for Objective 4, and this is permissible because there is no reason to expect that their experiences in the Objective 3 study would affect their future performance. Signing a new consent form is required to participate in this objective.

July 2022 Modification: Objective 6. (Note: Work on this objective has been terminated due to poor response rate.)
Because this is a survey only study we are requesting a waiver of informed consent for it. Waiver of informed consent allows survey respondents to have a single, efficient interaction with the study; factors that improve compliance with survey parameters and respondent satisfaction. The waiver is justified by the absence of risk to the participants.
Complaints or requests for information will be referred to the PI, who will offer to meet individually with each subject and answer their questions, and also provide the subject with contact information for ORI staff. In these meetings, we are prepared to show subjects de-identified summary data (means and ranges of responses in the data) to reassure subjects that they do indeed have a functional sense of smell within the normal range of humans. In cases of a specific hyposmia, the not uncommon situation where a person has difficulty smelling one odor but not most others, these same comparisons will be used to reassure the subject that their case is not unusual, nor is it cause for concern. In the unlikely case of a complaint arising from a reaction to an odorant, the objective of the meeting will be to counsel the subject on how to avoid the odorant that caused the reaction, and to encourage the subject to discuss their hyper-responsiveness with their physician. The study personnel are taught to inform the PI of any adverse reactions so that the PI can pro-actively request a meeting with any subject with such a reaction. Subjects are given a card and an email message with the contact information of the PI and of ORI staff so that they can follow-up on concerns at any time.

January 2023 Modification: Objective 7.
The subjects for this survey will be current smokers, and therefore will be new participants different from those in the other Objectives, which excluded smokers. However, in the unlikely event that a participant in one of our prior studies has become a smoker in the interim, the person will be allowed to participate.

July 2024 Modification: Objective 8.
The subjects for this survey will be healthy adult non-smokers. Consent will be sought by the PI or IRB approved staff when potential subjects arrive for testing at MN509 Med Sci using consent form "Informed consent Bag Odors 071924". As part of this process

potential subjects are informed verbally and in writing that they suffer no consequences from refusing to participate.

October 2025 Modification: Objective 9.
The subjects for this will be current smokers. Smokers who participated in Objective 7 are eligible to participate. In the unlikely event that a participant in another prior study has become a smoker in the interim, the person will also be allowed to participate.

December 2025 Modification: Objective 10.
Subjects will be up to 100 healthy adults of all genders and ages 18 – 60. People who participated in other Objectives are eligible to participate.

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval to waive the requirement for the informed consent process, or to alter some or all of the elements of informed consent, complete, Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting a waiver of the requirement for the informed consent process.

☐ I am requesting an alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered and/or omitted, and justify the alteration.

SECTION 2.

Explain how each condition applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

☐ Request for Waiver of Signatures

If you are requesting IRB approval to waive the requirement for signatures on informed consent forms, **your research activities must fit into one of three regulatory options**:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (e.g., a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk to the subject, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study.

If the IRB approves a waiver of signatures, participants must still be provided oral or written information about the study. To ensure you include required elements in your consent document, use the ***Cover Letter Template*** *as a guide. There is an English and a Spanish version.*

○ **Option 1**

Describe how your study meets these criteria:

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

○ **Option 2**

Describe how your study meets these criteria:

a) The research presents no more than minimal risk to the participant:

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

○ **Option 3**

Describe how your study meets these criteria:

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

STUDY PERSONNEL **0 unresolved comment(s)**

Do you have study personnel who will be assisting with the research?
After selecting 'Yes' or 'No' you must click the 'Save Study Personnel Information' button.

◉ Yes ○ No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is required for a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed below. ***Residents and students who are PI's are encouraged to designate the faculty advisor or at least one other individual as a contact with an editor role (DP).***
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR/FR, MR) or 'Other Review", and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature:

- Search for personnel;
- Click "select" by the listing for the person you want to add;
- For each person, specify responsibility in the project, whether authorized to obtain informed consent, AND denote who should receive E-IRB notifications (contact status).

NOTE: Study personnel must complete human subject protection (HSP) and Responsible Conduct of Research (RCR) training before implementing any research procedures. For information about training requirements for study personnel, visit UK's HSP FAQ page, the RCR Home page, or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (HSPTrainingSupport@uky.edu) for credit.

Study personnel assisting in research project:

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Anaya	Paul	Co-Investigator	SP	N	N		P	Y	03/01/2024	Y	N	07/12/2024	N	Y
Ashford	Kristin	Co-Investigator	SP	N	N		P	Y	07/13/2024	Y	N	07/09/2024	N	N
Burris	Jessica	Co-Investigator	SP	N	N		P	Y	11/21/2025	Y	N	07/09/2024	N	Y
Campbell	Kenneth	Co-Investigator	SP	N	N		P	Y	02/04/2023	Y	N	07/12/2024	N	Y
Frazier	Abby	Data Collection	SP	Y	N	B.S.	P	Y	06/16/2023	Y	N	06/20/2023	N	Y
Han	Dong	Co-Investigator	SP	Y	N	PsyD	P	Y	09/27/2024	Y	N	11/30/2017	N	Y
Hawk	Gregory	Co-Investigator	SP	N	N		P	Y	03/01/2023	Y	N	07/12/2024	N	Y
Isaacs	Jennifer	Co-Investigator	SP	N	N		P	Y	02/13/2024	Y	N	07/12/2024	N	Y
Kotter	John	Co-Investigator	SP	N	N		P	Y	01/19/2023	Y	N	07/12/2024	N	Y
Rakesh	Gopalkumar	Co-Investigator	SP	N	N		P	Y	09/11/2025	Y	N	07/09/2024	N	Y
Schenk	Ashley	Co-Investigator	SP	N	N		P	Y	11/18/2025	Y	N	07/12/2024	N	Y
Sorrell	Vincent	Co-Investigator	SP	N	N		P	Y	03/31/2025	Y	N	07/12/2024	N	Y
Stoops	William	Co-Investigator	SP	N	N		P	Y	08/18/2025	Y	N	07/12/2024	N	Y
Abbott	Kayla	Co-Investigator	SP	N	N		P				Y	07/19/2024	N	Y
Alimova	Yelena	Data Collection	SP	Y	N	B.S.	P	N	12/19/2019	Y	Y	06/04/2021	N	N
Aulisio	Madeline	Data Collection	SP	Y	N		P	Y	03/21/2024	Y	Y	06/04/2021	N	Y
Chesser	Annissa	Data Collection	SP	Y	N	B.S.	P	N	09/13/2018		Y	12/11/2019	N	N
Khan	Naazneen	Data Collection	SP	Y	N	Ph.D.	P	N	12/17/2019		Y	01/25/2022	N	N
Meredith	Evan	Data Collection	SP	Y	N		S	N	03/17/2021	Y	Y	12/12/2025	N	Y
Schnabel	Samantha	Data Collection	SP	Y	N		P	Y	08/19/2025	Y	Y	12/12/2025	N	Y

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Sengoku	Tomoko	Data Collection	SP	Y	N	Ph.D.	P	N	10/28/2020		Y	09/17/2019	N	N
Titlow	William	Data Collection	SP	Y	N		P	N	01/19/2022	Y	Y	12/12/2025	N	Y

RESEARCH DESCRIPTION

0 unresolved comment(s)

You may attach a sponsor's protocol pages in the "Additional Information" section and refer to them where necessary in the Research Description. However, each prompt that applies to your study should contain at least a summary paragraph.

Pro Tips:

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section or under the Additional Information section to include supplemental information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background

Include a brief review of existing literature in the area of your research. You should identify gaps in knowledge that should be addressed and explain how your research will address those gaps or contribute to existing knowledge in this area. For interventional research, search PubMed and ClinicalTrials.gov for duplicative ongoing and completed trials with same condition and intervention(s).

The perception of odors is linked to several clinically important conditions. Reduced sensitivity to odors or a reduced ability to recognize odors is an early indicator of dementia and Parkinson's Disease in a substantial fraction of persons who eventually develop these syndromes. Head trauma often also causes a reduced ability to detect odors (hyposmia), or even a total loss of the sense of smell (anosmia). In addition to situations where olfactory deficits are caused by pathology, odors can also trigger clinical conditions. This famously include migraines, but also includes cravings for abused substances such as tobacco products. Lastly, odors are social cues we use to evaluate others. Controlling odor emissions are therefore major components of personal hygiene. In this project we seek to assess human odor perception in order to help evaluate putative blockers of unwanted odors. These odor blockers are being developed in studies in the laboratory of Dr. McClintock.

Natural odors are mixtures of many species of odorants. An odorant is any volatile chemical that can be detected as a scent by the olfactory system. Many decades of behavioral studies (humans and animals) and physiological experiments (animals) demonstrate that when odorants are mixed together to create a complex odor, the odorants may interact in unpredictable ways. This outcome is seen not only when measured at the perceptual level but also at the level of the sensory neurons in the olfactory epithelium. These findings argue that the interactions are happening at the receptor proteins expressed in these neurons. Indeed, work in the McClintock laboratory now confirm this prediction and demonstrate that receptors for one odorant can often be blocked by other odorants. These findings indicate that moving from simple masking agents or odor trapping agents (air fresheners, deodorizers, Febreze, etc.) to true blockers of specific unwanted, foul-smelling odors (malodors) is now possible. The data suggest that it will be possible to find pleasant or neutral odors that can block specific malodors. As preclinical studies in the McClintock laboratory develop blockers of mouse odorant receptors responsive to malodors, testing these true odor blockers in humans is the logical next step. Herein, we propose to establish protocols to do so.

Some facts about odorant perception that are relevant for evaluating this research. First, the impact of encountering odors is poorly understood. Olfactory scientists suspect that much of what odors do to humans occurs below the level of consciousness, making these effects difficult to identify and study rigorously. Fortunately, this research project need only be concerned with effects that reach consciousness, and therefore can easily be assessed. Second, females tend to be slightly more sensitive to odors than males, but the perception of odors and their pleasantness typically does not differ with sex. We are therefore able to treat sexes equally. However, perception of odor pleasantness can be greatly affected in pregnant females, and they will be excluded from the study. Third, many decades of work show that the percept of an odor, meaning the perceived quality (e.g., pleasant/unpleasant; or woody, floral, green, musky, etc.) almost never changes with odor concentration. We will use odors for which this "perceptual constancy" is known to be true. In addition, this constancy means that we need not be concerned that some subjects will sniff the odors more aggressively than others. Their assessment of odor pleasantness will not be affected. However, in cases where we identify specific blockers of malodors, understanding how these blockers shift perception is important information. We will measure these shifts in perception.

As of now, this project does not have extramural funding, but we have begun submitting grant applications on the topics investigated using human subjects. We continue to develop preliminary data for these applications.

Objectives

List your research objectives. Please include a summary of intended research objectives in the box below.

Objective 1. Determine the relative foulness of malodors that we target for development of blocking odors.
Objective 2. Determine the effectiveness of malodor blockers on reducing negative perceptions of targeted malodors
March 2018 Modification: Objective 3. Identify odor mixtures that are perceived as tobacco smoke or include odors that suppress the perception of tobacco smoke.
December 2019 Modification: Objective 4. Test predicted odorant antagonists for pentanethiol-responsive odorant receptors and 2-methoxyphenol-responsive odorant receptors to find those effective at blocking perception of these cigarette smoke odor molecules.
January 2022 Modification: Objective 5. Test additional odorants or odor mixtures that are predicted to block the perception of cigarette smoke odor or the cigarette flavor additive, menthol, and determine the concentration-dependence of these effects.

July 2022 Modification. Objective 6. Collect data via survey on whether selected factors cause an urge to smoke a cigarette or increase the urge to smoke a cigarette.
January 2023 Modification: Objective 7. Determine whether odorants and odorant mixtures that suppress perception of the intensity of cigarette smoke odors (Objective 5) interfere with the ability of cigarette smoke odor to increase the urge to smoke in smokers.
July 2024 Modification: Objective 8. Identify new odors that suppress perception of real cigarette smoke odor.
October 2025 Modification: Objective 9. Identify neural pathways affected by odors that suppress both perception of real cigarette smoke odor and the urge to smoke.
We have discovered odors that suppress perception of real cigarette smoke odor at isointense dilutions and consequently reduce the ability of cigarette smoke odor to increase the urge to smoke. These two findings predict that central nervous system circuits mediating odor perception, as well as emotional and reward pathways linked to smell, respond differently to cigarette smoke odor when these blocking odors are present. We will test this hypothesis using fMRI of the brains of smokers exposed to cigarette smoke odor with and without the blocking odors also being present.
December 2025 Modification: Objective 10. Determine how odors that effectively block perception of cigarette smoke odor by acting in the olfactory periphery (the nose) alter the perception of cigarette smoke compared to odors that are ineffective blockers.

Study Design

Describe and explain the study design (e.g., observational, secondary analysis, single/double blind, parallel, crossover, deception, etc.).

- *Clinical Research*: Indicate whether subjects will be randomized and whether subjects will receive any placebo.
- *Community-Based Participatory Research*: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.
- *Qualitative research*: Indicate ranges where flexibility is needed, if a fixed interview transcript is not available, describe interview topics including the most sensitive potential questions.
- *Research Repositories*: If the purpose of this submission is to establish a Research Repository (bank, registry) and the material you plan to collect is already available from a commercial supplier, clinical lab, or established IRB approved research repository, provide scientific justification for establishing an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance or the UK Research Registry Guidance.

This is a single blind study where the researcher interacting with the subjects and recording their ratings does not know which odorants are in which bottles.

Design for Objective 1.
N = 30 subjects per experiment.
Each subject completes all 40 trials for the experiment in a single session.
Each subject is asked to smell 20 air samples, in a random order, with 1 minute between each sample. Each sample comes from a different squeeze bottle containing a different solution absorbed into a cotton ball. One solution is water, the other 19 are odorants. The 19 odorants span the range of pleasantness, from strongly foul to very appealing. The subject rates the pleasantness of each sample experienced using a sliding scale that ranges from 0 to 100. The scale device is set at 50 prior to smelling each sample. A 10 min break is taken after the first 15 trials, then the subject is asked to rate the 20 samples again, presented in a different random order

Design for Objective 2.
N = 30 subjects per experiment.
The only difference from the design for Objective 1 is that one malodor is present in 3 of the 20 bottles: in one by itself, in another as a mixture with an odorant that blocks mouse receptors responsive to the malodor, and in the third as a mixture with a pleasant odorant that does not block the mouse receptors responsive to the odorant (mimicking a masking odor). Effective blockers will cause the pleasantness rating of their mixture with a malodor to be higher than the rating for a mixture of a malodor with a simple masking agent.

Note: Why we test 20 samples rather than just a few? Three reasons. First, this allows us to more easily identify subjects that have problems performing the task or have general olfactory deficiencies, so that their responses can be excluded. Second, 20 odors are enough to help the subjects spread the ratings across the 100 units of the scale provided, but not so many that rating fatigue becomes a problem. Third, it allows us to generate two measures of response from the same data; quantitative values for each odor tested, and relative pleasantness ratings for the panel of odors.

March 2018 Modification: Design for Objective 3. (Note: This objective as been completed)
N = 30 subjects per experiment
The researcher performing this test is blind to the identify of all but two of the samples used. These two samples are used to teach the subjects to recognize tobacco smoke and to set the numerical scale for the experiment.
Each subject is asked to smell 40 samples, in a random order, with 1 minute between each sample. Each sample comes from a different squeeze bottle containing a different solution absorbed into a cotton ball. One sample, which contains 32 odorants mixed together in the ratios they are found in tobacco smoke, is known as synthetic tobacco smoke odor and it is highly effective at evoking the perception of tobacco smoke odor. One sample is water. The other 38 samples are either simpler formulations being tested for their ability to be perceived as tobacco smoke odor, or formulations of synthetic tobacco smoke odor to which a candidate blocking odor has been added. Each subject is allowed to experience the synthetic tobacco smoke odor first, followed by water, to set the rating scale being used. Then each subject rates whether each of the other 38 odors is similar to tobacco smoke using a sliding scale that ranges from 0 to 100. 100 = tobacco smoke odor, 0 = no odor, and the values in between denote how similar each odor is to tobacco smoke odor. The scale device is set at 50 prior to smelling each sample.

December 2019 Modification: Design for Objective 4.
N = 200 subjects
Each subject is asked to familiarize themselves with a training odor, either pentanethiol or beta-ionone, odor molecules critical for the perception of cigarette smoke odor (a result obtained from Objective 3).
Each subject is asked to smell 32 - 42 samples, in a random order, with 1 - 2 minute intervals between each sample. Each sample comes from a different vial or squeeze bottle containing a different odor solution absorbed into a cotton ball. 2 samples are part of every test session: the training sample of pentanethiol or beta-ionone and the water negative control. The other samples are 10 - 20 odor molecules (odorants) that have been predicted to bind to an odorant receptor protein highly sensitive to pentanethiol or beta-ionone, and 15 - 20 samples in which these candidate antagonists have been mixed with pentanethiol or beta-ionone - usually at 2 different concentrations of the candidate antagonists. Then each subject rates the pleasantness of each odor sample on a scale of 0 - 100, and the similarity of each odor sample to pentanethiol or beta-ionone on a scale of 0 - 100. Finally, each subject is asked whether they detect the training odor in each odor sample. Because we expect to test several sets of 10 - 20 candidate antagonists, subjects are allowed to return and rate multiple sets of candidate antagonists. The revised consent requests permission to contact subjects each time we prepare to test a new set of candidate antagonists. This study is completely separate from Objective 3, which has been completed. Whether people who were subjects for objective 3 is irrelevant to Objective 4 and we are not tracking subjects from Objective 3, nor will we contact them individually. It is possible that subjects from Objective 3 may volunteer for Objective 4, and this is permissible because there is no reason to expect that their experiences in the Objective 3 study would affect their future performance. Signing a new consent form is required to participate in this objective.

January 2022 Modification: Design for Objective 5.
N = 100 subjects
Each subject is asked to familiarize themselves with a training odor, also called the target odor: a cigarette smoke odor mimic or the flavor additive, menthol. Each subject is asked to smell 20 - 60 samples, in a random order, with 1 - 2 minute intervals between each sample. Each sample consists of a vial containing an odor solution absorbed into a cotton ball. Three types of control samples are part of every test session: the training odor itself, an irrelevant odor such as 2-heptanone, and a blank control. The other samples are the test samples contain the training odor mixed with predicted masking or blocking odors. These masking/blocking odors are pure monomolecular odorants or odor mixtures containing several odorants. Three concentrations of each test odor are used, each mixed with the same amount of target odor. Subjects are asked to determine if the target odor can be perceived and rate the intensity of the target odor in each vial on a scale of 0 – 100. They also rate the similarity of the overall odor to the target odor on a scale of 0 - 100. Finally, subjects are asked whether each sample is pleasant or unpleasant (a forced choice test). Each target odor and its candidate masking odors are tested in separate sessions. This study does not require that the same subjects rate effects on each of the target odors, but subjects who complete one session are allowed to return and rate effects on the different targets in subsequent sessions. This study is completely separate from Objectives 3 and 4, which have been completed. Whether people who volunteer for this objective were subjects for objectives 3 or 4 is irrelevant to Objective 5, and we are not tracking subject's responses across these objectives. There is no reason to expect that experiences in prior objectives would affect future performance so previous subjects who have indicated a willingness to be contacted for future studies in prior consent forms are eligible for objective 5 and are likely to be contacted.

July 2022 Modification: Design for Objective 6.
N = 200 respondents (former smokers) are expected.
The objective is to determine whether former smokers find that the smell of cigarette smoke causes an urge to smoke. What we hear from clinical psychologists working with smokers and former smokers and the only published paper on this topic to date differ in terms of whether the smell of cigarette smoke is a lasting trigger of the urge to smoke. An online REDCap survey of 30 questions will be used to gather data that will settle this question. The questions also include additional factors thought to increase the urge to smoke, and demographic information used to cross-correlate with data on the factors queried. Respondents to the survey are not paid but have a chance to win a drawing for $150. We will use REDCap's automated features to close the survey once 200 respondents is reached. We will then use REDCap's powerful statistical tools to evaluate whether any of the factors show evidence of affecting the urge to smoke, and whether these effects correlate with the time since quitting cigarettes, demographic factors, or use of other forms of nicotine or tobacco.

January 2023 Modification: Design for Objective 7.
N = 40 subjects.
The subjects for this survey will be current smokers, and therefore will be new participants different from those in the other Objectives, and not currently enrolled as subjects in our other studies. They will be recruited through contacts within the University of Kentucky campus community, with help advertising from the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. Each smoker is asked to smell up to 20 samples per session. The samples include controls (clean air, irrelevant odor), blocking odors identified in Objective 5, cigarette smoke, and cigarette smoke mixed with blocking odors or irrelevant odor. To obtain cigarette smoke a 1 inch length of the 1R6F research cigarette (produced here at UK) is burned to completion in a sealed 5 gallon chamber fitted with septa. Using a syringe fit with a needle and filter, 0.5 mL aliquots of smoke odor are obtained. These smoke odor aliquots, along with blocking odors, are injected into odor sample bags. These 10L bags are each fit with a septum at one end and a valve at the other that can be attached to the CPAP nose mask worn by each smoker (see attached document). Smokers open the valve, inhale once through the nose, close the valve, and then remove the bag from the mask. They then report three values on a score sheet: Whether the odor is pleasant or unpleasant (a forced choice test), a subjective rating of their desire to smoke on a scale of 0 – 100, and a Cigarette Purchase Task amount. The Cigarette Purchase Task (Strickland et al., 2016; attached) requires selecting how much the smoker is willing to spend for a single cigarette (their preferred brand) from a list of 19 amounts ranging from $0.00 (free) to $1,120. A 2 – 3 min wait period is enforced between each odor presentation to prevent odor adaptation and to allow acute motivational effects to subside. A nature documentary is shown on a TV screen during sessions.
Smokers are allowed to enroll in multiple sessions. Each session tests 4 – 8 concentrations of 1 – 2 blocking odors. Presentation order is randomized. Each smoker is assigned their own CPAP nose mask, and masks are disinfected after use. Smokers also

provide demographic (age, sex, ethnic and racial background) and smoking history information (cigarettes per day, preferred brand, age at onset, and time since last cigarette).

July 2024 Modification: Design for Objective 8. This experiment is patterned after Objective 5 and uses the odor bag method from Objective 7 for delivery of real cigarette smoke odor as the target odor. It tests odorants and odor mixtures that are predicted to block the perception of real cigarette smoke odor.
N = 60 subjects
Subjects are healthy non-smokers, ages 18 – 60. Each subject first familiarizes themselves with the odor of cigarette smoke. To obtain cigarette smoke a 1 inch length of the 1R6F research cigarette (produced here at UK) is burned to completion in a sealed 5 gallon chamber fitted with septa. Using a syringe fit with a needle, a 40 mL aliquot of smoke odor is withdrawn and injected into a 20L odor sample bag. Candidate blocking odors are added in the same way. The bag is fit with a septum at one end and a valve at the other that can be attached to a CPAP nose mask. To sample the odor in the bag, subjects open the valve, inhale once through the nose, close the valve, and then remove the bag from the mask. Cigarette smoke is not visible in the bags, so no visual cue to the odor is present.

Each subject then samples odors from 20 - 30 bags in a unique random order. The odor bags are of several types: Cigarette smoke alone, cigarette smoke plus a candidate blocking odor, or no odor. A 1 - 2 minute interval is enforced between each sample to minimize adaptation. The candidate blocking odors are pure monomolecular odorants or odor mixtures containing several odorants. Subjects are asked to rate the intensity of the target odor (cigarette smoke) in each odor bag on a scale of 0 - 100. Finally, subjects are asked whether each sample is pleasant or unpleasant (a forced choice test).

A single session is sufficient for each subject to rate all samples. Subjects from our previous experiments are allowed to participate. There is no reason to expect that experiences in prior objectives would affect future performance so previous subjects who have indicated a willingness to be contacted for future studies in prior consent forms are eligible and are likely to be contacted.

October 2025 Modification: Design for Objective 9.
N = 10 - 20 participants. Each participant does only 1 session and experiences a unique random order of the odors being tested. Participants are fitted with ear protection, a CPAP nose mask or cannulae that open into the nostrils for odor delivery, and allowed to practice breathing through them and experiencing irrelevant odor samples. Instructions on being in the scanner and communicating with the experimenter and MRI technologist are then given. Once familiar with these procedures participants are made comfortable on the scanner bed, then inserted into the scanner and asked to lie motionless. The participant will be able to hear the experimenter's instructions through the ear protection. The experimenter and MRI technologist speak to the subject frequently throughout the experiment and inform the participant about events that will occur next, what kind of responses they will make, what kind of noises they will expect to hear from the MRI scanner, and how long it will be before the experimenter speaks to the subject again. Once these preparations are complete, participants sniff an odor sample every 1 - 2 minutes. The entire procedure, from arrival to completion, will last 1 – 2 hours. Upon completion of the MRI portion of the study, the participant is taken out of the scanner and off the bed slowly, taken back into the control room and all of their personal items are returned to them. They are then escorted back to the public area of the medical center most convenient to their mode of transportation.

December 2025 Modification: Design for Objective 10.
N = up to 100 participants. Each participant does only 1 session.
This experiment is designed to evaluate perception of a malodor, alone and in mixtures with other odors. This is accomplished using a Rate All That Apply (RATA) method. Dr. McClintock learned this method while on sabbatical at the Monell Chemical Senses Center in 2023, working with a team using this method (Lee et al., 2023, attached). Participants familiarize themselves with 50 descriptive terms used for odors, most of which are familiar. Then using a scale from 0 - 5, they rate how well each of the 50 descriptors applies to odors we present to them.
Note that no odor vials contain liquid capable of spilling. The odor sources are cotton balls that have absorbed 100 - 200 ul of a diluted essential oil; or they are solids, such as the pennies used as an example of the odor of metal.

Attachments

Attach Type	File Name
StudyDesign	Odor Sample Bag Description.pdf
StudyDesign	Strickland Rush Demand Model 16.pdf
StudyDesign	Lee Principle Odor map 23.pdf

Subject Recruitment Methods & Advertising

Describe how the study team will identify and recruit subjects. Please consider the following items and provide additional information as needed so that the IRB can follow each step of the recruitment process.

- How will the study team identify potential participants?
- Who will first contact the potential subjects, and how?
- Will you use advertisements? If so, how will you distribute those?
- How and where will the research team meet with potential participants?
- If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations.
- How you will minimize undue influence in recruitment?
- Attach copies of all recruiting and advertising materials (emails, verbal scripts, flyers, posts, messages, etc.).

For additional information on recruiting and advertising:

- IRB Application Instructions - Advertisements
- PI Guide to Identification and Recruitment of Human Subjects for Research

Subjects will be recruited through contacts within the University of Kentucky campus community, with help on advertising from the CCTS. A flyer will be printed and posted on campus, and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. Interested people who contact the PI by email will be provided the questionnaire by email. Anyone who contacts the PI or other study personnel in person will be given their choice of a hard copy of the questionnaire or a digital copy by email. Persons whose questionnaires show no reason for exclusion will be scheduled for participation via email communication.

July 2022 Modification: Design for Objective 6.
The subjects for this survey will be new participants different from those in the other Objectives, and not currently enrolled as subjects in our other studies. They will be recruited through contacts within the University of Kentucky campus community, with help on advertising from the CCTS. A flyer will be printed and posted on campus, and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. All information will include a link to the survey.
See attached flyer. Methods of advertising are as follows.

Print advertisements: The study will recruit subjects through flyers, brochures, posters, Research Spotlights, ads placed on campus and in the surrounding community and region (Study Team will place/remove ads), including but not limited to the UK Medical Center, UK Clinics, Good Samaritan Hospital, Student Center, UHS, the 5 UK Center for Clinical and Translational Research wall mounts, Cardinal Hill, monitor screens, and area facilities and businesses.

Internet and Social Media: This study will be advertised on recruitment internet webpages in digital or video form (e.g., UKclinicalresearch.com, ResearchMatch.org, CenterWatch.com, CISCRP, UK, CCTS and may utilize Google Adwords). The study will be promoted via social media, including Facebook boost ads, UK_CCTS Facebook, UK_CCTS Twitter, UK_CCTS Instagram, UK and UKHC social media, and departmental/lab pages. If advertised on UKClinicalresearch.com, the online study flyer will include an option for interested individuals to enter and submit their contact information, they will be asked whether study team can contact them (Yes or No) via study-related text messages, and CCTS will also ask, ‘How did you learn about the study? Internet and social media recruitment will follow the terms of use for each site utilized. The study will also be promoted through UK HC monitor screens.

Outreach activities: The CCTS attends outreach activities to promote research participation in general (e.g., Roots & Heritage Festival, Latino Festival, Eastern Kentucky University, Transylvania Health fairs, etc.) and will bring all relevant study flyers that are enrolling participants.

July 2022 Modification: Design for Objective 6.
REDCap:This study may employ a pre-screening eligibility survey to determine if a volunteer meets basic inclusion/exclusion criteria. The study team will build and disseminate the eligibility survey on UK’s REDCap which provides HIPAA compliant storage on UK servers and encrypted transmission of survey responses. The portable devices do not download the data, it is directly stored into the secure web-based connection (https) behind the firewall. All files are password protected once entered into the system. All project data is stored and hosted locally. If the study team provides a link to the eligibility survey, PRS will fold that link into recruitment materials. The link will also be included in study information sent to ResearchMatch participants who have indicated interest in the study. Before
redirecting the volunteer outside of ResearchMatch and to the REDCap survey, the volunteer is once again asked to confirm their interest in completing the pre-screening survey.

A set of advertisements specific to this survey study have been produced for use in print, on social media, and at outreach activities.

January 2023 Modification: Objective 7.
N = 40 subjects.
The subjects for this survey will be current smokers, and therefore will be new participants different from those in the other Objectives, and not currently enrolled as subjects in our other studies. They will be recruited through contacts within the University of Kentucky campus community and Lexington area, with help advertising from the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising, incuding the CCTS ResearchMatch program. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes.

October 2024 Modification to recruitment methods for Objective 7. In addition to previously approved recruitment methods co-investigator Dr. Rakesh Gopalkumar will contact smokers who have consented to be contacted for future studies on consent forms when they participated on studies approved on other approved protocols on which he is an investigator. Specifically, these protocols are 64473 and 56570. He will send approved flyer "PHYS_009b flyer-STAMPED.pdf" to these individuals.

July 2024 Modification: Objective 8.
N = 60 subjects.
The subjects for this survey will be healthy adult non-smokers. Participants in prior objectives are eligible. They will be recruited through contacts within the University of Kentucky campus community, with help advertising from Participant Recruitment Services in the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. To prevent coercion students receiving the flyer are informed that participation in the study is not required for the class and refusal to participate has no connection to grades for the class.

April 2025 Modification: Objective 7
To expand advertising on social media to reddit, Instagram, and Craigslist new social media text and flyer for these sited have been

made. The approved versions, labeled 2025, are attached.

October 2025 Modification: Objective 9. The participants in the study will be current smokers, and may include smokers who participated in other Objectives of this project. They will be recruited through contacts within the University of Kentucky campus community and Lexington area, with help advertising from Participant Recruitment Services (PRS) in the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising, including the CCTS ResearchMatch program. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. We have found social media to be a good source of smokers for our studies, so in addition to the sites PRS normally uses (e.g., UK_CCTS Facebook, UK_CCTS Twitter, UK and UKHC social media), we will advertise on reddit, Instagram, and Craigslist. The approved media for these recruiting efforts are attached.

Smokers fail to make scheduled appointments more than half the time in our experience. To reduce this problem at the time of scheduling we will offer rideshare (Lyft or Uber) or taxi service for persons from Fayette County and the counties contiguous to Fayette County. Participants will not be responsible for the costs associated with this transportation. We will organize this service over the phone with the participant on the day of each appointment and pay for it directly. In many cases, we will be on the phone with the participants as they wait to meet the car.

December 2025 Modification: Objective 10.
We will recruit by contacting participants in our other objectives by email. Nearly every one of them, more than sufficient for this objective, has agreed to be contacted about additional studies. Examples of our email scripts for first contacts with potential subjects are attached.

Attachments

Attach Type	File Name
Advertising	PHYS-009_1_Webpage-STAMPED.pdf
Advertising	PHYS-009_1_Social Media-STAMPED.pdf
Advertising	McClintock MRI flyer-STAMPED.pdf
Advertising	PHYS-009c_Social media-STAMPED.pdf
Advertising	McClintock Social media post text 2025-STAMPED.pdf
Advertising	43123 Prescreening Appendix.pdf
Advertising	PHYS-009 APPROVED 2020.pdf
Advertising	PHYS-009_MON[1] APPROVED 2020.pdf
Advertising	PHYS-009-rm[1] APPROVED 2020.pdf
Advertising	PHYS-009-sm APPROVED 2020.pdf
Advertising	Highlighted Odor rating Research flyer Jan22.pdf
Advertising	Clean Odor rating Research flyer Jan22.pdf
Advertising	PHYS-0xxmonitor-STAMPED.pdf
Advertising	PHYS_0xx flyer-STAMPED.pdf
Advertising	Research Match screen.png
Advertising	Social Media page.png
Advertising	Pre Screening survey.pdf
Advertising	PHYS_009b flyer-STAMPED.pdf
Advertising	PHYS-009b_MON-STAMPED.pdf
Advertising	PHYS-009b_Social media-STAMPED.pdf
Advertising	PHYS-009b_Research Match-STAMPED.pdf
Advertising	PHYS_009b flyer.pdf
Advertising	Recruit email scripts new and prior participants.pdf
Advertising	Email script recruitment for RATA.pdf

Research Procedures

Describe how the research will be conducted.

- What experience will study participants have?
- What will study participants be expected to do?
- How long will the study last?
- Outline the schedule and timing of study procedures.
- Provide visit-by-visit listing of all procedures that will take place.
- Identify all procedures that will be carried out with each group of participants.
- Describe deception and debrief procedures if deception is involved.

Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project. List medications that are explicitly forbidden or permitted during study participation.

Participants will be seated at a table whose surface is clear of all but a display of a scale numbered from 0 to 100, a pencil and a scoring sheet. At this point, the researcher will provide instructions to the subject:
1. For pleasantness ratings, a score of 50 represents an odor with neutral pleasantness, or an odor that is not detectable. Higher numbers represent progressively greater pleasantness; lower numbers represent progressively greater unpleasantness. For forced choice ratings of pleasantness, the subject marks the odor as either pleasant or unpleasant on the scoring sheet.
2. For similarity and intensity ratings using the 0-100 scale, higher numbers indicate greater similarity or intensity, and 0 means no similarity or intensity.
3. The subject is instructed to use the squeeze bottle by placing the spout a few inches below the nose and squeezing gently, or if vials are being used, to open the vial and place under the nose. The researcher demonstrates with an empty vial or bottle.
4. Upon verbal agreement of readiness, the researcher hands the first sample vial or bottle to the subject to smell. (The order of the vials/bottles is determined previously using a random number generator. The bottles are coded using a letter code.) The subject enters one or more ratings on a scoring sheet. Upon receiving the bottle back from the subject the research activates a 1 min timer.
5. When 1 - 2 min has elapsed, the researcher gives the subject the next bottle. Steps 4 and 5 are repeated until half the vials/bottles have been tested.
6. The subject is allowed a 10 min break.
7. Steps 4 and 5 are repeated with the remainder of the vials/bottles.
8. Upon completion the subject is thanked and released.

July 2022 amendment. Participants will access and complete a REDCap survey online via the device of their choice. The survey has 30 questions that provide demographic information, smoking history, and data on the effects of factors that may cause an urge to smoke. Participants provide an answer to each question, with most questions allowing the option to refuse to answer. REDCap will be set to allow participants to navigate back to previous questions and change answers. Upon completion of the survey REDCap will show a message confirming completion and thanking the participant. We will set the enrollment cap tool in REDCap at 200 completed surveys, thereby closing the survey at 200 complete responses and triggering notification of the investigators. Incomplete surveys are not counted against the cap. To match the demographics of our other human experiments we will discard data from those outside the desired age range of 18-60 years.

January 2023 Modification: Objective 7.
Participants will be seated at a small table in our odor control room whose negative pressure and fume evacuation devices reduce the ability of odors to accumulate. The table is clear of all but a score sheet and a pencil.
1. A researcher will instruct the participant on how to use the score sheet.
2. A researcher will then instruct the participant in how to wear the nose mask, how to fit odor sample bags to the mask, and how to remove bags from the mask.
3. Using the unique random order assigned to the current session and participant, the smoker fits the first bag onto their mask, opens the valve, inhales once through the nose, closes the valve, removes the bag, and hands it to the researcher.
4. The participant then reports three values on a score sheet: Whether the odor is pleasant or unpleasant (a forced choice test), a subjective rating of their desire to smoke on a scale of 0 – 100, and a Cigarette Purchase Task amount. The Cigarette Purchase Task (Strickland et al., 2016; attached) requires selecting how much the smoker is willing to spend for a single cigarette (their preferred brand) from a list of 19 amounts ranging from $0.00 (free) to $1,120.
5. A 2 – 3 min wait period is enforced between each odor presentation to prevent odor adaptation and to allow acute motivational effects to subside. A nature documentary is available on the TV screen in the room for entertainment during the wait period.
6. When the wait period has elapsed the researcher hands the next bag to the participant, and steps 3-5 are repeated until all bags have been scored.
7. Upon completion of the session the participant is thanked and released.

July 2024 Modification: Objective 8.
Participants will be seated at a small table in our odor control room whose negative pressure and fume evacuation devices minimize the ability of odors to accumulate. The table is clear of all but a laptop computer used to record scores. Alternatively, a score sheet and pencil can be substituted for the laptop.
1. A researcher will instruct the participant on how to score samples.
2. A researcher will then instruct the participant in how to wear the nose mask, how to fit odor sample bags to the mask, and how to remove bags from the mask.
3. Using the unique random order assigned to the current session and participant, the participant fits the first bag onto their mask, opens the valve, inhales once through the nose, closes the valve, removes the bag, and hands it to the researcher.

4. The participant then reports two values: Whether the overall odor is pleasant or unpleasant (a forced choice test) and a subjective rating of the intensity of cigarette smoke odor (the target odor) in the bag.
5. A 1 – 2 min wait period is enforced between each odor presentation to minimize odor adaptation. A nature documentary is available on the TV screen in the room for entertainment during the wait period.
6. When the wait period has elapsed the researcher hands the next bag to the participant, and steps 3-5 are repeated until all bags have been scored.
7. Upon completion of the session the participant is thanked and released.

October 2025 Modification: Objective 9.
1. Recruited participants are scheduled, informed where to report, and told to wear comfortable clothing, contact lenses (rather than glasses, if applicable), and that they may want to prevent dry eyes by using eye drops before the study.
2. Upon arrival, participants meet with a member of the study staff to do a brief questionnaire to confirm their eligibility and obtain their nicotine exposure history.
3. They are then brought to the MRISC and deposit all personal items (e.g., jewelry, hair accessories, shoes, wallets, credit cards and loose change) into secure storage. They are then screened with a metal detector to ensure that they do not have metal in their body.
4. Participants are fitted with ear protection, a CPAP nose mask or cannulae that open into the nostrils for odor delivery, and allowed to practice breathing and sniffing irrelevant odor samples.
5. Instructions on being in the scanner and communicating with the experimenter and MRI technologist are then given. Once familiar with these procedures participants are made comfortable on the scanner bed, then inserted into the scanner and asked to lie motionless.
6. The participant will be able to hear the experimenter's instructions through the ear protection. The experimenter and MRI technologist work together to manage the experiment. They speak to the subject frequently throughout the experiment and inform the participant about events that will occur next, what kind of responses they will make, what kind of noises they will expect to hear from the MRI scanner, and how long it will be before the experimenter speaks to the subject again.
7. Once these preparations are complete, participants sniff an odor every 1 minute in a block design where each odor is repeatedly sniffed before moving to the next odor. Each participant will repeatedly sniff 3 - 6 different odors.
8. Upon completion of MRI, the participant is taken out of the scanner and off the bed slowly, taken back into the control room and their personal items are returned to them. They are then escorted back to the public area of the medical center most convenient to their mode of transportation. The entire procedure, from arrival to completion, will last 1 – 2 hours.

December 2025 Modification: Objective 10.
N = up to 100 participants. Each participant does only 1 session of 1-2 hrs in length.
Participants will be seated at a table or bench at a fume hood or odor capture device used to prevent odors from accumulating in the room. A researcher is available throughout the session to answer questions and attend to problems.
1. A researcher will provide a list of up to 50 verbal descriptors used for odors and a tray of 50 labeled vials, each containing an odor exemplifying the corresponding descriptor. Participants will be allowed to familiarize themselves with these 50 odors at their own pace.

2. Once a participant is comfortable with the descriptors, a researcher will give them a different tray of up to 30 vials, each containing an unidentified odor for them to rate. Participants will be given a score sheet (digital or hard copy) listing the 50 descriptors and asked to rate how well each descriptor applies to each unidentified odor using a scale of 0 - 5. Here again, participants proceed at their own pace. A score sheet is attached.

Attachments

Attach Type	File Name
ResearchProcedures	PreScrnF.pdf
ResearchProcedures	Smoking History Form.pdf
ResearchProcedures	RATA scoring sheet.pdf

Data Collection & Research Materials

In this section, please provide the following:

- Describe all sources or methods for obtaining research materials about or from living individuals (such as specimens, records, surveys, interviews, participant observation, etc.), and explain why this information is needed to conduct the study.
- For each source or method described, please list or attach all data to be collected (such as genetic information, interview scripts, survey tools, data collection forms for existing data, etc.).
- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.

The data collection tool is a worksheet that displays only the date, the subject's code, and a column displaying the bottle codes. The researcher running the testing operates the worksheet. Empty columns are used to record the subject's scores. If a slider device is used for scoring the researcher records each score immediately. If the subject selects a scoring sheet, the researcher may instead record the scores at the completion of the testing.

July 2022 Modification: Design for Objective 6.
An online REDCap survey of 30 questions will be used to gather data that will provide information about potential causes of the urge to smoke in reformed smokers. We will then use REDCap's powerful statistical tools to evaluate whether any of the factors queried show evidence of affecting the urge to smoke, and whether these effects correlate with the time since quitting cigarettes, demographic factors, or use of other forms of nicotine or tobacco. Participants will access and complete a REDCap survey online via the device of their choice. We will set the enrollment cap tool in REDCap at 200 completed surveys, thereby closing the survey at 200 complete

responses. Incomplete surveys are not counted against the cap. To match the demographics of our other human experiments we will discard data from those outside the desired age range of 18-60 years.

January 2023 Modification: Objective 7.
The data collection tool (score sheet) is a worksheet that displays the date, the participant's unique code, a column for recording the sequence of odor bags (letter codes), and columns to score whether the odor is pleasant or unpleasant (a forced choice test), a subjective rating of their desire to smoke on a scale of 0 – 100, and a Cigarette Purchase Task amount ranging from $0.00 (free) to $1,120. At the top of the score sheet are spaces for demographic data (age, sex, ethnic and racial background) and smoking history information (cigarettes per day, preferred brand, age at onset, and time since last cigarette).

July 2024 Modification: Objective 8.
Data collection scoring is done on a worksheet (paper or digital) that displays the date, the participant's unique code, a column for recording the sequence of odor bags (letter codes), and columns to score whether the odor is pleasant or unpleasant (a forced choice test), and a column to rate the intensity of cigarette smoke odor in each bag.

October 2025 Modification: Objective 9.
The data collected are MRI scan images plus questionnaires about nicotine exposure history and eligibility for MRI scanning. These are de-identified via numerical codes and used for research purposes only.

December 2025 Modification: Objective 10.
Participants use a score sheet (digital or hard copy) to rate how strongly each of the 50 descriptors applies to each unidentified odor they are given. Ratings are a linear scale of 0 - 5. The scoring sheet is attached here and under Research Procedures.

Attachments

Attach Type	File Name
DataCollection	Smoker Score sheet.pdf
DataCollection	Response Sheet Objective 8.pdf
DataCollection	RATA scoring sheet.pdf

Resources

Describe the availability of the resources and adequacy of the facilities that you will use to perform the research. Such resources may include:

- Staffing and personnel, in terms of availability, number, expertise, and experience;
- Computer or other technological resources, mobile or otherwise, required or created during the conduct of the research;
- Psychological, social, or medical services, including equipment needed to protect subjects, medical monitoring, ancillary care, or counseling or social support services that may be required because of research participation;
- Resources for communication with subjects, such as language translation/interpretation services.

Staff in the McClintock laboratory will prepare the vials or squeeze bottles of odorants. Fresh ones are prepared daily.
Testing of subjects will be done by Dr. McClintock or a member of his staff who did not prepare the bottles on that day.
Testing will be done in MS509 Medical Sciences, a room where odors are carefully controlled.
Equipment used: A small table, two chairs, a personal computer (property of the University of Kentucky), a scoring slider or scoring sheet, and the 16 bottles.
The data entered into this computer is de-identified. A code, rather than the subject's name, is used to identify the set of responses belonging to each individual person (e.g., F102 or M119). No record is kept of which subject belongs to each code. The computer is password protected and kept in a locked room. Dr. McClintock is the only person who has access to this computer at this time, but staff who are recording data are given access during the period of the study. A secure server that is used to store back-ups of the files (cifs://prdltcancifs01.mc.uky.edu/research/lab/mcclintock-t).

Signed consent forms are stored in a safe in Dr. McClintock's office. Only Dr. McClintock has access into this safe.

July 2022 amendment. Objective 6. Staff in the McClintock laboratory are preparing a REDCap survey using the access to REDCap provided by the University of Kentucky. They will monitor progress weekly, with completion set at 200 complete responses. To match the demographics of our other human experiments they will discard data from those outside the desired age range of 18-60 years. Data will be analyzed via the extensive statistical tools available in REDCap, with contributions from University of Kentucky biostatisticians should that prove advisable.

January 2023 Modification: Objective 7.
Staff in the McClintock laboratory will prepare the odors and odor sample bags. Fresh bags are prepared at least monthly.
Testing of subjects will be done by Dr. McClintock or a member of his staff.
Testing will be done in MS509 Medical Sciences, a room where odors are carefully controlled.
Equipment used: A small table, two chairs, a personal computer (property of the University of Kentucky), a worksheet sheet, and the odor bags. The TV showing the nature documentary is also present in the room.

July 2024 Modification: Objective 9.
Staff in the McClintock laboratory will prepare the odors and odor sample bags. Fresh ones are prepared weekly.
Testing of subjects will be done by Dr. McClintock or a member of his staff.

Testing will be done in MS509 Medical Sciences, a room where odors are carefully controlled.
Equipment used: A small table, two chairs, a personal computer (property of the University of Kentucky) or a paper worksheet sheet, CPAP nose masks, and the odor bags. A TV showing a nature documentary is also present in the room.

October 2025 Modification: Objective 9.
The MRISC occupies the ground level of the Whitney Hendrickson building on the UK Medical Center campus and is connected to the main University Hospital by underground tunnel. Gated parking for research subjects is available just outside the scanner building. The MRISC has 6,100 sq. ft. of space that contains five staff offices, two behavioral testing rooms, a mock scanner room, trainee carrel space, electronics and fabrication shops, and extensive computing facilities. The MRISC research facility provides a certified MRI technologist to run the research scans and full clinical support for any emergencies. Thousands of research MRI studies have been conducted at the MRISC site since its opening in 1992. The newly renovated facility will also include convenient, comfortable, professional quality subject preparation and waiting areas that are important for a participant's subjective ease and confidence in the research imaging procedures.
Staff in the McClintock laboratory will prepare the odors in bottles or odor sample bags. Fresh ones are prepared weekly.
Each testing session is managed by two people, a certified MRI technologist and either Dr. McClintock or a member of his staff.

December 2025 Modification: Objective 10.
Staff in the McClintock laboratory will prepare the odor vials used.
Testing of subjects will be overseen by Dr. McClintock or a member of his staff.
Testing will be done in MS509 Medical Sciences or in B236 BBSRB.

Potential Risks & Benefits

Risks

- Describe any potential risks – including physical, psychological, social, legal, ability to re-identify subjects, or other risks. Assess the seriousness and likelihood of each risk.
- Which risks may affect a subject's willingness to participate in the study?
- Describe likely adverse effects of drugs, biologics, devices or procedures participants may encounter while in the study.
- *Qualitative research* - describe ethical issues that could arise while conducting research in the field and strategies you may use to handle those situations.
- Describe any steps to mitigate these risks.

Benefits

- Describe potential direct benefits to study participants – including diagnostic or therapeutic, physical, psychological or emotional, learning benefits. This cannot include incentives or payments.
- State if there are no direct benefits.
- Describe potential benefits to society and/or general knowledge to be gained.

Describe why potential benefits are reasonable in relation to potential risks. If applicable, justify why risks to vulnerable subjects are reasonable to potential benefits.

Risks are minimal. The odorants are prepared and delivered in a way that prevents subjects experiencing known toxic concentrations. The potential physical risks are therefore hyper-responsive conditions, such as allergic reactions or odor-triggered migraines, of which the subjects were previously unaware. Testing will be stopped immediately for any subject who shows signs of an allergic reaction or complains of a headache.

To minimize the risk of breaches of confidentiality, completed questionnaires will be stored only in a password-protected computer in MS585 Med. Sci, separate from the computer used to acquire the data. Dr. McClintock is the only people who have access to this computer, and to the secure server that is used to store back-ups of the files (cifs://prdltcancifs01.mc.uky.edu/research/lab/mcclintock-t). Signed consent forms for studies in progress are kept locked in a safe in MS535 Medical Sciences, to which only Dr. McClintock and the staff member administering testing (Ms. Frazier) have the combination. Once a study is completed the signed informed consent forms are transferred to in a safe in Dr. McClintock's office. Only he can open this safe.
Like the risks involved, potential benefits to the subjects are small. For some the exercise will fulfill their curiosity about their sense of smell. For a few that are attracted to the study because they perceive problems with their ability to smell or taste, the exercise will be reassuring. Unlikely, but possible, is that we might discover cases of undiagnosed chronic deficits in smell perception. These persons will be directed to: 1) ask their physicians to investigate the cause of hyposmia/anosmia and 2) seek counseling on how to cope with smell deficits in their daily lives (employing gas and smoke detectors in their living spaces; adjusting the flavoring of the foods they eat to help maintain nutrition are two examples.)

The benefits to society and general knowledge are more substantial. We will determine whether odor blockers that work at mouse odorant receptors are also effective in humans, opening the door to the use of these blockers to improve quality of life for many people. For example, the objectives in this protocol are increasingly focused on identify odorants that block perception of cigarette smoke. Ultimately, these odorant antagonists could be used to prevent cigarette smoke odor from triggering the urge to smoke in smokers and former smokers. This could be used to improve smoking cessation.

October 2025 Modification: Objective 9.
Risks of participating in MRI studies are minimal. Several measures are taken to detect the presence of metal in the body, including using a hand-held metal detection device. If there is any chance that metal exists in the subject's body that individual is not allowed to

enter the MRI scanner. To address the risk of loud noise from the MRI scanner, ear protection is worn. To protect confidentiality, the participant's brain images and nicotine use history are only identified by a code. No unauthorized personnel are allowed in the MRI area while a subject is participating in a study. There are no known interactions between odor exposure and MRI scanning.

Available Alternative Opportunities/Treatments

Describe alternative treatments or opportunities that might be available to those who choose not to participate in the study, and which offer the subject equal or greater advantages. If applicable, this should include a discussion of the current standard of care treatment(s).

Not Applicable.

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Records, Privacy, and Confidentiality

Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Specify who will have access to the data/specimens and why they need access.

Describe how data will be managed after the study is complete:

- If data/specimens will be maintained, specify whether identifiers will be removed from the maintained information/material.
- If identifiers will not be removed, provide justification for retaining them and describe how you will protect confidentiality.
- If the data/specimens will be destroyed, verify that this will not violate retention policies and will adhere to applicable facility requirements.

If this study will use de-identified data from another source, describe what measures will be taken to ensure that subject identifiers are not given to the investigator.

If applicable, describe procedures for sharing data/specimens with collaborators not affiliated with UK.

For additional considerations:
Return of Research Results or Incidental Research Findings
HIPAA policies
FERPA policies
Procedures for Transfer agreements
Information regarding multi-site studies
NIH Genomic Data Sharing (GDS) Policy
Digital Data

The new data security compliance requirements under 28 CFR Part 202 are in effect as of 10/6/25. For any questions please contact Sara Poll, UK's Research Security Administrator, researchsecurity@uky.edu

Only sensory perception data is obtained from the subjects in this study. This study is not expected to discover findings that could affect the health of a subject, but upon request from a subject we will provide summary data, the means and ranges of responses across the full data set, and a brief description of the meaning of the findings.
Confidentiality. A subject's identity will not be recorded into the data file, but rather a unique study number will be given to each subject and this study number is entered into the data file instead of a name. Data are therefore always de-identified. Only the study personnel will interact with subjects. The pre-screening questionnaire will be seen only by study personnel. Data records will be kept for six years and then any record that identifies the individuals tested will be destroyed. Signed consent forms are kept in a safe in Dr. McClintock's office. Only Dr. McClintock has access into this safe.

Breach of confidentiality. To minimize opportunities for breaches of confidentiality, completed questionnaires will be stored only in a password-protected computer in B236 BBSRB separate from the computer used to acquire the data. Dr. McClintock and Ms. Frazier are the only people who have access to this computer, and to the secure server that is used to store back-ups of the files (cifs://prdltcancifs01.mc.uky.edu/research/lab/mcclintock-t).

Security. Until subjects have completed their participation, questionnaires will be stored only in a password-protected computer in B236 BBSRB, separate from the computer used to acquire the data. They will also be stored on a secure UK server as a back-up. As additional security, B236 BBSRB is key card access only. Emails containing questionnaire responses will be deleted as soon as the responses are stored on the password-protected computer. Once subjects have completed their participation in the study, their questionnaire responses will be deleted. Other records, such as the data files and consent forms will be kept for six years and then destroyed.
Contact with odorant chemicals is limited to the small amounts that volatilize into air. Subjects are not allowed to come into contact with the cotton ball containing the odor source.

October 2025 Modification: Objective 9.
To protect privacy and confidentiality, the participant's brain images and nicotine use history are only identified by a numerical code. All code labeled data will be permanently (or for at least for 6 years) stored on computers at MRISC, which are behind secured doors. Random code labeled data will only be made available to the principle investigator and co-investigators, who also keep the data on secured computers.

UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Check this item to confirm that you will retain all IRB-related records for a minimum of 6 years after study closure.

Payment

Describe the incentives (monetary or other) being offered to subjects for their participation. If monetary compensation is offered, indicate the amount and describe the terms and schedule of payment. Please review this guidance for more information on payments to subjects, including restrictions and expectations.

Some student subjects may be in classes that provide them the opportunity to earn extra credit by participating in this study. In these cases, participating in the study will be only one of the ways in which extra credit may be earned, and all options for extra credit will be equivalent in the amount of time and effort required.

As of December, 2021 we have resources available to pay subjects $20 for each rating session. This is true not only for the objective of the January, 2022 modification, but also for all objectives not yet completed (1 and 2). Subjects are allowed make multiple return visits to rate new sets of candidate antagonists, each time receiving a $20 payment. Payments will be made in the form of a check or cash.

July 2022 Modification: Design for Objective 6.
Former smoker survey. These respondents will not be paid but are entered into a lottery for one of two $150 gift payments. Using a random number generator we have identified completed surveys number 41 and number 167 as the recipients of these payments. Upon completion of these two surveys, REDCap will notify the respondents that they are the winners of the awards, providing them with information on how to submit information to receive payment.

January 2023 Modification: Objective 7.
As of December, 2022 we have resources available to pay subjects $30 for each rating session. Payments will be made in the form of a check or cash.

July 2024 Modification: Objective 8.
We have resources available to pay subjects $30 for each rating session. Payments will be made in the form of a check or cash.

October 2025 Modification: Objective 9.
For fMRI sessions, participants are paid $50 per session. Payments will be made in the form of a check. In addition, transportation costs (ride share or taxi) and parking costs may also be paid to participants.

December 2025 Modification: Objective 10.
We have resources available to pay subjects $30 for each rating session. Payments will be made in the form of a check.

Costs to Subjects

Include a list of services and/or tests that will not be paid for by the sponsor and/or the study (e.g., MRI, HIV). Keep in mind that a subject will not know what is “standard” – and thus not covered by the sponsor/study – unless you tell them.

Not Applicable

Data and Safety Monitoring

The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research or NIH-funded/FDA-regulated clinical investigations.

- If you are conducting greater than minimal risk research, or your clinical investigation is NIH-funded, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.
- If this is a non-sponsored investigator-initiated protocol considered greater than minimal risk research, and if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

Not Applicable

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Future Use and Sharing of Material (e.g., Data/Specimens/Information)

If the material collected for this study will be used by members of the research team or shared with other researchers for future studies, please address the following:

- list the biological specimens and/or information that will be kept
- briefly describe the types, categories and/or purposes of the future research

- describe any risks of the additional use
- describe privacy/confidentiality protections that will be put into place
- describe the period of time specimens/information may be used
- describe procedures for sharing specimens/information with secondary researchers
- describe the process for, and limitations to, withdrawal of specimens/data

The de-identified responses of participants for all objectives will be kept for 10 years. Future research by the PI may mine these data. For examples, correlations between responses and participant demographics in Objective 7 are a likely topic for future research. There are no additions risks associated with these future uses. Even the initial scoring sheets are de-identified so once data collection for studies are complete even the PI cannot determine which responses belong to which participants. Signed informed consent forms are kept in a locked safe to which only the PI has access. Though not anticipated, if data is shared with secondary researchers only de-identified data will be shared.

October 2025 Modification: Objective 9.
All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information or samples collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information or samples may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information or samples stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

Are you recruiting or expect to enroll **Non-English Speaking Subjects or Subjects from a Foreign Culture**? (does not include short form use for incidentally encountered non-English subjects)

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.
When recruiting Non-English-speaking subjects, provide a consent document in the subject's primary language. After saving this section, attach both the English and translated consent documents in the "Informed Consent" section.

Cultural and Language Consultants:

The PI is required to identify someone who is willing to serve as the cultural consultant to the IRB.

- This person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted.
- The consultant should not be involved with the study or have any interest in its IRB approval.
- Please include the name, address, telephone number, and email of the person who agrees to be the cultural consultant for your study.
- ORI staff will facilitate the review process with your consultant. Please do not ask them to review your protocol separately.

For more details, see the IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

Local Requirements:

If you will conduct research at an international location, identify and describe:

- relevant local regulations
- data privacy regulations
- applicable laws
- ethics review requirements for human subject protection

Please provide links or sources where possible. If the project has been or will be reviewed by a local ethics review board, attach a copy in the "Additional Information/Materials" section. You may also consult the current edition of the International Compilation of Human Research Standards

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?
○ Yes ◉ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the "Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing" [D65.0000] [PDF], and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Initiated FDA-Regulated Research

Is this an investigator-initiated study that:

1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?
○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the investigator assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials [PDF], IDE regulatory requirements for SR device trials [PDF], and abbreviated regulatory requirements for NSR device trials [PDF]. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe the experience/knowledge/training (if any) of the investigator serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if any sponsor obligations have been transferred to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?
○ Yes ○ No
If the sponsor-investigator has completed equivalent sponsor-investigator training, submit documentation of the content for the IRB's consideration.

Attachments

Attach Type	File Name
SponsorInvTraining	WT citiCompletionReport6811346.pdf
SponsorInvTraining	TS citiCompletionReport6811326 2.pdf
SponsorInvTraining	citiCompletionReport6845666 Chesser.pdf

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ○ Yes ◉ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

I have attached a HIPAA Waiver of Authorization. ○ Yes ◉ No

Attachments

STUDY DRUG INFORMATION

0 unresolved comment(s)

Drugs are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and articles (other than food) intended to affect the structure or any function of the body of man or other animals.

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- complementary and alternative medicine products such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of e-cigarettes examining a potential therapeutic purpose.

Does this protocol involve a drug including an FDA approved drug; unapproved use of an FDA approved drug; and/or an investigational drug?

○ Yes ◉ No

If yes, complete the questions below. Additional study drug guidance.

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Note: Inpatient studies are required by Hospital Policy to utilize Investigational Drug Service (IDS) pharmacies (Oncology or Non-Oncology). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

Is the study being conducted under a valid Investigational New Drug (IND) application?

○ Yes ○ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Checkmark if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND) or if this is an Individual Patient Expanded Access IND (FDA Form 3926).

See FDA's Expanded Access Program Information for Individual Patient Expanded Access INDs, and attach the following:

- FDA Form 3926;
- FDA expanded access approval or correspondence;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Expanded Access SOP.

Complete and attach the required Study Drug Form picking "Study Drug Form" for the document type. Any applicable drug documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.) should be attached using "Other Drug Documentation" for the document type.

Attachments

STUDY DEVICE INFORMATION

0 unresolved comment(s)

Medical devices are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals.

A DEVICE may be a:

- component, part, accessory;
- assay, reagent, or in-vitro diagnostic device;
- software, digital health, or mobile medical app;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's Use of Any Device Being Tested in Research web page.

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

○ Yes ◉ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer “no” above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE) or Compassionate Use?

○ Yes ○ No

If Yes, complete the following:
IDE or HDE #(s)

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Check if this is a Treatment IDE or Compassionate Use under the Food and Drug Administration (FDA) Expanded Access program.

For Individual or Small Group Expanded Access, see FDA's Early Expanded Access Program Information, and attach the following:

- FDA expanded access approval or sponsor’s authorization;
- An independent assessment from an uninvolved physician, if available;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Medical Device SOP.

Does the intended use of any research device being tested (not clinically observed) in this study meet the regulatory definition [FDA's PDF] of Significant Risk (SR) device?

- Yes. Device(s) being tested in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- No. All devices being tested in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Complete and attach the required Study Device Form, picking the "Study Device Form" for the document type. Any applicable device documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.) should be attached using "Other Device Documentation" for the document type.

Attachments

RESEARCH SITES

0 unresolved comment(s)

To complete this section, ensure the responses are accurate then click "SAVE".

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- [x] UK Classroom(s)/Lab(s)
- [ ] UK Clinics in Lexington
- [ ] UK Clinics outside of Lexington
- [ ] UK Healthcare Good Samaritan Hospital
- [ ] UK Hospital

Schools/Education Institutions

- [ ] Fayette Co. School Systems *
- [ ] Other State/Regional School Systems
- [ ] Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's IRB Application Instructions - Off-site Research web page for details.**

Other Medical Facilities

- [ ] Bluegrass Regional Mental Health Retardation Board
- [ ] Cardinal Hill Hospital
- [ ] Eastern State Hospital
- [ ] Norton Healthcare
- [ ] Nursing Homes
- [ ] Shriner's Children's Hospital
- [ ] Veterans Affairs Medical Center
- [ ] Other Hospitals and Med. Centers

- [ ] Correctional Facilities
- [ ] Home Health Agencies
- [ ] International Sites

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky (UK) or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page), including:

- A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the IRB Application Instructions - Off-Site Research web page for more information.
- Supportive documentation, including letters of support, can be attached below. When attaching reliance documents, please ensure that you select the correct 'Document Type' from the drop-down menu. See below for the "**Document Types**" in bold, followed by examples of reliance documents for each type:
  - **Individual Investigator Agreement (IIA)**
    - A completed Individual Investigator Agreement

- IRB Approval (Non-UK)
- A Letter of Approval from a Non-UK IRB

- IRB Authorization Agreement (IAA)
- A SMART IRB Agreement
- An OHRP Agreement
- A DoD Agreement
- An IREx Reliance Notification
- Any Reliance Agreement

- Letter of Support & Local Context
- A Letter of Support from an organization at which some research activities are occurring
- Communications Plan
- Local Context Form

Please reach out to IRBReliance@uky.edu if you have any questions or concerns.

- NOTE: If the non-UK sites or non-UK personnel are engaged in the research, there are additional federal and university requirements which need to be completed for their participation. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK sites.
- Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

List all other non-UK owned/operated locations where the research will be conducted:

Describe the role of any non-UK site(s) or non-UK personnel who will be participating in your research.

Please describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites:

Attachments

B) If your research involves collaboration with any sites and/or personnel outside the University of Kentucky, then it is considered multisite research and IRB reliance issues will need to be addressed. This may include national multi-center trials as well local studies involving sites/personnel external to UK. If you would like to request that the University of Kentucky IRB (UK IRB) serve as the lead IRB for your study, or if you would like the UK IRB to defer review to another IRB, please contact the IRBReliance@uky.edu.

RESEARCH ATTRIBUTES

0 unresolved comment(s)

Instructions: For various reasons, it is necessary to determine whether your research activities meet the definition of clinical research and/or a clinical trial. Your responses to the next series of questions will make that determination. For more details on the definitions, go to ORI's clinical research vs. clinical trial web page or visit NIH's decision tree for the NIH Clinical Trial definition.

Contact the Clinical Research Support Office (CRSO) if your study provides clinical services (e.g., labs, biopsies, tissue samples, physical exams, PT, counseling) regardless of payer (grant, federal, UK, industry), utilizes UKHC space, or meets the NIH definition of a clinical trial (thereby requiring registry with CT.gov) as your study will need to be entered in OnCore to ensure appropriate regulatory tracking and billing. Visit CRSO FAQs for more information; requests for CCTS/CRSO services can be submitted via their service request form. For other questions, you can contact the CRSO Director, Jessica Heskel.

My research activities include one or more of the following:

Patient-oriented research regarding mechanisms of human disease, therapeutic interventions, clinical studies, or development of new technologies
(•) Yes ( ) No

Material of human origin (such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects
( ) Yes (•) No

Epidemiologic or Behavioral Studies
(•) Yes ( ) No

Outcomes Research or Health Services Research
(•) Yes ( ) No

Does your research study involve one or more human subjects prospectively assigned into one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes? **If yes, your study meets the NIH definition of a clinical trial.**
(•) Yes ( ) No

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☑ Not applicable

Check All That Apply

☐ Academic Degree/Required Research
☐ Alcohol/Drug/Substance Abuse Research
☐ Biological Specimen Bank Creation (for sharing)
☐ Cancer Research
☐ CCTS-Center for Clinical & Translational Science
☐ Certificate of Confidentiality
☐ Collection of Biological Specimens for banking and use
☐ Community-Based Participatory Research
☐ Deception
☐ Educational/Student Records (e.g., GPA, test scores)
☐ Emergency Use (Single Patient)
☐ Gene Transfer

For additional requirements and information:

- Cancer Research (MCC PRMC)
- Certificate of Confidentiality (look up "Confidentiality/Privacy...")
- CCTS (Center for Clinical and Translational Science)
- Clinical Research (look up "What is the definition of....)
- Clinical Trial
- Collection of Biological Specimens for Banking (look up "Banks, Repositories, Registries...")
- Collection of Biological Specimens (look up "Repositories, Registries, Specimen/Tissue Banks...")
- Community-Based Participatory Research (look up "Community-Engaged...")
- Data & Safety Monitoring Board (DSMB)

  *For Medical IRB: Service Request Form for CCTS DSMB

- Data & Safety Monitoring Plan
- Deception*

- ☐ Genetic Research
- ☐ NIH Genomic Data Sharing (GDS) (databases such as GWAS, dbGaP, GenBank)
- ☐ Treatment with Human Cells, Tissues, and Cellular and Tissue Based Products
- ☐ Individual Expanded Access or Compassionate Use
- ☐ International Research
- ☐ Planned Emergency Research Involving Exception from Informed Consent
- ☐ Recombinant DNA
- ☐ Registry or data repository creation
- ☐ Stem Cell Research
- ☐ Suicide Ideation or Behavior Research
- ☐ Survey Research
- ☐ Transplants
- ☐ Use, storage and disposal of radioactive material and radiation producing devices
- ☐ Vaccine Trials

*For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
- Genetic Research (look up "Banks, Repositories, ...Genetic/Genomic Data Sharing...")
- Gene Transfer

*For gene transfer research, also go to the E-IRB Application Other Review Committees section, and checkmark Institutional Biosafety Committee

- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Exception to Informed Consent*

*For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Use, storage and disposal of radioactive material and radiation producing devices

FUNDING/SUPPORT

0 unresolved comment(s)

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply.

☐ Not applicable

Check All That Apply

- ☑ Grant application pending
- ☑ (HHS) Dept. of Health & Human Services
  - ☑ (NIH) National Institutes of Health
  - ☐ (CDC) Centers for Disease Control & Prevention
  - ☐ (HRSA) Health Resources and Services Administration
  - ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☑ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Click applicable listing(s) for additional requirements and information:

- (HHS) Dept. of Health & Human Services
- (NIH) National Institutes of Health
- (CDC) Centers for Disease Control & Prevention
- (HRSA) Health Resources & Services Administration
- (SAMHSA) Substance Abuse & Mental Health Services Administration
- Industry (Other than Pharmaceutical Companies) [IRB Fee Info-look up "Does the IRB Charge a Fee..."]
- National Science Foundation
- (DoEd) U.S. Department of Education
- (DoJ) Department of Justice or Bureau of Prisons
- (DoE) Department of Energy Summary and Department of Energy Identifiable Information Compliance Checklist
- (EPA) Environmental Protection Agency

Other:

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

University of Kentucky College of Medicine LIFT program Pilot Award (ended)
National Institutes of Health (National Institute on Deafness and Other Communication Disorders) K18 award (ended April 2024)
University of Kentucky EXCEL Initiative award to the MERIT program (current)
National Institutes of Health NIDA CEBRA program R21 application submitted March 2025
National Institutes of Health (National Institute on Deafness and Other Communication Disorders) R01 application will be submitted February 2026

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application using the "Add Related Grants" button.
If required by your funding agency, upload your grant using the "Grant/Contract Attachments" button.

Add Related Grants

Grant/Contract Attachments

Attach Type	File Name
GrantContract	061724 - EXCEL Research Fully Executed Award Letter (Kotter McClintock Han).pdf
GrantContract	McClintock VPR IRC application 2018.pdf
GrantContract	McClintock_FinalDraft.pdf
GrantContract	4718618_Egrant Submitted K18 2022.pdf

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (See DoD SOP

and DoD Summary for details)

○ Yes ◉ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

Assurance/Certification Attachments

OTHER REVIEW COMMITTEES

0 unresolved comment(s)

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

○ Yes ◉ No

Additional Information

- ☐ Institutional Biosafety Committee
- ☐ Radiation Safety Committee
- ☐ Radioactive Drug Research Committee
- ☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
- ☐ Graduate Medical Education Committee (GME)
- ☐ Office of Medical Education (OME)

- Institutional Biosafety Committee (IBC) - Attach required IBC materials
- Radiation Safety Committee (RSC) - For applicability, see instructions
- Radioactive Drug Research Committee (RDRC)
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)** - Attach MCC PRMC materials, if any, per instructions.
- Office of Medical Education (OME)
- Graduate Medical Education Committee (GME)

Attachments

**** If your study involves cancer research, be sure to select "Cancer Research" in the "Research Attributes" section.** ORI will send your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRMC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

Do you want specific information inserted into your approval letter? ○ Yes ◉ No

Approval Letter Details:

If you wish to have specific language included in your approval letter (e.g., serial #, internal tracking identifier, etc…), type that language in the box below exactly as it should appear in the letter. The text you enter will automatically appear at the top of all approval letters, identical to how you typed it, until you update it. Don't include instructions or questions to ORI staff as those will appear in your approval letter. **If these details need to be changed for any reason, you are responsible for updating the content of this field.**

Additional Materials:

If you have other materials you would like to include for the IRB's consideration, check all that apply and attach the corresponding documents using the Attachments button below.

☐ Detailed protocol
☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
☑ Other Documents

Protocol/Other Attachments

Attach Type	File Name
Other	E-IRB 43123 1st Set of Comments Consent Form.pdf
Other	E-IRB 43123 1st Set of Comments Objective 8 Healthy Adult Non-Somkers Consent Form.pdf
Other	Memo Comments for CR of 43123.pdf
Other	E-IRB 43123 1st Set of Comments Consent Form.pdf

NOTE: [Instructions for Dept. of Health & Human Services (DHHS)-approved protocol]

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

To view the materials currently attached to your application, click “All Attachments” on the left menu bar.

SIGNATURES (ASSURANCES)

0 unresolved comment(s)

Introduction

All IRB applications require additional assurances by a Department Chairperson or equivalent (DA), and when applicable, a Faculty Advisor or equivalent (FA). This signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans. The person assigned as DA *should not* also be listed in the Study Personnel section, and the individual assigned as FA *should* be listed in the Study Personnel section.

For a list of responsibilities reflected by signing the Assurance Statement, refer to "What does the Department Chairperson's Assurance Statement on the IRB application mean?"

For a detailed illustration of how to complete this section, please review the short online video tutorial "Signatures (Assurance) Section - How to Complete." Otherwise, follow the steps below.

Required Signatures:

Individuals chosen as signees may remove the application from their Inbox without signing the Assurance Statement by clicking "Return to PI" with a comment about why it is being returned (e.g., specific edits are deemed necessary).

The PI, and personnel chosen as a contact, will receive an email notification that edits are needed, and can find the draft application in both the "Draft" folder and the "Signatures Status" folder located in the menu in the left margin of the default Inbox page. The researcher does not have a 'reply' option to the signee's comments and must make the requested edits directly in the application, or communicate outside the E-IRB system as to why not. Once the response is finalized, the researcher must re-visit the "Assurances Required" section to click the "Return to Signee" button for their re-consideration; the signee will receive an email notification at that time.

Hover your mouse cursor here for additional instructions.

First Name	Last Name	Role	Department	Signee Return Comment	Date Signed	
Alan	Daugherty	Department Authorization	Physiology		12/03/2017 09:20 PM	View/Sign
Timothy	McClintock	Principal Investigator	Physiology		12/03/2017 02:06 PM	View/Sign

Department Authorization

☑ This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator has been notified of the additional regulatory requirements of the sponsor and by signing the principal investigator Assurance Statement, confirms he/she can comply with them.

*If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should complete the "Department Authorization".

**IF APPLICABLE FOR RELIANCE: I attest that the principal investigator has been notified of the regulatory requirements of both the Reviewing and Relying IRBs, according to the information provided in the E-IRB application. The attached Reliance Assurance Statement, signed by the principal investigator, confirms that he/she can comply with both sets of IRB requirements.

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. To accept responsibility for the scientific and ethical conduct of this research study;
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. To report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. To complete, on request by the IRB for Full and Expedited studies, the Continuation/Final Review Forms;
6. To notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. Each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., CITI);
8. Each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

☑ Furthermore, by checking this box, I also attest that:

- I have appropriate facilities and resources for conducting the study;
- I am aware of and take full responsibility for the accuracy of all materials submitted to the IRB for review;
- If applying for an exemption, I also certify that the only involvement of human subjects in this research study will be in the categories specified in the Protocol Type: Exemption Categories section.
- If applying for an Abbreviated Application (AA) to rely on an external IRB, I understand that certain items above (1, 3, 4, 7-8) may not apply, or may be altered due to external institutional/IRB policies. I document my agreement with the Principal Investigator Reliance Assurance Statement by digitally signing this application.

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Once all Assurance Statement signatures have been acquired, return to this section to submit your application to ORI.

SUBMISSION INFORMATION

0 unresolved comment(s)

***** If this Continuation Review entails a change in the scope of your activities to include COVID-19 related research, please insert "COVID19" at the start of your Project and Short Titles.*****

Each Section/Subsection in the menu on the left must have a checkmark beside it (except this Submission section) indicating the Section/Subsection has been completed. Otherwise your submission for IRB review and approval cannot be sent to the Office of Research Integrity/IRB.

If applicable, remember to update the Approval Letter Details text box under the Additional Information section

If your materials require review at a convened IRB meeting which you will be asked to attend, it will be scheduled on the next available agenda and you will receive a message to notify you of the date.

If you are making a change to an attachment, you need to delete the attachment, upload a highlighted version that contains the changes (use Document Type of "Highlighted Changes"), and a version that contains the changes without any highlights (use the appropriate Document Type for the item(s)). Do **not** delete approved attachments that are still in use.

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects, and I attest to:

1. Having reviewed all the investigational data from this study, including a compilation of all internal and external unanticipated problems.
2. Having reviewed, if applicable, information from the sponsor including updated investigator brochures and data and safety monitoring board reports.

I also attest that I have reviewed pertinent materials concerning the research and concluded either:

A. The human subject risk/benefit relationship is NOT altered, and that it is not necessary to modify the protocol or the informed consent process,
OR,
B. The human subject risk/benefit relationship has been altered, and have previously submitted or am including with this continuation review submission, a modification of the research protocol and informed consent process.

☑ By checking this box, I am providing assurances for the applicable items listed above.

Your protocol has been submitted.

Download all

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.109	klars2	1/7/2026 9:29:24 AM
	Stamped Consent Form	Informed consent Odors 020724.pdf		0.149	klars2	1/7/2026 9:29:23 AM
	Stamped Consent Form	Informed consent Smokers 020724.pdf		0.149	klars2	1/7/2026 9:29:23 AM
	Stamped Consent Form	Informed consent Bag Odors 121725.pdf		0.258	klars2	1/7/2026 9:29:23 AM
	Stamped Consent Form	Informed consent fMRI odors Oct 2025 v4.pdf		0.259	klars2	1/7/2026 9:29:23 AM
	Stamped Consent Form	Informed consent RATA 2026 v2.pdf		0.257	klars2	1/7/2026 9:29:23 AM
	Advertising	Email script recruitment for RATA.pdf	RATA recruitment script email	0.031	mcclint	12/19/2025 12:44:34 PM
	CR_EntireConsent	Consent 3 smoker stamped.pdf	Additional signed consent form Smoker	0.790	mcclint	12/19/2025 8:20:06 AM
	Advertising	Recruit email scripts new and prior participants.pdf	Scripts for contacts with new and returning participants	0.064	mcclint	12/18/2025 4:22:37 PM
	Informed ConsentParental Permission	Informed consent RATA 2026 v2.pdf	Consent form RATA study	0.258	mcclint	12/17/2025 9:46:41 AM
	Informed ConsentParental Permission	Informed consent fMRI odors Oct 2025 v4.pdf	Consent form MRI study	0.262	mcclint	12/17/2025 9:46:06 AM
	Informed ConsentParental Permission	Informed consent Bag Odors 121725.pdf	Consent form CPAP mask method	0.259	mcclint	12/17/2025 9:45:33 AM
	DataCollection	RATA scoring sheet.pdf	RATA score sheet listing 50 descriptors	0.021	mcclint	12/12/2025 5:13:10 PM
	ResearchProcedures	RATA scoring sheet.pdf	RATA score sheet listing 50 descriptors	0.021	mcclint	12/12/2025 5:12:01 PM
	StudyDesign	Lee Principle Odor map 23.pdf	Example of the use of the RATA method	5.884	mcclint	12/12/2025 5:06:13 PM
	CR_InterimFindings	Interim findings 2025.pdf	Interim findings for 2025	0.020	mcclint	12/12/2025 2:37:05 PM
	CR_EntireConsent	Consent 2 SplitNostril 25.pdf	Informed consent odors 2	0.466	mcclint	12/11/2025 4:49:38 PM
	CR_EntireConsent	Consent 1 SplitNostril 25.pdf	Informed consent odors 1	0.910	mcclint	12/11/2025 4:49:27 PM
	CR_EntireConsent	Consent 1 Smoker 25.pdf	Smoker consent form 1	0.378	mcclint	12/11/2025 4:46:34 PM
	CR_EntireConsent	Consent 2 Smoker 25.pdf	Smoker consent form 2	0.380	mcclint	12/11/2025 4:46:10 PM
	ResearchProcedures	Smoking History Form.pdf	Nicotine exposure smoking history form	0.047	mcclint	11/24/2025 8:49:00 AM
	ResearchProcedures	PreScrnF.pdf	MRI eligibility prescreening form	0.459	mcclint	11/24/2025 8:48:25 AM
	AddInfoProduct	E-IRB 43123 1st Set of Comments Consent Form.pdf	1st Set of Comments Consent Form	0.294	klars2	11/12/2025 9:33:35 AM
	Advertising	McClintock MRI flyer-STAMPED.pdf	Flyer for MRI study recruitment	0.626	mcclint	11/7/2025 4:25:41 PM
	Advertising	PHYS-009_1_Social Media-STAMPED.pdf	text for social media for MRI study recruitment	0.382	mcclint	11/7/2025 4:25:07 PM
	Advertising	PHYS-009_1_Webpage-STAMPED.pdf	Webpage text for MRI study recruitment	0.373	mcclint	11/7/2025 4:24:20 PM
	Advertising	McClintock Social media post text 2025-STAMPED.pdf	Social media text	0.123	mcclint	4/1/2025 11:13:14 AM

Advertising	PHYS-009c_Social media-STAMPED.pdf	Social media flyer, text and image	1.123	mcclint	4/1/2025 11:12:40 AM
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DataCollection	Response Sheet Objective 8.pdf	Scoring sheet Objective 8	0.041	mcclint	7/19/2024 11:38:07 AM
AddInfoProduct	E-IRB 43123 1st Set of Comments Objective 8 Healthy Adult Non-Somkers Consent Form.pdf	1st Set of Comments Consent Form Objective 8	0.152	klars2	7/18/2024 10:11:56 AM
GrantContract	061724 - EXCEL Research Fully Executed Award Letter (Kotter McClintock Han).pdf	Award letter for EXCEL Initiative Award	8.162	mcclint	7/12/2024 10:58:49 AM
Informed ConsentParental Permission	Informed consent Smokers 020724.pdf	Informed consent smokers	0.150	mcclint	2/7/2024 1:49:11 PM
Informed ConsentParental Permission	Informed consent Odors 020724.pdf	Consent form for healthy subjects odor perception	0.150	mcclint	2/7/2024 1:48:36 PM
GrantContract	4718618_Egrant Submitted K18 2022.pdf	Career Development Award for sabbatical to learn new methods	4.576	mcclint	2/7/2024 9:43:55 AM
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Advertising	PHYS-009b_Research Match-STAMPED.pdf	Approved Smoker test Research Match text	0.164	mcclint	2/16/2023 10:35:16 AM
Advertising	PHYS-009b_Social media-STAMPED.pdf	Approved smoker test Social Media text	1.119	mcclint	2/16/2023 10:34:44 AM
Advertising	PHYS-009b_MON-STAMPED.pdf	Approved Smoker test Monitor page	0.132	mcclint	2/16/2023 10:33:45 AM
Advertising	PHYS_009b flyer-STAMPED.pdf	Approved Smoker test print flyer	8.587	mcclint	2/16/2023 10:32:23 AM
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StudyDesign	Strickland Rush Demand Model 16.pdf	Cigarette purchase demand task reference	0.299	mcclint	1/22/2023 1:49:17 PM
StudyDesign	Odor Sample Bag Description.pdf	Odor Sample bag description	0.187	mcclint	1/22/2023 1:48:19 PM
DataCollection	Smoker Score sheet.pdf	Scoring sheet for Smoker study	0.046	mcclint	1/22/2023 1:46:22 PM
Advertising	Pre Screening survey.pdf	Pre-screening survey questions	0.008	mcclint	8/14/2022 10:45:03 AM
Advertising	Social Media page.png	Social Media survey recruitment flyer 2022	0.405	mcclint	8/14/2022 10:30:58 AM
Advertising	Research Match screen.png	Research Match survey recruitment text 2022	0.151	mcclint	8/14/2022 10:28:07 AM
Advertising	PHYS_0xx flyer-STAMPED.pdf	Survey flyer 2022	8.566	mcclint	8/12/2022 10:16:33 AM
Advertising	PHYS-0xxmonitor-STAMPED.pdf	Monitor version of survey flyer	1.242	mcclint	8/12/2022 10:09:57 AM
Advertising	Clean Odor rating Research flyer Jan22.pdf	Revised flyer, clean	2.500	mcclint	1/25/2022 10:49:44 AM

Advertising	Highlighted Odor rating Research flyer Jan22.pdf	Revised flyer, highlighted changes	2.500	mcclint	1/25/2022 10:48:30 AM
Advertising	PHYS-009-sm APPROVED 2020.pdf	Social media version of recruitment flyer 2020	0.366	mcclint	1/9/2020 4:30:42 PM
Advertising	PHYS-009-rm[1] APPROVED 2020.pdf	ResearchMatch recruitment text 2020	0.048	mcclint	1/9/2020 4:30:17 PM
Advertising	PHYS-009_MON[1] APPROVED 2020.pdf	Monitor version of recruitment flyer 2020	2.488	mcclint	1/9/2020 4:29:44 PM
Advertising	PHYS-009 APPROVED 2020.pdf	2020 Recruitment flyer Approved	0.247	mcclint	1/9/2020 4:29:12 PM
GrantContract	McClintock_FinalDraft.pdf	Cigarette smoke antagonist R21 application	1.303	mcclint	12/12/2019 8:16:18 AM
Advertising	43123 Prescreening Appendix.pdf	Redcap prescreening questions	0.186	mcclint	2/13/2019 8:07:39 AM
GrantContract	McClintock VPR IRC application 2018.pdf	Grant proposal	0.994	mcclint	11/15/2018 9:50:22 AM
SponsorInvTraining	citiCompletionReport6845666 Chesser.pdf	HSP training certificate: Chesser	0.400	mcclint	9/17/2018 11:02:44 AM
StudyPopulation	Odor Pleasantness Research Questionnaire2.pdf	Health Questionnaire	0.307	mcclint	1/26/2018 2:42:02 PM
SponsorInvTraining	TS citiCompletionReport6811326 2.pdf	HSP training certificate: Sengoku	0.400	mcclint	12/11/2017 3:42:36 PM
SponsorInvTraining	WT citiCompletionReport6811346.pdf	HSP training certificate: Titlow	0.530	mcclint	12/11/2017 3:42:09 PM

Click link to sort Changed Date
IsFedFunded changed by mcclint on 12/12/2025 5:24:17 PM
~~N~~Y
Funding/Support FundingSource changed by mcclint on 12/19/2025 4:07:52 PM
University of Kentucky College of Medicine LIFT program Pilot Award (ended) ¶
National Institutes of Health (National Institute on Deafness and Other Communication Disorders) K18 award (ended April 2024) ¶
University of Kentucky EXCEL Initiative award to the MERIT program (current) ¶
National Institutes of Health NIDA CEBRA program R21 application submitted March 2025 ¶
National Institutes of Health (National Institute on Deafness and Other Communication Disorders) R01 application will be submitted February 2026
Funding/Support FundingSource changed by mcclint on 12/19/2025 4:02:53 PM
University of Kentucky College of Medicine LIFT program Pilot Award (ended) ¶
University of Kentucky EXCEL Initiative award to the MERIT program (current) ¶
National Institutes of Health NIDA CEBRA program R21 application submitted March 2025 ¶
National Institutes of Health (National Institute on Deafness and Other Communication Disorders) R01 application will be submitted February 2026
Funding/Support GrantAppPending changed by mcclint on 12/19/2025 3:59:52 PM
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Funding/Support HealthHumanServ changed by mcclint on 12/12/2025 5:24:17 PM
Y
Funding/Support NationalInstitutesOfHealth changed by mcclint on 12/12/2025 5:24:17 PM
Y
Funding/Support PrivateFoundAssociation changed by mcclint on 12/19/2025 4:02:53 PM
~~Y~~
Funding/Support PrivateFoundAssociation changed by mcclint on 12/12/2025 5:24:17 PM
Y
Informed Consent CoverLetterSurvey changed by mcclint on 12/19/2025 8:17:55 AM
~~Y~~N
Informed Consent InformedConsentProcess changed by mcclint on 12/12/2025 3:31:25 PM
Informed consent will be obtained when subjects first arrive for their sessions. An informed consent form for this study is attached. Signed consent forms for studies in progress are kept locked in a safe in MS535 Medical Sciences, to which only Dr. McClintock and Ms Frazier have the combination. Once a study is completed the signed informed consent forms are transferred to in a safe in Dr. McClintock's office. Only he can open this safe. ¶
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December 2019 Modification. This study is completely separate from the one objective already completed, Objective 3. We are not tracking subjects from Objective 3, nor will we contact them individually. It is possible that subjects from Objective 3 may volunteer for Objective 4, and this is permissible because there is no reason to expect that their experiences in the Objective 3 study would affect their future performance. Signing a new consent form is required to participate in this objective. ¶
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July 2022 Modification: Objective 6. (Note: Work on this objective has been terminated due to poor response rate.) ¶
Because this is a survey only study we are requesting a waiver of informed consent for it. Waiver of informed consent allows survey respondents to have a single, efficient interaction with the study; factors that improve compliance with survey parameters and respondent satisfaction. The waiver is justified by the absence of risk to the participants. ¶
Complaints or requests for information will be referred to the PI, who will offer to meet individually with each subject and answer their questions, and also provide the subject with contact information for ORI staff. In these meetings, we are prepared to show subjects de-identified summary data (means and ranges of responses in the data) to reassure subjects that they do indeed have a functional sense of smell within the normal range of humans. In cases of a specific hyposmia, the not uncommon situation where a person has difficulty smelling one odor but not most others, these same comparisons will be used to reassure the subject that their case is not unusual, nor is it cause for concern. In the unlikely case of a complaint arising from a reaction to an odorant, the objective of the meeting will be to counsel the subject on how to avoid the odorant that caused the reaction, and to encourage the subject to discuss their hyper-responsiveness with their physician. The study personnel are taught to inform the PI of any adverse reactions so that the PI can pro-actively request a meeting with any subject with such a reaction. Subjects are given a card and an email message with the contact information of the PI and of ORI staff so that they can follow-up on concerns at any time. ¶
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January 2023 Modification: Objective 7. ¶
The subjects for this survey will be current smokers, and therefore will be new participants different from those in the other Objectives, which excluded smokers. However, in the unlikely event that a participant in one of our prior studies has become a smoker in the interim, the person will be allowed to participate. ¶
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July 2024 Modification: Objective 8. ¶
The subjects for this survey will be healthy adult non-smokers. Consent will be sought by the PI or IRB approved staff when potential subjects arrive for testing at MN509 Med Sci using consent form "Informed consent Bag Odors 071924". As part of this process potential subjects are informed verbally and in writing that they suffer no consequences from refusing to participate. ¶
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October 2025 Modification: Objective 9. ¶
The subjects for this will be current smokers. Smokers who participated in Objective 7 are eligible to participate. In the unlikely event that a participant in another prior study has become a smoker in the interim, the person will also be allowed to participate. ¶
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December 2025 Modification: Objective 10. ¶
Subjects will be up to 100 healthy adults of all genders and ages 18 – 60. People who participated in other Objectives are eligible to participate.
Informed Consent InformedConsentProcess changed by mcclint on 12/12/2025 3:17:07 PM
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Informed Consent RequestWaiverInformedConsent changed by mcclint on 12/12/2025 3:04:30 PM
~~Y~~N
Informed Consent WaiveIC changed by mcclint on 12/12/2025 3:04:30 PM
~~Y~~N
Informed Consent WaiveICInfoAfterStudy changed by mcclint on 12/12/2025 3:04:30 PM
~~There is no reason the survey would produce additional pertinent information for participants. However, participants have access to the PI's contact information and can request information or answers to questions.~~
Informed Consent WaiveICMinRisk changed by mcclint on 12/12/2025 3:04:30 PM
~~This waiver applies only to Objective 6, which is a survey only, and therefore involves no risk.~~
Informed Consent WaiveICPracticably changed by mcclint on 12/12/2025 3:04:30 PM
~~Waiver of informed consent allows survey respondents to have a single, efficient interaction with the study; factors that improve compliance with survey parameters and respondent satisfaction.~~
Informed Consent WaiveICRights changed by mcclint on 12/12/2025 3:04:30 PM
~~Identifiable information is removed before analysis of the data collected.~~
Project Information ProjectEndDate changed by mcclint on 12/11/2025 5:00:47 PM
12/31/2026~~7~~ 12:00:00 AM
Project Information SubjectCount changed by mcclint on 12/12/2025 2:43:39 PM
~~5~~810
Research Description Background changed by mcclint on 12/12/2025 5:02:40 PM
The perception of odors is linked to several clinically important conditions. Reduced sensitivity to odors or a reduced ability to recognize odors is an early indicator of dementia and Parkinson's Disease in a substantial fraction of persons who eventually develop these syndromes. Head trauma often also causes a reduced ability to detect odors (hyposmia), or even a total loss of the sense of smell (anosmia). In addition to situations where olfactory deficits are caused by pathology, odors can also trigger clinical conditions. This famously include migraines, but also includes cravings for abused substances such as tobacco products. Lastly, odors are social cues we use to evaluate others. Controlling odor emissions are therefore major components of personal hygiene. In this project we seek to assess human odor perception in order to help evaluate putative blockers of unwanted odors. These odor blockers are being developed in ~~preclinical~~ studies in the laboratory of Dr. McClintock. ¶
¶
Natural odors are mixtures of many species of odorants. An odorant is any volatile chemical that can be detected as a scent by the olfactory system. Many decades of behavioral studies (humans and animals) and physiological experiments (animals) demonstrate that when odorants are mixed together to create a complex odor, the odorants may interact in unpredictable ways. This outcome is seen not only when measured at the perceptual level but also at the level of the sensory neurons in the olfactory epithelium. These findings argue that the interactions are happening at the receptor proteins expressed in these neurons. Indeed, work in the McClintock laboratory now confirm this prediction and demonstrate that receptors for one odorant can often be blocked by other odorants. These findings indicate that moving from simple masking agents or odor trapping agents (air fresheners, deodorizers, Febreze, etc.) to true blockers of specific unwanted, foul-smelling odors (malodors) is now possible. The data suggest that it will be possible to find pleasant or neutral odors that can block specific malodors. As preclinical studies in the McClintock laboratory develop blockers of mouse odorant receptors responsive to malodors, testing these true odor blockers in humans is the logical next step. Herein, we propose to establish protocols to do so. ¶
¶
Some facts about odorant perception that are relevant for evaluating this research. First, the impact of encountering odors is poorly understood. Olfactory scientists suspect that much of what odors do to humans occurs below the level of consciousness, making these effects difficult to identify and study rigorously. Fortunately, this research project need only be concerned with effects that reach consciousness, and therefore can easily be assessed. Second, females tend to be slightly more sensitive to odors than males, but the perception of odors and their pleasantness typically does not differ with sex. We are therefore able to treat sexes equally. However, perception of odor pleasantness can be greatly affected in pregnant females, and they will be excluded from the study. Third, many decades of work show that the percept of an odor, meaning the perceived quality (e.g., pleasant/unpleasant; or woody, floral, green, musky, etc.) almost never changes with odor concentration. We will use odors for which this "perceptual constancy" is known to be true. In addition, this constancy means that we need not be concerned that some subjects will sniff the odors more aggressively than others. Their assessment of odor pleasantness will not be affected. However, in cases where we identify specific blockers of malodors, understanding how these blockers shift perception is important information. We will measure these shifts in perception. ¶
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As of now, this project does not have extramural funding, but we have begun submitting grant applications on the topics investigated using human subjects. We continue to develop preliminary data for these applications.
Research Description Background changed by mcclint on 12/12/2025 3:25:05 PM
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Research Description DataCollection changed by mcclint on 12/19/2025 8:27:07 AM
The data collection tool is a worksheet that displays only the date, the subject's code, and a column displaying the bottle codes. The researcher running the testing operates the worksheet. Empty columns are used to record the subject's scores. If a slider device is used for scoring the researcher records each score immediately. If the subject selects a scoring sheet, the researcher may instead record the scores at the completion of the testing. ¶
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July 2022 Modification: Design for Objective 6. ¶

An online REDCap survey of 30 questions will be used to gather data that will provide information about potential causes of the urge to smoke in reformed smokers. We will then use REDCap's powerful statistical tools to evaluate whether any of the factors queried show evidence of affecting the urge to smoke, and whether these effects correlate with the time since quitting cigarettes, demographic factors, or use of other forms of nicotine or tobacco. Participants will access and complete a REDCap survey online via the device of their choice. We will set the enrollment cap tool in REDCap at 200 completed surveys, thereby closing the survey at 200 complete responses. Incomplete surveys are not counted against the cap. To match the demographics of our other human experiments we will discard data from those outside the desired age range of 18-60 years. ¶
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January 2023 Modification: Objective 7. ¶
The data collection tool (score sheet) is a worksheet that displays the date, the participant's unique code, a column for recording the sequence of odor bags (letter codes), and columns to score whether the odor is pleasant or unpleasant (a forced choice test), a subjective rating of their desire to smoke on a scale of 0 – 100, and a Cigarette Purchase Task amount ranging from $0.00 (free) to $1,120. At the top of the score sheet are spaces for demographic data (age, sex, ethnic and racial background) and smoking history information (cigarettes per day, preferred brand, age at onset, and time since last cigarette). ¶
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July 2024 Modification: Objective 8. ¶
Data collection scoring is done on a worksheet (paper or digital) that displays the date, the participant's unique code, a column for recording the sequence of odor bags (letter codes), and columns to score whether the odor is pleasant or unpleasant (a forced choice test), and a column to rate the intensity of cigarette smoke odor in each bag. ¶
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October 2025 Modification: Objective 9. ¶
The data collected are MRI scan images plus questionnaires about nicotine exposure history and eligibility for MRI scanning. These are de-identified via numerical codes and used for research purposes only. ¶
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December 2025 Modification: Objective 10. ¶
Participants use a score sheet (digital or hard copy) to rate how strongly each of the 50 descriptors applies to each unidentified odor they are given. Ratings are a linear scale of 0 - 5. ~~A~~The scoreing sheet is attached here and under Research Procedures.
Research Description DataCollection changed by mcclint on 12/12/2025 5:15:10 PM
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~~N = up to 100 participants. Each participant does only 1 session. ¶~~
~~Participants will be seated at a table or bench at a fume hood or odor capture device used to prevent odors from accumulating in the room. A researcher is available throughout the session to answer questions and attend to problems. ¶~~
~~1. A researcher will provide a list of up to 50 verbal descriptors used for odors and a tray of 50 labeled vials, each containing an odor exemplifying the corresponding descriptor. Participants will be allowed to familiarize themselves with these 50 odors at their own pace. ¶~~
~~2. Once a participant is comfortable with the~~Participants use a score sheet (digital or hard copy) to rate how strongly each of the 50 descriptors~~, a researcher will give them a different tray of up to 30 vials, each containing an unidentified odor for them to rate. Participants will be given a score sheet (digital or hard copy) listing the 50 descriptors and asked to rate how well each descriptor applies to each unidentified odor using a scale of 0 - 5. Here again, participants proceed at their own pace~~pplies to each unidentified odor they are given. Ratings are a linear scale of 0 - 5. A score sheet is attached.
Research Description DataCollection changed by mcclint on 12/12/2025 5:10:44 PM
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Research Description Objectives changed by mcclint on 12/12/2025 5:03:31 PM
Objective 1. Determine the relative foulness of malodors that we target for development of blocking odors. ¶
Objective 2. Determine the effectiveness of malodor blockers on reducing negative perceptions of targeted malodors ¶
March 2018 Modification: Objective 3. Identify odor mixtures that are perceived as tobacco smoke or include odors that suppress the perception of tobacco smoke. ¶
December 2019 Modification: Objective 4. Test predicted odorant antagonists for pentanethiol-responsive odorant receptors and 2-methoxyphenol-responsive odorant receptors to find those effective at blocking perception of these cigarette smoke odor molecules. ¶
January 2022 Modification: Objective 5. Test additional odorants or odor mixtures that are predicted to block the perception of cigarette smoke odor or the cigarette flavor additive, menthol, and determine the concentration-dependence of these effects. ¶
July 2022 Modification. Objective 6. Collect data via survey on whether selected factors cause an urge to smoke a cigarette or increase the urge to smoke a cigarette. ¶
January 2023 Modification: Objective 7. Determine whether odorants and odorant mixtures that suppress perception of the intensity of cigarette smoke odors (Objective 5) interfere with the ability of cigarette smoke odor to increase the urge to smoke in smokers. ¶
July 2024 Modification: Objective 8. Identify new odors that suppress perception of real cigarette smoke odor. ¶
October 2025 Modification: Objective 9. Identify neural pathways affected by odors that suppress both perception of real cigarette smoke odor and the urge to smoke. ¶
We have discovered odors that suppress perception of real cigarette smoke odor at isointense dilutions and consequently reduce the ability of cigarette smoke odor to increase the urge to smoke. These two findings predict that central nervous system circuits mediating odor perception, as well as emotional and reward pathways linked to smell, respond differently to cigarette smoke odor when these blocking odors are present. We will test this hypothesis using fMRI of the brains of smokers exposed to cigarette smoke odor with and without the blocking odors also being present. ¶
December 2025 Modification: Objective 10. Determine how odors that effectively block perception of cigarette smoke odor by acting in the olfactory periphery (the nose) alter the perception of cigarette smoke compared to odors that are ineffective blockers.
Research Description Payment changed by mcclint on 12/12/2025 5:21:46 PM
Some student subjects may be in classes that provide them the opportunity to earn extra credit by participating in this study. In these cases, participating in the study will be only one of the ways in which extra credit may be earned, and all options for extra credit will be equivalent in the amount of time and effort required. ¶
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As of December, 2021 we have resources available to pay subjects $20 for each rating session. This is true not only for the objective of the January, 2022 modification, but also for all objectives not yet completed (1 and 2). Subjects are allowed make multiple return visits to rate new sets of candidate antagonists, each time receiving a $20 payment. Payments will be made in the form of a check or cash. ¶
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July 2022 Modification: Design for Objective 6. ¶
Former smoker survey. These respondents will not be paid but are entered into a lottery for one of two $150 gift payments. Using a random number generator we have identified completed surveys number 41 and number 167 as the recipients of these payments. Upon completion of these two surveys, REDCap will notify the respondents that they are the winners of the awards, providing them with information on how to submit information to receive payment. ¶
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January 2023 Modification: Objective 7. ¶
As of December, 2022 we have resources available to pay subjects $30 for each rating session. Payments will be made in the form of a check or cash. ¶
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July 2024 Modification: Objective 8. ¶
We have resources available to pay subjects $30 for each rating session. Payments will be made in the form of a check or cash. ¶
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October 2025 Modification: Objective 9. ¶
For fMRI sessions, participants are paid $50 per session. Payments will be made in the form of a check. In addition, transportation costs (ride share or taxi) and parking costs may also be paid to participants. ¶
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December 2025 Modification: Objective 10. ¶
We have resources available to pay subjects $30 for each rating session. Payments will be made in the form of a check.
Research Description PotentialRisks changed by mcclint on 12/12/2025 5:17:51 PM
Risks are minimal. The odorants are prepared and delivered in a way that prevents subjects experiencing known toxic concentrations. The potential physical risks are therefore hyper-responsive conditions, such as allergic reactions or odor-triggered migraines, of which the subjects were previously unaware. Testing will be stopped immediately for any subject who shows signs of an allergic reaction or complains of a headache. ¶
¶
To minimize the risk of breaches of confidentiality, completed questionnaires will be stored only in a password-protected computer in MS585 Med. Sci, separate from the computer used to acquire the data. Dr. McClintock is the only people who have access to this computer, and to the secure server that is used to store back-ups of the files (cifs://prdltcancifs01.mc.uky.edu/research/lab/mcclintock-t). Signed consent forms for studies in progress are kept locked in a safe in MS535 Medical Sciences, to which only Dr. McClintock and the staff member administering testing (Ms. Frazier) have the combination. Once a study is completed the signed informed consent forms are transferred to in a safe in Dr. McClintock's office. Only he can open this safe. ¶
Like the risks involved, potential benefits to the subjects are small. For some the exercise will fulfill their curiosity about their sense of smell. For a few that are attracted to the study because they perceive problems with their ability to smell or taste, the exercise will be reassuring. Unlikely, but possible, is that we might discover cases of undiagnosed chronic deficits in smell perception. These persons will be directed to: 1) ask their physicians to investigate the cause of hyposmia/anosmia and 2) seek counseling on how to cope with smell deficits in their daily lives (employing gas and smoke detectors in their living spaces; adjusting the flavoring of the foods they eat to help maintain nutrition are two examples.) ¶
¶
The benefits to society and general knowledge are more substantial. We will determine whether odor blockers that work at mouse odorant receptors are also effective in humans, opening the door to the use of these blockers to improve quality of life for many people. For example, the objective~~ of the December 2019 modification is to identify odorants that block odorant receptors responsive to pentanethiol, a key odorant in~~ in this protocol are increasingly focused on identify odorants that block perception of cigarette smoke. Ultimately, ~~such~~these odorant antagonists could be used to ~~block the perception of cigarette smoke odor. This is useful because the detection of cigarette smoke odor~~prevent cigarette smoke odor from triggering the urge to smoke in smokers and former smokers. This could be used to improve smoking cessation. ¶
¶
October 2025 Modification: Objective 9. ¶
Risks of participating in MRI studies are minimal. Several measures are taken to detect the presence of metal in the body, including using a hand-held metal detection device. If there is any chance that metal exists in the subject's body that individual is not allowed to enter the MRI scanner. To address the risk of loud noise from the MRI scanner, ear protection is worn. To protect confidentiality, the participant's brain images and nicotine use history are only identified by a code. No unauthorized personnel are allowed in the MRI area while a subject is participating in a study. There are no known interactions between odor exposure and MRI scanning.
Research Description ResearchMaterialsRecordsPrivacy changed by mcclint on 12/12/2025 5:21:46 PM
Only sensory perception data is obtained from the subjects in this study. This study is not expected to discover findings that could affect the health of a subject, but upon request from a subject we will provide summary data, the means and ranges of responses across the full data set, and a brief description of the meaning of the findings. ¶
¶
Confidentiality. A subject's identity will not be recorded into the data file, but rather a unique study number will be given to each subject and this study number is entered into the data file instead of a name. Data are therefore always de-identified. Only the study personnel will interact with subjects. The pre-screening questionnaire will be seen only by study personnel. Data records will be kept for six years and then any record that identifies the individuals tested will be destroyed. Signed consent forms are kept in a safe in Dr. McClintock's office. Only Dr. McClintock has access into this safe. ¶
¶
Breach of confidentiality. To minimize opportunities for breaches of confidentiality, completed questionnaires will be stored only in a password-protected computer in ~~MS535 Med. Sci.~~B236 BBSRB separate from the computer used to acquire the data. Dr. McClintock~~, Ms. Aulicio,~~ and Ms. ~~Chess~~Frazier are the only people who have access to this computer, and to the secure server that is used to store back-ups of the files (cifs://prdltcancifs01.mc.uky.edu/research/lab/mcclintock-t). ¶
¶
Security. Until subjects have completed their participation, questionnaires will be stored only in a password-protected computer in ~~MS535 Med. Sci~~B236 BBSRB, separate from the computer used to acquire the data. They will also be stored on a secure UK server as a back-up. As additional security, ~~MS535 is kept locked when not in use~~B236 BBSRB is key card access only. Emails containing questionnaire responses will be deleted as soon as the responses are stored on the password-protected computer. Once subjects have completed their participation in the study, their questionnaire responses will be deleted. Other records, such as the data files and consent forms will be kept for six years and then destroyed. ¶
Contact with odorant chemicals is limited to the small amounts that volatilize into air. Subjects are not allowed to come into contact with the cotton ball containing the odor source. ¶
¶
October 2025 Modification: Objective 9. ¶
To protect privacy and confidentiality, the participant's brain images and nicotine use history are only identified by a numerical code. All code labeled data will be permanently (or for at least for 6 years) stored on computers at MRISC, which are behind secured doors. Random code labeled data will only be made available to the principle investigator and co-investigators, who also keep the data on secured computers.
Research Description ResearchProcedures changed by mcclint on 12/17/2025 12:33:21 PM
Participants will be seated at a table whose surface is clear of all but a display of a scale numbered from 0 to 100, a pencil and a scoring sheet. At this point, the researcher will provide instructions to the subject: ¶
1. For pleasantness ratings, a score of 50 represents an odor with neutral pleasantness, or an odor that is not detectable. Higher numbers represent progressively greater pleasantness; lower numbers represent progressively greater unpleasantness. For forced choice ratings of pleasantness, the subject marks the odor as either pleasant or unpleasant on the scoring sheet. ¶
2. For similarity and intensity ratings using the 0-100 scale, higher numbers indicate greater similarity or intensity, and 0 means no similarity or intensity. ¶
3. The subject is instructed to use the squeeze bottle by placing the spout a few inches below the nose and squeezing gently, or if vials are being used, to open the vial and place under the nose. The researcher demonstrates with an empty vial or bottle. ¶
4. Upon verbal agreement of readiness, the researcher hands the first sample vial or bottle to the subject to smell. (The order of the vials/bottles is determined previously using a random number generator. The bottles are coded using a letter code.) The subject enters one or more ratings on a scoring sheet. Upon receiving the bottle back from the subject the research activates a 1 min timer. ¶
5. When 1 - 2 min has elapsed, the researcher gives the subject the next bottle. Steps 4 and 5 are repeated until half the vials/bottles have been tested. ¶
6. The subject is allowed a 10 min break. ¶
7. Steps 4 and 5 are repeated with the remainder of the vials/bottles. ¶
8. Upon completion the subject is thanked and released. ¶
¶
July 2022 amendment. Participants will access and complete a REDCap survey online via the device of their choice. The survey has 30 questions that provide demographic information, smoking history, and data on the effects of factors that may cause an urge to smoke. Participants provide an answer to each question, with most questions allowing the option to refuse to answer. REDCap will be set to allow participants to navigate back to previous questions and change answers. Upon completion of the survey REDCap will show a message confirming completion and thanking the participant. We will set the enrollment cap tool in REDCap at 200 completed surveys, thereby closing the survey at 200 complete responses and triggering notification of the investigators. Incomplete surveys are not counted against the cap. To match the demographics of our other human experiments we will discard data from those outside the desired age range of 18-60 years. ¶
¶
January 2023 Modification: Objective 7. ¶
Participants will be seated at a small table in our odor control room whose negative pressure and fume evacuation devices reduce the ability of odors to accumulate. The table is clear of all but a score sheet and a pencil. ¶
1. A researcher will instruct the participant on how to use the score sheet. ¶
2. A researcher will then instruct the participant in how to wear the nose mask, how to fit odor sample bags to the mask, and how to remove bags from the mask. ¶
3. Using the unique random order assigned to the current session and participant, the smoker fits the first bag onto their mask, opens the valve, inhales once through the nose, closes the valve, removes the bag, and hands it to the researcher. ¶
4. The participant then reports three values on a score sheet: Whether the odor is pleasant or unpleasant (a forced choice test), a subjective rating of their desire to smoke on a scale of 0 – 100, and a Cigarette Purchase Task amount. The Cigarette Purchase Task (Strickland et al., 2016; attached) requires selecting how much the smoker is willing to spend for a single cigarette (their preferred brand) from a list of 19 amounts ranging from $0.00 (free) to $1,120. ¶
5. A 2 – 3 min wait period is enforced between each odor presentation to prevent odor adaptation and to allow acute motivational effects to subside. A nature documentary is available on the TV screen in the room for entertainment during the wait period. ¶
6. When the wait period has elapsed the researcher hands the next bag to the participant, and steps 3-5 are repeated until all bags have been scored. ¶
7. Upon completion of the session the participant is thanked and released. ¶

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July 2024 Modification: Objective 8. ¶
Participants will be seated at a small table in our odor control room whose negative pressure and fume evacuation devices minimize the ability of odors to accumulate. The table is clear of all but a laptop computer used to record scores. Alternatively, a score sheet and pencil can be substituted for the laptop. ¶
1. A researcher will instruct the participant on how to score samples. ¶
2. A researcher will then instruct the participant in how to wear the nose mask, how to fit odor sample bags to the mask, and how to remove bags from the mask. ¶
3. Using the unique random order assigned to the current session and participant, the participant fits the first bag onto their mask, opens the valve, inhales once through the nose, closes the valve, removes the bag, and hands it to the researcher. ¶
4. The participant then reports two values: Whether the overall odor is pleasant or unpleasant (a forced choice test) and a subjective rating of the intensity of cigarette smoke odor (the target odor) in the bag. ¶
5. A 1 – 2 min wait period is enforced between each odor presentation to minimize odor adaptation. A nature documentary is available on the TV screen in the room for entertainment during the wait period. ¶
6. When the wait period has elapsed the researcher hands the next bag to the participant, and steps 3-5 are repeated until all bags have been scored. ¶
7. Upon completion of the session the participant is thanked and released. ¶
¶
October 2025 Modification: Objective 9. ¶
1. Recruited participants are scheduled, informed where to report, and told to wear comfortable clothing, contact lenses (rather than glasses, if applicable), and that they may want to prevent dry eyes by using eye drops before the study. ¶
2. Upon arrival, participants meet with a member of the study staff to do a brief questionnaire to confirm their eligibility and obtain their nicotine exposure history. ¶
3. They are then brought to the MRISC and deposit all personal items (e.g., jewelry, hair accessories, shoes, wallets, credit cards and loose change) into secure storage. They are then screened with a metal detector to ensure that they do not have metal in their body. ¶
4. Participants are fitted with ear protection, a CPAP nose mask or cannulae that open into the nostrils for odor delivery, and allowed to practice breathing and sniffing irrelevant odor samples. ¶
5. Instructions on being in the scanner and communicating with the experimenter and MRI technologist are then given. Once familiar with these procedures participants are made comfortable on the scanner bed, then inserted into the scanner and asked to lie motionless. ¶
6. The participant will be able to hear the experimenter's instructions through the ear protection. The experimenter and MRI technologist work together to manage the experiment. They speak to the subject frequently throughout the experiment and inform the participant about events that will occur next, what kind of responses they will make, what kind of noises they will expect to hear from the MRI scanner, and how long it will be before the experimenter speaks to the subject again. ¶
7. Once these preparations are complete, participants sniff an odor every 1 minute in a block design where each odor is repeatedly sniffed before moving to the next odor. Each participant will repeatedly sniff 3 - 6 different odors. ¶
8. Upon completion of MRI, the participant is taken out of the scanner and off the bed slowly, taken back into the control room and their personal items are returned to them. They are then escorted back to the public area of the medical center most convenient to their mode of transportation. The entire procedure, from arrival to completion, will last 1 – 2 hours. ¶
¶
December 2025 Modification: Objective 10. ¶
N = up to 100 participants. Each participant does only 1 session of 1-2 hrs in length. ¶
Participants will be seated at a table or bench at a fume hood or odor capture device used to prevent odors from accumulating in the room. A researcher is available throughout the session to answer questions and attend to problems. ¶
1. A researcher will provide a list of up to 50 verbal descriptors used for odors and a tray of 50 labeled vials, each containing an odor exemplifying the corresponding descriptor. Participants will be allowed to familiarize themselves with these 50 odors at their own pace. ¶
2. Once a participant is comfortable with the descriptors, a researcher will give them a different tray of up to 30 vials, each containing an unidentified odor for them to rate. Participants will be given a score sheet (digital or hard copy) listing the 50 descriptors and asked to rate how well each descriptor applies to each unidentified odor using a scale of 0 - 5. Here again, participants proceed at their own pace. A score sheet is attached.
Research Description ResearchProcedures changed by mcclint on 12/12/2025 5:12:14 PM
Participants will be seated at a table whose surface is clear of all but a display of a scale numbered from 0 to 100, a pencil and a scoring sheet. At this point, the researcher will provide instructions to the subject: ¶
1. For pleasantness ratings, a score of 50 represents an odor with neutral pleasantness, or an odor that is not detectable. Higher numbers represent progressively greater pleasantness; lower numbers represent progressively greater unpleasantness. For forced choice ratings of pleasantness, the subject marks the odor as either pleasant or unpleasant on the scoring sheet. ¶
2. For similarity and intensity ratings using the 0-100 scale, higher numbers indicate greater similarity or intensity, and 0 means no similarity or intensity. ¶
3. The subject is instructed to use the squeeze bottle by placing the spout a few inches below the nose and squeezing gently, or if vials are being used, to open the vial and place under the nose. The researcher demonstrates with an empty vial or bottle. ¶
4. Upon verbal agreement of readiness, the researcher hands the first sample vial or bottle to the subject to smell. (The order of the vials/bottles is determined previously using a random number generator. The bottles are coded using a letter code.) The subject enters one or more ratings on a scoring sheet. Upon receiving the bottle back from the subject the research activates a 1 min timer. ¶
5. When 1 - 2 min has elapsed, the researcher gives the subject the next bottle. Steps 4 and 5 are repeated until half the vials/bottles have been tested. ¶
6. The subject is allowed a 10 min break. ¶
7. Steps 4 and 5 are repeated with the remainder of the vials/bottles. ¶
8. Upon completion the subject is thanked and released. ¶
¶
July 2022 amendment. Participants will access and complete a REDCap survey online via the device of their choice. The survey has 30 questions that provide demographic information, smoking history, and data on the effects of factors that may cause an urge to smoke. Participants provide an answer to each question, with most questions allowing the option to refuse to answer. REDCap will be set to allow participants to navigate back to previous questions and change answers. Upon completion of the survey REDCap will show a message confirming completion and thanking the participant. We will set the enrollment cap tool in REDCap at 200 completed surveys, thereby closing the survey at 200 complete responses and triggering notification of the investigators. Incomplete surveys are not counted against the cap. To match the demographics of our other human experiments we will discard data from those outside the desired age range of 18-60 years. ¶
¶
January 2023 Modification: Objective 7. ¶
Participants will be seated at a small table in our odor control room whose negative pressure and fume evacuation devices reduce the ability of odors to accumulate. The table is clear of all but a score sheet and a pencil. ¶
1. A researcher will instruct the participant on how to use the score sheet. ¶
2. A researcher will then instruct the participant in how to wear the nose mask, how to fit odor sample bags to the mask, and how to remove bags from the mask. ¶
3. Using the unique random order assigned to the current session and participant, the smoker fits the first bag onto their mask, opens the valve, inhales once through the nose, closes the valve, removes the bag, and hands it to the researcher. ¶
4. The participant then reports three values on a score sheet: Whether the odor is pleasant or unpleasant (a forced choice test), a subjective rating of their desire to smoke on a scale of 0 – 100, and a Cigarette Purchase Task amount. The Cigarette Purchase Task (Strickland et al., 2016; attached) requires selecting how much the smoker is willing to spend for a single cigarette (their preferred brand) from a list of 19 amounts ranging from $0.00 (free) to $1,120. ¶
5. A 2 – 3 min wait period is enforced between each odor presentation to prevent odor adaptation and to allow acute motivational effects to subside. A nature documentary is available on the TV screen in the room for entertainment during the wait period. ¶
6. When the wait period has elapsed the researcher hands the next bag to the participant, and steps 3-5 are repeated until all bags have been scored. ¶
7. Upon completion of the session the participant is thanked and released. ¶
¶
July 2024 Modification: Objective 8. ¶
Participants will be seated at a small table in our odor control room whose negative pressure and fume evacuation devices minimize the ability of odors to accumulate. The table is clear of all but a laptop computer used to record scores. Alternatively, a score sheet and pencil can be substituted for the laptop. ¶
1. A researcher will instruct the participant on how to score samples. ¶
2. A researcher will then instruct the participant in how to wear the nose mask, how to fit odor sample bags to the mask, and how to remove bags from the mask. ¶
3. Using the unique random order assigned to the current session and participant, the participant fits the first bag onto their mask, opens the valve, inhales once through the nose, closes the valve, removes the bag, and hands it to the researcher. ¶
4. The participant then reports two values: Whether the overall odor is pleasant or unpleasant (a forced choice test) and a subjective rating of the intensity of cigarette smoke odor (the target odor) in the bag. ¶
5. A 1 – 2 min wait period is enforced between each odor presentation to minimize odor adaptation. A nature documentary is available on the TV screen in the room for entertainment during the wait period. ¶
6. When the wait period has elapsed the researcher hands the next bag to the participant, and steps 3-5 are repeated until all bags have been scored. ¶
7. Upon completion of the session the participant is thanked and released. ¶
¶
October 2025 Modification: Objective 9. ¶
1. Recruited participants are scheduled, informed where to report, and told to wear comfortable clothing, contact lenses (rather than glasses, if applicable), and that they may want to prevent dry eyes by using eye drops before the study. ¶
2. Upon arrival, participants meet with a member of the study staff to do a brief questionnaire to confirm their eligibility and obtain their nicotine exposure history. ¶
3. They are then brought to the MRISC and deposit all personal items (e.g., jewelry, hair accessories, shoes, wallets, credit cards and loose change) into secure storage. They are then screened with a metal detector to ensure that they do not have metal in their body. ¶
4. Participants are fitted with ear protection, a CPAP nose mask or cannulae that open into the nostrils for odor delivery, and allowed to practice breathing and sniffing irrelevant odor samples. ¶
5. Instructions on being in the scanner and communicating with the experimenter and MRI technologist are then given. Once familiar with these procedures participants are made comfortable on the scanner bed, then inserted into the scanner and asked to lie motionless. ¶
6. The participant will be able to hear the experimenter's instructions through the ear protection. The experimenter and MRI technologist work together to manage the experiment. They speak to the subject frequently throughout the experiment and inform the participant about events that will occur next, what kind of responses they will make, what kind of noises they will expect to hear from the MRI scanner, and how long it will be before the experimenter speaks to the subject again. ¶
7. Once these preparations are complete, participants sniff an odor every 1 minute in a block design where each odor is repeatedly sniffed before moving to the next odor. Each participant will repeatedly sniff 3 - 6 different odors. ¶
8. Upon completion of MRI, the participant is taken out of the scanner and off the bed slowly, taken back into the control room and their personal items are returned to them. They are then escorted back to the public area of the medical center most convenient to their mode of transportation. The entire procedure, from arrival to completion, will last 1 – 2 hours.¶
¶
December 2025 Modification: Objective 10. ¶
N = up to 100 participants. Each participant does only 1 session. ¶
Participants will be seated at a table or bench at a fume hood or odor capture device used to prevent odors from accumulating in the room. A researcher is available throughout the session to answer questions and attend to problems. ¶
1. A researcher will provide a list of up to 50 verbal descriptors used for odors and a tray of 50 labeled vials, each containing an odor exemplifying the corresponding descriptor. Participants will be allowed to familiarize themselves with these 50 odors at their own pace. ¶
2. Once a participant is comfortable with the descriptors, a researcher will give them a different tray of up to 30 vials, each containing an unidentified odor for them to rate. Participants will be given a score sheet (digital or hard copy) listing the 50 descriptors and asked to rate how well each descriptor applies to each unidentified odor using a scale of 0 - 5. Here again, participants proceed at their own pace. A score sheet is attached.
Research Description Resources changed by mcclint on 12/12/2025 5:17:51 PM
Staff in the McClintock laboratory will prepare the vials or squeeze bottles of odorants. Fresh ones are prepared daily. ¶
Testing of subjects will be done by Dr. McClintock or a member of his staff who did not prepare the bottles on that day. ¶
Testing will be done in MS509 Medical Sciences, a room where odors are carefully controlled. ¶
Equipment used: A small table, two chairs, a personal computer (property of the University of Kentucky), a scoring slider or scoring sheet, and the 16 bottles. ¶
The data entered into this computer is de-identified. A code, rather than the subject's name, is used to identify the set of responses belonging to each individual person (e.g., F102 or M119). No record is kept of which subject belongs to each code. The computer is password protected and kept in a locked room. Dr. McClintock is the only person who has access to this computer at this time, but staff who are recording data are given access during the period of the study. A secure server that is used to store back-ups of the files (cifs://prdltcancifs01.mc.uky.edu/research/lab/mcclintock-l). ¶
¶
Signed consent forms are stored in a safe in Dr. McClintock's office. Only Dr. McClintock has access into this safe. ¶
¶
July 2022 amendment. Objective 6. Staff in the McClintock laboratory are preparing a REDCap survey using the access to REDCap provided by the University of Kentucky. They will monitor progress weekly, with completion set at 200 complete responses. To match the demographics of our other human experiments they will discard data from those outside the desired age range of 18-60 years. Data will be analyzed via the extensive statistical tools available in REDCap, with contributions from University of Kentucky biostatisticians should that prove advisable. ¶
¶
January 2023 Modification: Objective 7. ¶
Staff in the McClintock laboratory will prepare the odors and odor sample bags. Fresh bags are prepared at least monthly. ¶
Testing of subjects will be done by Dr. McClintock or a member of his staff. ¶
Testing will be done in MS509 Medical Sciences, a room where odors are carefully controlled. ¶
Equipment used: A small table, two chairs, a personal computer (property of the University of Kentucky), a worksheet ¶
sheet, and the odor bags. The TV showing the nature documentary is also present in the room. ¶
¶
July 2024 Modification: Objective 9. ¶
Staff in the McClintock laboratory will prepare the odors and odor sample bags. Fresh ones are prepared weekly. ¶
Testing of subjects will be done by Dr. McClintock or a member of his staff. ¶
Testing will be done in MS509 Medical Sciences, a room where odors are carefully controlled. ¶
Equipment used: A small table, two chairs, a personal computer (property of the University of Kentucky) or a paper worksheet ¶
sheet, CPAP nose masks, and the odor bags. A TV showing a nature documentary is also present in the room. ¶
¶
October 2025 Modification: Objective 9. ¶
The MRISC occupies the ground level of the Whitney Hendrickson building on the UK Medical Center campus and is connected to the main University Hospital by underground tunnel. Gated parking for research subjects is available just outside the scanner building. The MRISC has 6,100 sq. ft. of space that contains five staff offices, two behavioral testing rooms, a mock scanner room, trainee carrel space, electronics and fabrication shops, and extensive computing facilities. The MRISC research facility provides a certified MRI technologist to run the research scans and full clinical support for any emergencies. Thousands of research MRI studies have been conducted at the MRISC site since its opening in 1992. The newly renovated facility will also include convenient, comfortable, professional quality subject preparation and waiting areas that are important for a participant's subjective ease and confidence in the research imaging procedures. ¶
Staff in the McClintock laboratory will prepare the odors in bottles or odor sample bags. Fresh ones are prepared weekly. ¶
Each testing session is managed by two people, a certified MRI technologist and either Dr. McClintock or a member of his staff.¶
¶
December 2025 Modification: Objective 10. ¶
Staff in the McClintock laboratory will prepare the odor vials used. ¶
Testing of subjects will be overseen by Dr. McClintock or a member of his staff. ¶
Testing will be done in MS509 Medical Sciences or in B236 BBSRB.
Research Description StudyDesign changed by mcclint on 12/19/2025 8:27:07 AM
This is a single blind study where the researcher interacting with the subjects and recording their ratings does not know which odorants are in which bottles. ¶
¶
Design for Objective 1. ¶
N = 30 subjects per experiment. ¶
Each subject completes all 40 trials for the experiment in a single session. ¶
Each subject is asked to smell 20 air samples, in a random order, with 1 minute between each sample. Each sample comes from a different squeeze bottle containing a different solution absorbed into a cotton ball. One solution is water, the other 19 are odorants. The 19 odorants span the range of pleasantness, from strongly foul to very appealing. The subject rates the pleasantness of each sample experienced using a sliding scale that ranges from 0 to 100. The scale device is set at 50 prior to smelling each sample. A 10 min break is taken after the first 15 trials, then the subject is asked to rate the 20 samples again, presented in a different random order. ¶
¶
Design for Objective 2. ¶
N = 30 subjects per experiment. ¶
The only difference from the design for Objective 1 is that one malodor is present in 3 of the 20 bottles: in one by itself, in another as a mixture with an odorant that blocks mouse receptors responsive to the malodor, and in the third as a mixture with a pleasant odorant that does not block the mouse receptors responsive to the odorant (mimicking a masking odor). Effective blockers will cause the pleasantness rating of their mixture with a malodor to be higher than the rating for a mixture of a malodor with a simple masking agent. ¶
¶
Note: Why we test 20 samples rather than just a few? Three reasons. First, this allows us to more easily identify subjects that have problems performing the task or have general olfactory deficiencies, so that their responses can be excluded. Second, 20 odors are enough to help the subjects spread the ratings across the 100 units of the scale provided, but not so many that rating fatigue becomes a problem. Third, it allows us to generate two measures of response from the same data; quantitative values for each odor tested, and relative pleasantness ratings for the panel of odors. ¶
¶
March 2018 Modification: Design for Objective 3. (Note: This objective as been completed) ¶
N = 30 subjects per experiment ¶
The researcher performing this test is blind to the identify of all but two of the samples used. These two samples are used to teach the subjects to recognize tobacco smoke and to set the numerical scale for the experiment. ¶
Each subject is asked to smell 40 samples, in a random order, with 1 minute between each sample. Each sample comes from a different squeeze bottle containing a different solution absorbed into a cotton ball. One sample, which contains 32 odorants mixed together in the ratios they are found in tobacco smoke, is known as synthetic tobacco smoke odor and it is highly effective at evoking the perception of tobacco smoke odor. One sample is water. The other 38 samples are either simpler formulations being tested for their ability to be perceived as tobacco smoke odor, or formulations of synthetic tobacco smoke odor to which a candidate blocking odor has been added. Each subject is allowed to experience the synthetic tobacco smoke odor first, followed by water, to set the rating scale being used. Then each subject rates whether each of the other 38 odors is similar to tobacco smoke using a sliding scale that ranges from 0 to 100. 100 = tobacco smoke odor, 0 = no odor, and the values in between denote how similar each odor is to tobacco smoke odor. The scale device is set at 50 prior to smelling each sample. ¶
¶
December 2019 Modification: Design for Objective 4. ¶
N = 200 subjects ¶
Each subject is asked to familiarize themselves with a training odor, either pentanethiol or beta-ionone, odor molecules critical for the perception of cigarette smoke odor (a result obtained from Objective 3). ¶
Each subject is asked to smell 32 - 42 samples, in a random order, with 1 - 2 minute intervals between each sample. Each sample comes from a different vial or squeeze bottle containing a different odor solution absorbed into a cotton ball. 2 samples are part of every test session: the training sample of pentanethiol or beta-ionone and the water negative control. The other samples are 10 - 20 odor molecules (odorants) that have been predicted to bind to an odorant receptor protein highly sensitive to pentanethiol or beta-ionone, and 15 - 20 samples in which these candidate antagonists have been mixed with pentanethiol or beta-ionone - usually at 2 different concentrations of the candidate antagonists. Then each subject rates the pleasantness of each odor sample on a scale of 0 - 100, and the similarity of each odor sample to pentanethiol or beta-ionone on a scale of 0 - 100. Finally, each subject is asked whether they detect the training odor in each odor sample. Because we expect to test several sets of 10 - 20 candidate antagonists, subjects are allowed to return and rate multiple sets of candidate antagonists. The revised consent requests permission to contact subjects each time we prepare to test a new set of candidate antagonists. This study is completely separate from Objective 3, which has been completed. Whether people who were subjects for objective 3 is irrelevant to Objective 4 and we are not tracking subjects from Objective 3, nor will we contact them individually. It is possible that subjects from Objective 3 may volunteer for Objective 4, and this is permissible because there is no reason to expect that their experiences in the Objective 3 study would affect their future performance. Signing a new consent form is required to participate in this objective. ¶
¶
January 2022 Modification: Design for Objective 5. ¶
N = 100 subjects ¶
Each subject is asked to familiarize themselves with a training odor, also called the target odor: a cigarette smoke odor mimic or the flavor additive, menthol. Each subject is asked to smell 20 - 60 samples, in a random order, with 1 - 2 minute intervals between each sample. Each sample consists of a vial containing an odor solution absorbed into a cotton ball. Three types of control samples are part of every test session: the training odor itself, an irrelevant odor such as 2-heptanone, and a blank control. The other samples are the test samples contain the training odor mixed with predicted masking or blocking odors. These masking/blocking odors are pure monomolecular odorants or odor mixtures containing several odorants. Three concentrations of each test odor are used, each mixed with the same amount of target odor. Subjects are asked to determine if the target odor can be perceived and rate the intensity of the target odor in each vial on a scale of 0 – 100. They also rate the similarity of the overall odor to the target odor on a scale of 0 - 100. Finally, subjects are asked whether each sample is pleasant or unpleasant (a forced choice test). Each target odor and its candidate masking odors are tested in separate sessions. This study does not require that the same subjects rate effects on each of the target odors, but subjects who complete one session are allowed to return and rate effects on the different targets in subsequent sessions. This study is completely separate from Objectives 3 and 4, which have been completed. Whether people who volunteer for this objective were subjects for objectives 3 or 4 is irrelevant to Objective 5,

and we are not tracking subject's responses across these objectives. There is no reason to expect that experiences in prior objectives would affect future performance so previous subjects who have indicated a willingness to be contacted for future studies in prior consent forms are eligible for objective 5 and are likely to be contacted. ¶
¶
July 2022 Modification: Design for Objective 6. ¶
N = 200 respondents (former smokers) are expected. ¶
The objective is to determine whether former smokers find that the smell of cigarette smoke causes an urge to smoke. What we hear from clinical psychologists working with smokers and former smokers and the only published paper on this topic to date differ in terms of whether the smell of cigarette smoke is a lasting trigger of the urge to smoke. An online REDCap survey of 30 questions will be used to gather data that will settle this question. The questions also include additional factors thought to increase the urge to smoke, and demographic information used to cross-correlate with data on the factors queried. Respondents to the survey are not paid but have a chance to win a drawing for $150. We will use REDCap's automated features to close the survey once 200 respondents is reached. We will then use REDCap's powerful statistical tools to evaluate whether any of the factors show evidence of affecting the urge to smoke, and whether these effects correlate with the time since quitting cigarettes, demographic factors, or use of other forms of nicotine or tobacco. ¶
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January 2023 Modification: Design for Objective 7. ¶
N = 40 subjects. ¶
The subjects for this survey will be current smokers, and therefore will be new participants different from those in the other Objectives, and not currently enrolled as subjects in our other studies. They will be recruited through contacts within the University of Kentucky campus community, with help advertising from the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. ¶
Each smoker is asked to smell up to 20 samples per session. The samples include controls (clean air, irrelevant odor), blocking odors identified in Objective 5, cigarette smoke, and cigarette smoke mixed with blocking odors or irrelevant odor. To obtain cigarette smoke a 1 inch length of the 1R6F research cigarette (produced here at UK) is burned to completion in a sealed 5 gallon chamber fitted with septa. Using a syringe fit with a needle and filter, 0.5 mL aliquots of smoke odor are obtained. These smoke odor aliquots, along with blocking odors, are injected into odor sample bags. These 10L bags are each fit with a septum at one end and a valve at the other that can be attached to the CPAP nose mask worn by each smoker (see attached document). Smokers open the valve, inhale once through the nose, close the valve, and then remove the bag from the mask. They then report three values on a score sheet: Whether the odor is pleasant or unpleasant (a forced choice test), a subjective rating of their desire to smoke on a scale of 0 – 100, and a Cigarette Purchase Task amount. The Cigarette Purchase Task (Strickland et al., 2016; attached) requires selecting how much the smoker is willing to spend for a single cigarette (their preferred brand) from a list of 19 amounts ranging from $0.00 (free) to $1,120. A 2 – 3 min wait period is enforced between each odor presentation to prevent odor adaptation and to allow acute motivational effects to subside. A nature documentary is shown on a TV screen during sessions. ¶
Smokers are allowed to enroll in multiple sessions. Each session tests 4 – 8 concentrations of 1 – 2 blocking odors. Presentation order is randomized. Each smoker is assigned their own CPAP nose mask, and masks are disinfected after use. Smokers also provide demographic (age, sex, ethnic and racial background) and smoking history information (cigarettes per day, preferred brand, age at onset, and time since last cigarette). ¶
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July 2024 Modification: Design for Objective 8. This experiment is patterned after Objective 5 and uses the odor bag method from Objective 7 for delivery of real cigarette smoke odor as the target odor. It tests odorants and odor mixtures that are predicted to block the perception of real cigarette smoke odor. ¶
N = 60 subjects ¶
Subjects are healthy non-smokers, ages 18 – 60. Each subject first familiarizes themselves with the odor of cigarette smoke. To obtain cigarette smoke a 1 inch length of the 1R6F research cigarette (produced here at UK) is burned to completion in a sealed 5 gallon chamber fitted with septa. Using a syringe fit with a needle, a 40 mL aliquot of smoke odor is withdrawn and injected into a 20L odor sample bag. Candidate blocking odors are added in the same way. The bag is fit with a septum at one end and a valve at the other that can be attached to a CPAP nose mask. To sample the odor in the bag, subjects open the valve, inhale once through the nose, close the valve, and then remove the bag from the mask. Cigarette smoke is not visible in the bags, so no visual cue to the odor is present. ¶
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Each subject then samples odors from 20 - 30 bags in a unique random order. The odor bags are of several types: Cigarette smoke alone, cigarette smoke plus a candidate blocking odor, or no odor. A 1 - 2 minute interval is enforced between each sample to minimize adaptation. The candidate blocking odors are pure monomolecular odorants or odor mixtures containing several odorants. Subjects are asked to rate the intensity of the target odor (cigarette smoke) in each odor bag on a scale of 0 - 100. Finally, subjects are asked whether each sample is pleasant or unpleasant (a forced choice test). ¶
¶
A single session is sufficient for each subject to rate all samples. Subjects from our previous experiments are allowed to participate. There is no reason to expect that experiences in prior objectives would affect future performance so previous subjects who have indicated a willingness to be contacted for future studies in prior consent forms are eligible and are likely to be contacted. ¶
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October 2025 Modification: Design for Objective 9. ¶
N = 10 - 20 participants. Each participant does only 1 session and experiences a unique random order of the odors being tested. ¶
Participants are fitted with ear protection, a CPAP nose mask or cannulae that open into the nostrils for odor delivery, and allowed to practice breathing through them and experiencing irrelevant odor samples. Instructions on being in the scanner and communicating with the experimenter and MRI technologist are then given. Once familiar with these procedures participants are made comfortable on the scanner bed, then inserted into the scanner and asked to lie motionless. The participant will be able to hear the experimenter's instructions through the ear protection. The experimenter and MRI technologist speak to the subject frequently throughout the experiment and inform the participant about events that will occur next, what kind of responses they will make, what kind of noises they will expect to hear from the MRI scanner, and how long it will be before the experimenter speaks to the subject again. Once these preparations are complete, participants sniff an odor sample every 1 - 2 minutes. The entire procedure, from arrival to completion, will last 1 – 2 hours. Upon completion of the MRI portion of the study, the participant is taken out of the scanner and off the bed slowly, taken back into the control room and all of their personal items are returned to them. They are then escorted back to the public area of the medical center most convenient to their mode of transportation. ¶
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December 2025 Modification: Design for Objective 10. ¶
N = up to 100 participants. Each participant does only 1 session. ¶
This experiment is designed to evaluate perception of a malodor, alone and in mixtures with other odors. This is accomplished using a Rate All That Apply (RATA) method. Dr. McClintock learned this method while on sabbatical at the Monell Chemical Senses Center in 2023, working with a team using this method (Lee et al., 2023, attached). Participants familiarize themselves with 50 descriptive terms used for odors, most of which are familiar. Then using a scale from 0 - 5, they rate how well each of the 50 descriptors applies to odors we present to them. ~~A score sheet showing the 50 descriptors is attached.~~ ¶
Note that no odor vials contain liquid capable of spilling. The odor sources are cotton balls that have absorbed 100 - 200 ul of a diluted essential oil; or they are solids, such as the pennies used as an example of the odor of metal.
Research Description StudyDesign changed by mcclint on 12/12/2025 5:04:43 PM
This is a single blind study where the researcher interacting with the subjects and recording their ratings does not know which odorants are in which bottles. ¶
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Design for Objective 1. ¶
N = 30 subjects per experiment. ¶
Each subject completes all 40 trials for the experiment in a single session. ¶
Each subject is asked to smell 20 air samples, in a random order, with 1 minute between each sample. Each sample comes from a different squeeze bottle containing a different solution absorbed into a cotton ball. One solution is water, the other 19 are odorants. The 19 odorants span the range of pleasantness, from strongly foul to very appealing. The subject rates the pleasantness of each sample experienced using a sliding scale that ranges from 0 to 100. The scale device is set at 50 prior to smelling each sample. A 10 min break is taken after the first 15 trials, then the subject is asked to rate the 20 samples again, presented in a different random order. ¶
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Design for Objective 2. ¶
N = 30 subjects per experiment. ¶
The only difference from the design for Objective 1 is that one malodor is present in 3 of the 20 bottles: in one by itself, in another as a mixture with an odorant that blocks mouse receptors responsive to the malodor, and in the third as a mixture with a pleasant odorant that does not block the mouse receptors responsive to the odorant (mimicking a masking odor). Effective blockers will cause the pleasantness rating of their mixture with a malodor to be higher than the rating for a mixture of a malodor with a simple masking agent. ¶
¶
Note: Why we test 20 samples rather than just a few? Three reasons. First, this allows us to more easily identify subjects that have problems performing the task or have general olfactory deficiencies, so that their responses can be excluded. Second, 20 odors are enough to help the subjects spread the ratings across the 100 units of the scale provided, but not so many that rating fatigue becomes a problem. Third, it allows us to generate two measures of response from the same data; quantitative values for each odor tested, and relative pleasantness ratings for the panel of odors. ¶
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March 2018 Modification: Design for Objective 3. (Note: This objective as been completed) ¶
N = 30 subjects per experiment ¶
The researcher performing this test is blind to the identify of all but two of the samples used. These two samples are used to teach the subjects to recognize tobacco smoke and to set the numerical scale for the experiment. ¶
Each subject is asked to smell 40 samples, in a random order, with 1 minute between each sample. Each sample comes from a different squeeze bottle containing a different solution absorbed into a cotton ball. One sample, which contains 32 odorants mixed together in the ratios they are found in tobacco smoke, is known as synthetic tobacco smoke odor and it is highly effective at evoking the perception of tobacco smoke odor. One sample is water. The other 38 samples are either simpler formulations being tested for their ability to be perceived as tobacco smoke odor, or formulations of synthetic tobacco smoke odor to which a candidate blocking odor has been added. Each subject is allowed to experience the synthetic tobacco smoke odor first, followed by water, to set the rating scale being used. Then each subject rates whether each of the other 38 odors is similar to tobacco smoke using a sliding scale that ranges from 0 to 100. 100 = tobacco smoke odor, 0 = no odor, and the values in between denote how similar each odor is to tobacco smoke odor. The scale device is set at 50 prior to smelling each sample. ¶
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December 2019 Modification: Design for Objective 4. ¶
N = 200 subjects ¶
Each subject is asked to familiarize themselves with a training odor, either pentanethiol or beta-ionone, odor molecules critical for the perception of cigarette smoke odor (a result obtained from Objective 3). ¶
Each subject is asked to smell 32 - 42 samples, in a random order, with 1 - 2 minute intervals between each sample. Each sample comes from a different vial or squeeze bottle containing a different odor solution absorbed into a cotton ball. 2 samples are part of every test session: the training sample of pentanethiol or beta-ionone and the water negative control. The other samples are 10 - 20 odor molecules (odorants) that have been predicted to bind to an odorant receptor protein highly sensitive to pentanethiol or beta-ionone, and 15 - 20 samples in which these candidate antagonists have been mixed with pentanethiol or beta-ionone - usually at 2 different concentrations of the candidate antagonists. Then each subject rates the pleasantness of each odor sample on a scale of 0 - 100, and the similarity of each odor sample to pentanethiol or beta-ionone on a scale of 0 - 100. Finally, each subject is asked whether they detect the training odor in each odor sample. Because we expect to test several sets of 10 - 20 candidate antagonists, subjects are allowed to return and rate multiple sets of candidate antagonists. The revised consent requests permission to contact subjects each time we prepare to test a new set of candidate antagonists. This study is completely separate from Objective 3, which has been completed. Whether people who were subjects for objective 3 is irrelevant to Objective 4 and we are not tracking subjects from Objective 3, nor will we contact them individually. It is possible that subjects from Objective 3 may volunteer for Objective 4, and this is permissible because there is no reason to expect that their experiences in the Objective 3 study would affect their future performance. Signing a new consent form is required to participate in this objective. ¶
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January 2022 Modification: Design for Objective 5. ¶
N = 100 subjects ¶
Each subject is asked to familiarize themselves with a training odor, also called the target odor: a cigarette smoke odor mimic or the flavor additive, menthol. Each subject is asked to smell 20 - 60 samples, in a random order, with 1 - 2 minute intervals between each sample. Each sample consists of a vial containing an odor solution absorbed into a cotton ball. Three types of control samples are part of every test session: the training odor itself, an irrelevant odor such as 2-heptanone, and a blank control. The other samples are the test samples contain the training odor mixed with predicted masking or blocking odors. These masking/blocking odors are pure monomolecular odorants or odor mixtures containing several odorants. Three concentrations of each test odor are used, each mixed with the same amount of target odor. Subjects are asked to determine if the target odor can be perceived and rate the intensity of the target odor in each vial on a scale of 0 – 100. They also rate the similarity of the overall odor to the target odor on a scale of 0 - 100. Finally, subjects are asked whether each sample is pleasant or unpleasant (a forced choice test). Each target odor and its candidate masking odors are tested in separate sessions. This study does not require that the same subjects rate effects on each of the target odors, but subjects who complete one session are allowed to return and rate effects on the different targets in subsequent sessions. This study is completely separate from Objectives 3 and 4, which have been completed. Whether people who volunteer for this objective were subjects for objectives 3 or 4 is irrelevant to Objective 5, and we are not tracking subject's responses across these objectives. There is no reason to expect that experiences in prior objectives would affect future performance so previous subjects who have indicated a willingness to be contacted for future studies in prior consent forms are eligible for objective 5 and are likely to be contacted. ¶
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July 2022 Modification: Design for Objective 6. ¶
N = 200 respondents (former smokers) are expected. ¶
The objective is to determine whether former smokers find that the smell of cigarette smoke causes an urge to smoke. What we hear from clinical psychologists working with smokers and former smokers and the only published paper on this topic to date differ in terms of whether the smell of cigarette smoke is a lasting trigger of the urge to smoke. An online REDCap survey of 30 questions will be used to gather data that will settle this question. The questions also include additional factors thought to increase the urge to smoke, and demographic information used to cross-correlate with data on the factors queried. Respondents to the survey are not paid but have a chance to win a drawing for $150. We will use REDCap's automated features to close the survey once 200 respondents is reached. We will then use REDCap's powerful statistical tools to evaluate whether any of the factors show evidence of affecting the urge to smoke, and whether these effects correlate with the time since quitting cigarettes, demographic factors, or use of other forms of nicotine or tobacco. ¶
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January 2023 Modification: Design for Objective 7. ¶
N = 40 subjects. ¶
The subjects for this survey will be current smokers, and therefore will be new participants different from those in the other Objectives, and not currently enrolled as subjects in our other studies. They will be recruited through contacts within the University of Kentucky campus community, with help advertising from the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. ¶
Each smoker is asked to smell up to 20 samples per session. The samples include controls (clean air, irrelevant odor), blocking odors identified in Objective 5, cigarette smoke, and cigarette smoke mixed with blocking odors or irrelevant odor. To obtain cigarette smoke a 1 inch length of the 1R6F research cigarette (produced here at UK) is burned to completion in a sealed 5 gallon chamber fitted with septa. Using a syringe fit with a needle and filter, 0.5 mL aliquots of smoke odor are obtained. These smoke odor aliquots, along with blocking odors, are injected into odor sample bags. These 10L bags are each fit with a septum at one end and a valve at the other that can be attached to the CPAP nose mask worn by each smoker (see attached document). Smokers open the valve, inhale once through the nose, close the valve, and then remove the bag from the mask. They then report three values on a score sheet: Whether the odor is pleasant or unpleasant (a forced choice test), a subjective rating of their desire to smoke on a scale of 0 – 100, and a Cigarette Purchase Task amount. The Cigarette Purchase Task (Strickland et al., 2016; attached) requires selecting how much the smoker is willing to spend for a single cigarette (their preferred brand) from a list of 19 amounts ranging from $0.00 (free) to $1,120. A 2 – 3 min wait period is enforced between each odor presentation to prevent odor adaptation and to allow acute motivational effects to subside. A nature documentary is shown on a TV screen during sessions. ¶
Smokers are allowed to enroll in multiple sessions. Each session tests 4 – 8 concentrations of 1 – 2 blocking odors. Presentation order is randomized. Each smoker is assigned their own CPAP nose mask, and masks are disinfected after use. Smokers also provide demographic (age, sex, ethnic and racial background) and smoking history information (cigarettes per day, preferred brand, age at onset, and time since last cigarette). ¶
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July 2024 Modification: Design for Objective 8. This experiment is patterned after Objective 5 and uses the odor bag method from Objective 7 for delivery of real cigarette smoke odor as the target odor. It tests odorants and odor mixtures that are predicted to block the perception of real cigarette smoke odor. ¶
N = 60 subjects ¶
Subjects are healthy non-smokers, ages 18 – 60. Each subject first familiarizes themselves with the odor of cigarette smoke. To obtain cigarette smoke a 1 inch length of the 1R6F research cigarette (produced here at UK) is burned to completion in a sealed 5 gallon chamber fitted with septa. Using a syringe fit with a needle, a 40 mL aliquot of smoke odor is withdrawn and injected into a 20L odor sample bag. Candidate blocking odors are added in the same way. The bag is fit with a septum at one end and a valve at the other that can be attached to a CPAP nose mask. To sample the odor in the bag, subjects open the valve, inhale once through the nose, close the valve, and then remove the bag from the mask. Cigarette smoke is not visible in the bags, so no visual cue to the odor is present. ¶
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Each subject then samples odors from 20 - 30 bags in a unique random order. The odor bags are of several types: Cigarette smoke alone, cigarette smoke plus a candidate blocking odor, or no odor. A 1 - 2 minute interval is enforced between each sample to minimize adaptation. The candidate blocking odors are pure monomolecular odorants or odor mixtures containing several odorants. Subjects are asked to rate the intensity of the target odor (cigarette smoke) in each odor bag on a scale of 0 - 100. Finally, subjects are asked whether each sample is pleasant or unpleasant (a forced choice test). ¶
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A single session is sufficient for each subject to rate all samples. Subjects from our previous experiments are allowed to participate. There is no reason to expect that experiences in prior objectives would affect future performance so previous subjects who have indicated a willingness to be contacted for future studies in prior consent forms are eligible and are likely to be contacted. ¶
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October 2025 Modification: Design for Objective 9. ¶
N = 10 - 20 participants. Each participant does only 1 session and experiences a unique random order of the odors being tested. ¶
Participants are fitted with ear protection, a CPAP nose mask or cannulae that open into the nostrils for odor delivery, and allowed to practice breathing through them and experiencing irrelevant odor samples. Instructions on being in the scanner and communicating with the experimenter and MRI technologist are then given. Once familiar with these procedures participants are made comfortable on the scanner bed, then inserted into the scanner and asked to lie motionless. The participant will be able to hear the experimenter's instructions through the ear protection. The experimenter and MRI technologist speak to the subject frequently throughout the experiment and inform the participant about events that will occur next, what kind of responses they will make, what kind of noises they will expect to hear from the MRI scanner, and how long it will be before the experimenter speaks to the subject again. Once these preparations are complete, participants sniff an odor sample every 1 - 2 minutes. The entire procedure, from arrival to completion, will last 1 – 2 hours. Upon completion of the MRI portion of the study, the participant is taken out of the scanner and off the bed slowly, taken back into the control room and all of their personal items are returned to them. They are then escorted back to the public area of the medical center most convenient to their mode of transportation.¶
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<u>December 2025 Modification: Design for Objective 10. ¶
N = up to 100 participants. Each participant does only 1 session. ¶
This experiment is designed to evaluate perception of a malodor, alone and in mixtures with other odors. This is accomplished using a Rate All That Apply (RATA) method. Dr. McClintock learned this method while on sabbatical at the Monell Chemical Senses Center in 2023, working with a team using this method (Lee et al., 2023, attached). Participants familiarize themselves with 50 descriptive terms used for odors, most of which are familiar. Then using a scale from 0 - 5, they rate how well each of the 50 descriptors applies to odors we present to them. A score sheet showing the 50 descriptors is attached. ¶
Note that no odor vials contain liquid capable of spilling. The odor sources are cotton balls that have absorbed 100 - 200 ul of a diluted essential oil; or they are solids, such as the pennies used as an example of the odor of metal.</u>
Research Description SubjectRecruitmentMethods changed by mcclint on 12/18/2025 5:05:14 PM
Subjects will be recruited through contacts within the University of Kentucky campus community, with help on advertising from the CCTS. A flyer will be printed and posted on campus, and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. Interested people who contact the PI by email will be provided the questionnaire by email. Anyone who contacts the PI or other study personnel in person will be given their choice of a hard copy of the questionnaire or a digital copy by email. Persons whose questionnaires show no reason for exclusion will be scheduled for participation via email communication. ¶
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July 2022 Modification: Design for Objective 6. ¶
The subjects for this survey will be new participants different from those in the other Objectives, and not currently enrolled as subjects in our other studies. They will be recruited through contacts within the University of Kentucky campus community, with help on advertising from the CCTS. A flyer will be printed and posted on campus, and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. All information will include a link to the survey. ¶
See attached flyer. Methods of advertising are as follows. ¶
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Print advertisements: The study will recruit subjects through flyers, brochures, posters, Research Spotlights, ads placed on campus and in the surrounding community and region (Study Team will place/remove ads), including but not limited to the UK Medical Center, UK Clinics, Good Samaritan Hospital, Student Center, UHS, the 5 UK Center for Clinical and Translational Research wall mounts, Cardinal Hill, monitor screens, and area facilities and businesses. ¶
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Internet and Social Media: This study will be advertised on recruitment internet webpages in digital or video form (e.g., UKclinicalresearch.com, ResearchMatch.org, CenterWatch.com, CISCRP, UK, CCTS and may utilize Google Adwords). The study will be promoted via social media, including Facebook boost ads, UK_CCTS Facebook, UK_CCTS Twitter, UK_CCTS Instagram, UK and UKHC social media, and departmental/lab pages. If advertised on UKClinicalresearch.com, the online study flyer will include an option for interested individuals to enter and submit their contact information, they will be asked whether study team can contact them (Yes or No) via study-related text messages, and CCTS will also ask, 'How did you learn about the study? Internet and social media recruitment will follow the terms of use for each site utilized. The study will also be promoted through UK HC monitor screens. ¶
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Outreach activities: The CCTS attends outreach activities to promote research participation in general (e.g., Roots & Heritage Festival, Latino Festival, Eastern Kentucky University, Transylvania Health fairs, etc.) and will bring all relevant study flyers that are enrolling participants. ¶
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July 2022 Modification: Design for Objective 6. ¶
REDCap:This study may employ a pre-screening eligibility survey to determine if a volunteer meets basic inclusion/exclusion criteria. The study team will build and disseminate the eligibility survey on UK's REDCap which provides HIPAA compliant storage on UK servers and encrypted transmission of survey responses. The portable devices do not download the data, it is directly stored into the secure web-based connection (https) behind the firewall. All files are password protected once entered into the system. All project data is stored and hosted locally. If the study team provides a link to the eligibility survey, PRS will fold that link into recruitment materials. The link will also be included in study information sent to ResearchMatch participants who have indicated interest in the study. Before ¶
redirecting the volunteer outside of ResearchMatch and to the REDCap survey, the volunteer is once again asked to confirm their interest in completing the pre-screening survey. ¶
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A set of advertisements specific to this survey study have been produced for use in print, on social media, and at outreach activities. ¶
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January 2023 Modification: Objective 7. ¶
N = 40 subjects. ¶
The subjects for this survey will be current smokers, and therefore will be new participants different from those in the other Objectives, and not currently enrolled as subjects in our other studies. They will be recruited through contacts within the University of Kentucky campus community and Lexington area, with help advertising from the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising, incuding the CCTS ResearchMatch program. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. ¶

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October 2024 Modification to recruitment methods for Objective 7. In addition to previously approved recruitment methods co-investigator Dr. Rakesh Gopalkumar will contact smokers who have consented to be contacted for future studies on consent forms when they participated on studies approved on other approved protocols on which he is an investigator. Specifically, these protocols are 64473 and 56570. He will send approved flyer "PHYS_009b flyer-STAMPED.pdf" to these individuals. ¶
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July 2024 Modification: Objective 8. ¶
N = 60 subjects. ¶
The subjects for this survey will be healthy adult non-smokers. Participants in prior objectives are eligible. They will be recruited through contacts within the University of Kentucky campus community, with help advertising from Participant Recruitment Services in the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. To prevent coercion students receiving the flyer are informed that participation in the study is not required for the class and refusal to participate has no connection to grades for the class. ¶
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April 2025 Modification: Objective 7 ¶
To expand advertising on social media to reddit, Instagram, and Craigslist new social media text and flyer for these sited have been made. The approved versions, labeled 2025, are attached. ¶
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October 2025 Modification: Objective 9. The participants in the study will be current smokers, and may include smokers who participated in other Objectives of this project. They will be recruited through contacts within the University of Kentucky campus community and Lexington area, with help advertising from Participant Recruitment Services (PRS) in the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising, including the CCTS ResearchMatch program. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. We have found social media to be a good source of smokers for our studies, so in addition to the sites PRS normally uses (e.g., UK_CCTS Facebook, UK_CCTS Twitter, UK and UKHC social media), we will advertise on reddit, Instagram, and Craigslist. The approved media for these recruiting efforts are attached. ¶
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Smokers fail to make scheduled appointments more than half the time in our experience. To reduce this problem at the time of scheduling we will offer rideshare (Lyft or Uber) or taxi service for persons from Fayette County and the counties contiguous to Fayette County. Participants will not be responsible for the costs associated with this transportation. We will organize this service over the phone with the participant on the day of each appointment and pay for it directly. In many cases, we will be on the phone with the participants as they wait to meet the car. ¶
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December 2025 Modification: Objective 10. ¶
We will recruit by contacting participants in our other objectives by email. Nearly every one of them, more than sufficient for this objective, has agreed to be contacted about additional studies. Examples of our email scripts for first contacts with potential subjects are attached.
Research Description SubjectRecruitmentMethods changed by mcclint on 12/17/2025 12:34:44 PM
Subjects will be recruited through contacts within the University of Kentucky campus community, with help on advertising from the CCTS. A flyer will be printed and posted on campus, and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. Interested people who contact the PI by email will be provided the questionnaire by email. Anyone who contacts the PI or other study personnel in person will be given their choice of a hard copy of the questionnaire or a digital copy by email. Persons whose questionnaires show no reason for exclusion will be scheduled for participation via email communication. ¶
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See attached flyer. Methods of advertising are as follows. ¶
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Internet and Social Media: This study will be advertised on recruitment internet webpages in digital or video form (e.g., UKclinicalresearch.com, ResearchMatch.org, CenterWatch.com, CISCRP, UK, CCTS and may utilize Google Adwords). The study will be promoted via social media, including Facebook boost ads, UK_CCTS Facebook, UK_CCTS Twitter, UK_CCTS Instagram, UK and UKHC social media, and departmental/lab pages. If advertised on UKClinicalresearch.com, the online study flyer will include an option for interested individuals to enter and submit their contact information, they will be asked whether study team can contact them (Yes or No) via study-related text messages, and CCTS will also ask, 'How did you learn about the study? Internet and social media recruitment will follow the terms of use for each site utilized. The study will also be promoted through UK HC monitor screens. ¶
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redirecting the volunteer outside of ResearchMatch and to the REDCap survey, the volunteer is once again asked to confirm their interest in completing the pre-screening survey. ¶
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A set of advertisements specific to this survey study have been produced for use in print, on social media, and at outreach activities. ¶
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January 2023 Modification: Objective 7. ¶
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The subjects for this survey will be current smokers, and therefore will be new participants different from those in the other Objectives, and not currently enrolled as subjects in our other studies. They will be recruited through contacts within the University of Kentucky campus community and Lexington area, with help advertising from the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising, incuding the CCTS ResearchMatch program. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. ¶
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July 2024 Modification: Objective 8. ¶
N = 60 subjects. ¶
The subjects for this survey will be healthy adult non-smokers. Participants in prior objectives are eligible. They will be recruited through contacts within the University of Kentucky campus community, with help advertising from Participant Recruitment Services in the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. To prevent coercion students receiving the flyer are informed that participation in the study is not required for the class and refusal to participate has no connection to grades for the class. ¶
¶
April 2025 Modification: Objective 7 ¶
To expand advertising on social media to reddit, Instagram, and Craigslist new social media text and flyer for these sited have been made. The approved versions, labeled 2025, are attached. ¶
¶
October 2025 Modification: Objective 9. The participants in the study will be current smokers, and may include smokers who participated in other Objectives of this project. They will be recruited through contacts within the University of Kentucky campus community and Lexington area, with help advertising from Participant Recruitment Services (PRS) in the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising, including the CCTS ResearchMatch program. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. We have found social media to be a good source of smokers for our studies, so in addition to the sites PRS normally uses (e.g., UK_CCTS Facebook, UK_CCTS Twitter, UK and UKHC social media), we will advertise on reddit, Instagram, and Craigslist. The approved media for these recruiting efforts are attached. ¶
¶
Smokers fail to make scheduled appointments more than half the time in our experience. To reduce this problem at the time of scheduling we will offer rideshare (Lyft or Uber) or taxi service for persons from Fayette County and the counties contiguous to Fayette County. Participants will not be responsible for the costs associated with this transportation. We will organize this service over the phone with the participant on the day of each appointment and pay for it directly. In many cases, we will be on the phone with the participants as they wait to meet the car. ¶
¶
December 2025 Modification: Objective 10. ¶
We will recruit by contacting participants in our other objectives by email. Nearly every one of them, more than sufficient for this objective, has agreed to be contacted about additional studies.
Research Description SubjectRecruitmentMethods changed by mcclint on 12/12/2025 5:07:22 PM
Subjects will be recruited through contacts within the University of Kentucky campus community, with help on advertising from the CCTS. A flyer will be printed and posted on campus, and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. Interested people who contact the PI by email will be provided the questionnaire by email. Anyone who contacts the PI or other study personnel in person will be given their choice of a hard copy of the questionnaire or a digital copy by email. Persons whose questionnaires show no reason for exclusion will be scheduled for participation via email communication. ¶
¶
July 2022 Modification: Design for Objective 6. ¶
The subjects for this survey will be new participants different from those in the other Objectives, and not currently enrolled as subjects in our other studies. They will be recruited through contacts within the University of Kentucky campus community, with help on advertising from the CCTS. A flyer will be printed and posted on campus, and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. All information will include a link to the survey. ¶
See attached flyer. Methods of advertising are as follows. ¶
¶
Print advertisements: The study will recruit subjects through flyers, brochures, posters, Research Spotlights, ads placed on campus and in the surrounding community and region (Study Team will place/remove ads), including but not limited to the UK Medical Center, UK Clinics, Good Samaritan Hospital, Student Center, UHS, the 5 UK Center for Clinical and Translational Research wall mounts, Cardinal Hill, monitor screens, and area facilities and businesses. ¶
¶
Internet and Social Media: This study will be advertised on recruitment internet webpages in digital or video form (e.g., UKclinicalresearch.com, ResearchMatch.org, CenterWatch.com, CISCRP, UK, CCTS and may utilize Google Adwords). The study will be promoted via social media, including Facebook boost ads, UK_CCTS Facebook, UK_CCTS Twitter, UK_CCTS Instagram, UK and UKHC social media, and departmental/lab pages. If advertised on UKClinicalresearch.com, the online study flyer will include an option for interested individuals to enter and submit their contact information, they will be asked whether study team can contact them (Yes or No) via study-related text messages, and CCTS will also ask, 'How did you learn about the study? Internet and social media recruitment will follow the terms of use for each site utilized. The study will also be promoted through UK HC monitor screens. ¶
¶
Outreach activities: The CCTS attends outreach activities to promote research participation in general (e.g., Roots & Heritage Festival, Latino Festival, Eastern Kentucky University, Transylvania Health fairs, etc.) and will bring all relevant study flyers that are enrolling participants. ¶
¶
July 2022 Modification: Design for Objective 6. ¶
REDCap:This study may employ a pre-screening eligibility survey to determine if a volunteer meets basic inclusion/exclusion criteria. The study team will build and disseminate the eligibility survey on UK's REDCap which provides HIPAA compliant storage on UK servers and encrypted transmission of survey responses. The portable devices do not download the data, it is directly stored into the secure web-based connection (https) behind the firewall. All files are password protected once entered into the system. All project data is stored and hosted locally. If the study team provides a link to the eligibility survey, PRS will fold that link into recruitment materials. The link will also be included in study information sent to ResearchMatch participants who have indicated interest in the study. Before ¶
redirecting the volunteer outside of ResearchMatch and to the REDCap survey, the volunteer is once again asked to confirm their interest in completing the pre-screening survey. ¶
¶
A set of advertisements specific to this survey study have been produced for use in print, on social media, and at outreach activities. ¶
¶
January 2023 Modification: Objective 7. ¶
N = 40 subjects. ¶
The subjects for this survey will be current smokers, and therefore will be new participants different from those in the other Objectives, and not currently enrolled as subjects in our other studies. They will be recruited through contacts within the University of Kentucky campus community and Lexington area, with help advertising from the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising, incuding the CCTS ResearchMatch program. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. ¶
¶
October 2024 Modification to recruitment methods for Objective 7. In addition to previously approved recruitment methods co-investigator Dr. Rakesh Gopalkumar will contact smokers who have consented to be contacted for future studies on consent forms when they participated on studies approved on other approved protocols on which he is an investigator. Specifically, these protocols are 64473 and 56570. He will send approved flyer "PHYS_009b flyer-STAMPED.pdf" to these individuals. ¶
¶
July 2024 Modification: Objective 8. ¶
N = 60 subjects. ¶
The subjects for this survey will be healthy adult non-smokers. Participants in prior objectives are eligible. They will be recruited through contacts within the University of Kentucky campus community, with help advertising from Participant Recruitment Services in the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. To prevent coercion students receiving the flyer are informed that participation in the study is not required for the class and refusal to participate has no connection to grades for the class. ¶
¶
April 2025 Modification: Objective 7 ¶
To expand advertising on social media to reddit, Instagram, and Craigslist new social media text and flyer for these sited have been made. The approved versions, labeled 2025, are attached. ¶
¶
October 2025 Modification: Objective 9. The participants in the study will be current smokers, and may include smokers who participated in other Objectives of this project. They will be recruited through contacts within the University of Kentucky campus community and Lexington area, with help advertising from Participant Recruitment Services (PRS) in the CCTS. A flyer will be printed and posted on campus and used in internet and social media advertising, including the CCTS ResearchMatch program. The PI, study personnel, and other interested faculty may also distribute the flyer to University of Kentucky classes. We have found social media to be a good source of smokers for our studies, so in addition to the sites PRS normally uses (e.g., UK_CCTS Facebook, UK_CCTS Twitter, UK and UKHC social media), we will advertise on reddit, Instagram, and Craigslist. The approved media for these recruiting efforts are attached. ¶
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Smokers fail to make scheduled appointments more than half the time in our experience. To reduce this problem at the time of scheduling we will offer rideshare (Lyft or Uber) or taxi service for persons from Fayette County and the counties contiguous to Fayette County. Participants will not be responsible for the costs associated with this transportation. We will organize this service over the phone with the participant on the day of each appointment and pay for it directly. In many cases, we will be on the phone with the participants as they wait to meet the car. ¶
¶
December 2025 Modification: Objective 10. ¶
We will recruit by contacting participants in our other objectives. Nearly every one of them, more than sufficient for this objective, has agreed to be contacted about additional studies.
Subject Demographics ArabMiddleEasternNorthAfricanFemale changed by mcclint on 12/12/2025 2:58:57 PM
~~0~~ 9
Subject Demographics ArabMiddleEasternNorthAfricanMale changed by mcclint on 12/12/2025 2:58:57 PM
~~0~~ 3
Subject Demographics AsianFemale changed by mcclint on 12/12/2025 2:58:57 PM
~~40~~ 80
Subject Demographics BlackAfricanAmericanFemale changed by mcclint on 12/12/2025 2:58:57 PM
~~20~~ 30
Subject Demographics BlackAfricanAmericanMale changed by mcclint on 12/12/2025 2:58:57 PM
~~20~~ 10
Subject Demographics HispanicLatinoFemale changed by mcclint on 12/12/2025 2:58:57 PM
~~40~~ 50
Subject Demographics HispanicLatinoFemale changed by mcclint on 12/12/2025 2:58:57 PM
~~40~~ 50
Subject Demographics HispanicLatinoMale changed by mcclint on 12/12/2025 2:58:57 PM
~~20~~ 20
Subject Demographics StudyPopulation changed by mcclint on 12/19/2025 8:12:09 AM
Subjects: Non-clinical healthy adults, ages 18 - 60. All gender identities and racial/ethnic groups are eligible to participate. N = 20-30 subjects per experiment. ¶
¶
Exclusions: ¶
1. Persons > 60 years of age are excluded to avoid the complications from the gradual decline in olfactory acuity that often occur at advanced ages. ¶
2. History of an odor-triggered clinical condition, such as migraines. Subjects who experience any sort of adverse reaction after smelling an odor during the study will be discontinued. ¶
3. Persons who claim to have deficiencies in smell or taste. (In most cases, taste perception depends greatly on the odors released from foods or beverages in the mouth). ¶
4. Smokers. Smoking alters sensitivity to odors. ¶
5. Persons who have experienced a fragrance allergy. ¶
6. Persons with diagnosed neurological or psychological conditions that could affect their ability to rate sensory perceptions, and persons taking medications or treatments known to alter the senses of smell or taste. ¶
7. Persons, who by long exposure to odors normally considered foul, may have come to enjoy such odors. ¶
8. Pregnant females ¶
9. Persons suffering from cold or allergies on the day of testing may be excluded or rescheduled. ¶
10. Persons < 18 years of age are excluded from this study ¶
¶
July 2022 Modification: Objective 6. Former smoker survey ¶
Subjects: All genders and ages 18-60. ¶
Exclusions: ¶
1. Current smoker ¶
2. Never smoked ¶
¶
January 2023 Modification: Objective 7. Suppression of desire to smoke ¶
Subjects: Smokers of all genders and ages 18 – 60. ¶
Exclusions: ¶

1. Non-smoker ¶
2. Outside age range ¶
3. Self-reported inability to smell or taste. ¶
¶
July 2024 Modification: Objective 8. Identify new odors that suppress perception of real cigarette smoke odor. ¶
Subjects: Healthy adults of all genders and ages 18 – 60. ¶
Exclusions: ¶
1. Current smoker ¶
2. Pregnant ¶
3. Outside age range ¶
4. Self-reported inability to smell or taste. ¶
¶
October 2025 Modification: Objective 9. Identify neural pathways affected by odors that suppress both perception of real cigarette smoke odor and the urge to smoke. ¶
Subjects: N = 10-20 healthy adults of all genders and ages 18 – 60. ¶
Exclusions: ¶
1. Pregnant ¶
2. Outside age range ¶
3. Self-reported inability to smell or taste. ¶
4. Metal that cannot be removed from body ¶
5. Having suffered a major head injury and/or concussion ¶
6. Having been diagnosed with a neurological disorder (e.g. stroke, seizures) ¶
7. Taking medications that affect the central nervous system (e.g., for depression, schizophrenia, panic disorder), as these medications can interfere with the MRI signal ¶
¶
December 2025 Modification: Objective 10. Determine how odors that effectively block perception of cigarette smoke odor by acting in the olfactory periphery (the nose) alter the perception of cigarette smoke compared to odors that are ineffective blockers. ¶
Subjects: ~~Participants in prior studies/objectives only.~~ N = up to 100 healthy adults of all genders and ages 18 – 60~~.~~ who have been participants in one or more of our prior studies/objectives. ¶
Exclusions: ¶
1. Pregnant ¶
2. Outside age range ¶
3. Self-reported inability to smell or taste. ¶
4. Experience migraine headaches ¶
5. Fragrance allergies
Subject Demographics StudyPopulation changed by mcclint on 12/19/2025 8:10:56 AM
Subjects: Non-clinical healthy adults, ages 18 - 60. All gender identities and racial/ethnic groups are eligible to participate. N = 20-30 subjects per experiment. ¶
¶
Exclusions: ¶
1. Persons > 60 years of age are excluded to avoid the complications from the gradual decline in olfactory acuity that often occur at advanced ages. ¶
2. History of an odor-triggered clinical condition, such as migraines. Subjects who experience any sort of adverse reaction after smelling an odor during the study will be discontinued. ¶
3. Persons who claim to have deficiencies in smell or taste. (In most cases, taste perception depends greatly on the odors released from foods or beverages in the mouth). ¶
4. Smokers. Smoking alters sensitivity to odors. ¶
5. Persons who have experienced a fragrance allergy. ¶
6. Persons with diagnosed neurological or psychological conditions that could affect their ability to rate sensory perceptions, and persons taking medications or treatments known to alter the senses of smell or taste. ¶
7. Persons, who by long exposure to odors normally considered foul, may have come to enjoy such odors. ¶
8. Pregnant females ¶
9. Persons suffering from cold or allergies on the day of testing may be excluded or rescheduled. ¶
10. Persons < 18 years of age are excluded from this study ¶
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July 2022 Modification: Objective 6. Former smoker survey ¶
Subjects: All genders and ages 18-60. ¶
Exclusions: ¶
1. Current smoker ¶
2. Never smoked ¶
¶
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Subjects: Smokers of all genders and ages 18 – 60. ¶
Exclusions: ¶
1. Non-smoker ¶
2. Outside age range ¶
3. Self-reported inability to smell or taste. ¶
¶
July 2024 Modification: Objective 8. Identify new odors that suppress perception of real cigarette smoke odor. ¶
Subjects: Healthy adults of all genders and ages 18 – 60. ¶
Exclusions: ¶
1. Current smoker ¶
2. Pregnant ¶
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4. Self-reported inability to smell or taste. ¶
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October 2025 Modification: Objective 9. Identify neural pathways affected by odors that suppress both perception of real cigarette smoke odor and the urge to smoke. ¶
Subjects: N = 10-20 healthy adults of all genders and ages 18 – 60. ¶
Exclusions: ¶
1. Pregnant ¶
2. Outside age range ¶
3. Self-reported inability to smell or taste. ¶
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5. Having suffered a major head injury and/or concussion ¶
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7. Taking medications that affect the central nervous system (e.g., for depression, schizophrenia, panic disorder), as these medications can interfere with the MRI signal ¶
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December 2025 Modification: Objective 10. Determine how odors that effectively block perception of cigarette smoke odor by acting in the olfactory periphery (the nose) alter the perception of cigarette smoke compared to odors that are ineffective blockers. ¶
Subjects: Participants in prior studies/objectives only. N = up to 100 healthy adults of all genders and ages 18 – 60. ¶
Exclusions: ¶
1. Pregnant ¶
2. Outside age range ¶
3. Self-reported inability to smell or taste. ¶
4. Experience migraine headaches ¶
5. Fragrance allergies
Subject Demographics StudyPopulation changed by mcclint on 12/12/2025 2:58:57 PM
Subjects: Non-clinical healthy adults, ages 18 - 60. All gender identities and racial/ethnic groups are eligible to participate. N = 20-30 subjects per experiment. ¶
¶
Exclusions: ¶
1. Persons > 60 years of age are excluded to avoid the complications from the gradual decline in olfactory acuity that often occur at advanced ages. ¶
2. History of an odor-triggered clinical condition, such as migraines. Subjects who experience any sort of adverse reaction after smelling an odor during the study will be discontinued. ¶
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July 2022 Modification: Objective 6. Former smoker survey ¶
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Exclusions: ¶
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Exclusions: ¶
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July 2024 Modification: Objective 8. Identify new odors that suppress perception of real cigarette smoke odor. ¶
Subjects: Healthy adults of all genders and ages 18 – 60. ¶
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October 2025 Modification: Objective 9. Identify neural pathways affected by odors that suppress both perception of real cigarette smoke odor and the urge to smoke. ¶
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2. Outside age range ¶
3. Self-reported inability to smell or taste. ¶
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5. Having suffered a major head injury and/or concussion ¶
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December 2025 Modification: Objective 10. Determine how odors that effectively block perception of cigarette smoke odor by acting in the olfactory periphery (the nose) alter the perception of cigarette smoke compared to odors that are ineffective blockers. ¶
Subjects: N = up to 100 healthy adults of all genders and ages 18 – 60. ¶
Exclusions: ¶
1. Pregnant ¶
2. Outside age range ¶
3. Self-reported inability to smell or taste.
Subject Demographics WhiteCaucasianFemale changed by mcclint on 12/12/2025 2:58:57 PM
~~297~~313
Subject Demographics WhiteCaucasianMale changed by mcclint on 12/12/2025 2:58:57 PM
2~~48~~61

Study Personnel Changes:

Status	PPIdentity	ProtocolID	PersonID	RoleInProtocol	IsContact	LastName	FirstName	Email	DeptCode	RoomBuilding	SpeedSort	PhoneNum	DeptDesc	AuthorizedConsent	ResponsibilityInProject	Degree	Rank	StatusFlag	IsRemoved	ModBy	ModDate	SFI	IsPIRN	MiddleName
Deleted	1144147	109820	12373886	SP	N	Schnabel	Samantha	Sam.schnabel@uky.edu						Y	Data Collection			P	Y	mcclint	12/12/2025 3:19:27 PM	N		
Updated	1144130	109820	00011578	PI	Y	McClintock	Timothy	mcclint@uky.edu	7H750	B281 BBSRB	405360298	8593231083	Physiology		Principal Investigator	Ph.D.	Professor	P	N	mcclint	12/12/2025 5:30:10 PM	N	N	S

Subject Demographics Comment by Karen Larson - ORI to PI on 12/15/2025 2:32:11 PM
Subject Demographics - Suggest add Objective 10- Prior enrolled subjects only. Include as an exclusion criteria experience migraine headaches and have a fragrance allergy as these are listed in the new CF page 2 under not qualify section.

Research Description Comment by Karen Larson - ORI to IRB/PI on 12/19/2025 11:38:27 AM
Recruitment- Objective 10 any recruitment materials should be specific to this objective. Please upload specific recruitment materials for Objective 10.

Research Description Comment by Karen Larson - ORI to PI on 12/15/2025 3:13:17 PM
Recruitment - Objective 10- How will prior enrolled subjects be contacted about if interested in participating in new objective? Please upload any recruitment emails or phone scripts.

Research Description Comment by Karen Larson - ORI to PI on 12/15/2025 3:00:17 PM
Research Procedures- Objective 10 - Please include 1 session is 1-2 hours long.

Informed Consent Comment by Timothy McClintock - PI to PI on 12/19/2025 4:09:04 PM
Because I have submitted, or will soon submit (Feb. 2026), NIH grants that use this protocol I would like to keep the NIH language in the consent form. If these NIH awards are not successful I will at that time modify the language on Informed Consent forms.

Informed Consent Comment by Karen Larson - ORI to IRB/PI on 12/19/2025 1:53:17 PM
Please revise all clean CFs uploaded to remove all mention of NIH. Delete current uploaded CFs and upload new clean revised versions. Call Karen if you have any questions at (859) 257-3038.

Informed Consent Comment by Karen Larson - ORI to IRB/PI on 12/19/2025 1:50:51 PM
If you will still use the Smokers and Healthy Adult clean CFs uploaded on 2.7.24, please revise them to remove all mention of NIH. Delete the current uploaded CFs of 2.7.24. Upload new clean revised CF versions.

Informed Consent Comment by Timothy McClintock - PI to PI on 12/19/2025 12:31:08 PM
We plan to use Informed consent Odors 020724.pdf in the future. I did not upload a new version because it already mentions the NIH in the two sections in question.

Yes, I deleted the Cover letter for the online survey of smoke triggers as we are no longer pursuing this objective.

Informed Consent Comment by Karen Larson - ORI to IRB/PI on 12/19/2025 11:37:40 AM
Please confirm you are no longer enrolling any subjects using Informed consent Odors 020724.pdf as a clean version (NIH in two sections) was not uploaded- see approved MR 11.26.25.

Informed Consent Comment by Karen Larson - ORI to IRB/PI on 12/19/2025 10:49:56 AM
Objective 6 was an approved MR of 8.16.22 and had an approved Cover Letter (consent document) for a survey. The IRB had approved a Waiver of Signature for it. It appears you have already deleted the clean Cover Letter TMc Smoker Trigger Cover Letter V3.

Informed Consent Comment by Timothy McClintock - PI to PI on 12/18/2025 4:19:30 PM
Objective 6 was a survey and did not have a consent form, at least as I recall.

Informed Consent Comment by Karen Larson - ORI to IRB/PI on 12/15/2025 3:17:35 PM
1. Consent Form (CF)-the new submitted CF for Objective #10 does not contain NIH under "What else do you know section" yet it is included under "Who will see the information that you give". Please add NIH under "What else do you need to know". You still have NIH marked under funding section.

2. New CF Objective 10- Signature Page- Remove in two places "Or, if applicable, parent or guardian." Please also remove gray bar.
Delete current new CF for Objective 10 and upload a new clean (no high-lights) revised version. Call Karen at (859) 257-3038 if you have any questions.

3. All current Consent Forms being used should be consistent in the listing of NIH as a funder of this study in applicable sections (Who will see the information that you give and What else do you need to know)..

2. Have you deleted the clean Consent Form for Objective 6 as you will no longer being conducting it?

Funding/Support Comment by Karen Larson - ORI to PI on 12/19/2025 1:32:25 PM
Please read email sent to you today at 1:21 pm. If you no longer have HHS/NIH funding, remove check marks for these items. In box below please add month and year that the HHS/NIH funding ended. Scroll down and click SAVE.

Continuation/Final Review Comment by Timothy McClintock - PI to PI on 12/19/2025 12:47:03 PM
Violation report has been submitted.

Continuation/Final Review Comment by Karen Larson - ORI to IRB/PI on 12/19/2025 11:04:25 AM
CR #2- 12.19.25- New add to Protocol Violation Form you will create and submit to the IRB:
Odor and Odor Blocker 1 Subject signed CF-
1. Why was not the stamped version of Cover Letter/Consent Form containing the date 2.5.25, used with this subject, instead of an older stamped version of 2.22.24? 2. Does the written content of the older version 2.22.24 stamped version match the written content in the

approved stamped version of 2.5.25? 3. Did all of the other enrolled subjects for this Objective sign an older stamped CF version? 4. How did it happen that an older stamped version was used to enroll this subject or subjects? 5. How will you prevent it from happening again? 6. Is there any external funding for this study, including federal? If yes, list all names of sources of funding.
Please confirm by adding in a comment there is not a second enrolled subjects's signed CF to be uploaded for this Objective who enrolled since last year's CR of 2.5.25?

Continuation/Final Review Comment by Karen Larson - ORI to IRB/PI on 12/15/2025 2:56:36 PM
CR #2- Please submit a Protocol Violation to the IRB:
In the e-IRB form for the Protocol Violation please address the following:
The IRB will likely ask the following questions: 1. Why was not the stamped version of Cover Letter/Consent Form containing the date 2.5.25, not used with the last four enrolled subjects (for two different objectives)? 2. Does the written content of the unstamped versions match the written content in the approved stamped versions? 3. Did all of the other enrolled subjects sign unstamped versions? 4. How did it happen that the stamped versions were not used to enroll subjects? 5. How will you prevent it from happening again? 6. Is there any external funding for this study, including federal? If yes, list all names of sources of funding. Please see E-IRB training module on how to create a Protocol Violation Report copy link into your browser: https://research.uky.edu/office-research-integrity/e-irb/video-tutorial-library#ABC
Submit the Protocol Violation Report and re-submit the CR.

Statistical Analysis Plan

Statistical analysis is done in R (R Foundation for Statistical Computing; Vienna, Austria). Pleasantness ratings, breakpoint data measuring urge to smoke, and subjective ratings of urge to smoke are analyzed using linear mixed models. Since breakpoint data are highly right-skewed, they are log-transformed prior to modeling. Likelihood ratio testing and Akaike Information Criterion (AIC) are used to determine an appropriate covariance structure for each model. When the overall main effect of odor is significant, relevant pairwise comparisons are performed using Fisher's Least Significant Differences (LSD). Across all analyses, a *p*-value less than 0.05 is considered statistically significant.