ID: 75N93024F00002

USING BITTER TASTE RECEPTOR BLOCKERS TO IMPROVE THE PALATABILITY OF PEDIATRIC MEDICINES

[NCT ID NOT YET ASSIGNED]

INFORMED CONSENT FORM, VERSION DATE 2/28/2025

MONELL CHEMICAL SENSES CENTER
RESEARCH PARTICIPANT
INFORMED CONSENT AND FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION
Monell Center Research Study Summary for Potential Participants

Study Title:	**"Using Bitter Taste Receptor Blockers to Improve the Palatability of Pediatric Medicines: Trained Human Sensory Panels"**
Protocol Number:	**75N93024F00002**
Sponsor/Funder	**Advanced Bioscience Laboratories (ABL) /The National Institute of Allergy and Infectious Diseases, Division of AIDS**
Principal Investigator:	**Paul Wise, Ph.D.**
Telephone:	**267-519-4799** **267-519-4900 (24 Hours)**
Address:	**Monell Chemical Senses Center** **3500 Market St** **Philadelphia, PA 19104**

Key Information

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, you may contact the Institutional Review Board (IRB) at the number listed below in the section titled "Whom to Contact About This Study."

Our main goal in this research study is find ingredients that might make drugs taste better. Many people, particularly small children, must take drugs in liquid form because they cannot swallow pills or capsules. The bad taste of some liquid drugs can keep patients from taking drugs they need for their health. You are being invited to volunteer to taste samples (liquids or gels) containing APIs (active pharmaceutical ingredients, or substances in drugs that produce desired health effects). Participants will be instructed to taste samples both with and without experimental flavor ingredients added and judge how the samples taste.

People who volunteer for the study will be instructed to complete many repeated visits to the study site listed on the first page of this form. We will start the first visit by reviewing this consent form with you. If you sign the form, we will ask some health questions to determine if you may qualify. If you can become pregnant, we will also give you a commercial pregnancy test to make sure you are not pregnant since it is possible that some APIs used in the study could affect unborn or nursing babies. If you qualify based on the health questions and pregnancy test, we will move on to tasting sessions, as described below.

Tasting visits will last between 1 and 2 hours. In the first 3-5 visits, we will test your ability to taste an API used to treat viral infections. We will also train you to recognize and rate sensations like bitterness, sourness, and pungency using examples (mostly foods or food ingredients). If your training goes well, we will then move on to study visits in which participants rate the taste of APIs and other experimental flavor ingredients. Participants will be instructed to taste up to about 20 samples each visit, which may include liquids or gels. After tasting each sample, you will be instructed to spit out the sample, rinse your mouth with water, and rate how the sample tasted. No samples will be swallowed. We expect to complete tasting visits for many APIs/experimental flavor ingredients over about three years.

As long as you remain qualified, you are welcome to participate in as many tasting visits as you want, but you may stop any time, for any reason, without affecting your future opportunities for research participation at Monell. If you leave the study, you will be paid for all visits completed up to that point. If you do continue, we may periodically ask health questions and repeat the pregnancy test to make sure you are still qualified.

You will not receive any direct benefit by participating. Some samples will almost certainly taste bad to you, perhaps very bad. For APIs, we will only use substances which have been approved by the United States (US) Food and Drug Administration (FDA) for treatment of illness. Total amount of API in samples tasted during a visit will not exceed a single adult dose, and samples will not be swallowed. Under these conditions, risk of serious harm is expected to be minimal. Serious side effects in patients taking these drugs are uncommon but have been seen, including life-threatening side effects. Your risks could be higher if you 1) swallow samples, 2) have a history of liver issues, diabetes, kidney issues, heart issues, or other serious illness, 3) if you regularly take medications (either prescription or over-the-counter), 4) if you have food or drug allergies, 5) if you are pregnant or are nursing, 6) if you are HIV positive, 7) if you have viral hepatitis, or 8) you are infected with the bacteria that causes tuberculosis (TB). If any of these conditions apply to you, you should not participate since you could be at greater risk of harm. Since the procedures do not diagnose or treat any illness or condition, you lose nothing if you decide not to participate. Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, and other possible risks not discussed here.

Why am I being asked to volunteer?

You are being invited to volunteer for a research study. You are being asked to volunteer since you meet the requirements for enrollment into this study, namely, that you are a healthy adult between the ages of 18 and 60. Your participation is voluntary, which means you can choose whether or not you want to volunteer. If you choose not to volunteer or if you withdraw for any reason, there will be no penalty or loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study and discuss this form with you. You may also decide to discuss it with others. Take all the time you need to make your decision. We will give you a copy of this form for your records. You may find some of the language difficult to understand. Please ask the study team about this form. If you decide to volunteer, you will be asked to sign this form.

What is the purpose of this research study?

This study is funded by a sub-contract from the US National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS, under Resources to Advance Pediatrics and HIV Prevention Science (RAPPS) Contract No. 75N93023D00001, Task Order No. 75N93024F00002. NIAID is interested in finding ways to make drugs taste better since flavor can be a serious barrier to taking prescribed medications for people who must take drugs in liquid form, especially kids who cannot swallow pills. Drugs of current interest in this study include those used to treat viral infection (HIV and Hepatitis B) and antibiotics used to treat tuberculosis (TB). One main goal is to better understand the nature of the bad taste of APIs (active pharmaceutical ingredients), for example, whether they are bitter, sour, pungent, or have more than one bad taste. Another main goal is to test whether experimental flavor ingredients can improve the taste of APIs. We will test both flavor ingredients which are already approved by the US Food and Drug Administration (FDA) for use foods or drugs, as well as experimental ingredients that are not currently approved flavor additives. The eventual goal is to create a flavor

blend that will make important drugs easier to take, though at this point we are just doing basic research and development toward this eventual goal.

There are no current plans to commercialize results of the research. However, if knowledge gained in this research study does eventually contribute to development of patents or products, research participants will not be entitled to royalties or other payments beyond compensation for participating in the research study **(**see "Will I be paid for being in this study?" below). We will collect and store saliva samples, from which we MAY extract and store genetic material (deoxyribonucleic acid, or DNA). We have no current plans to use these samples and DNA ("biospecimens") for commercial profit, but if we do research participants would not share in that profit or otherwise benefit financially. The principal investigators will NOT benefit financially from results or biospecimens collected in the research study, but in the past have received research funding, consulting fees, or had travel expenses paid by companies that make flavors and drugs.

How long will I be in the study? How many other people will be in the study?
If you agree to volunteer, you will be instructed to participate in at least 1 tasting session of about 1-2 hours in length. If, based on this first session, you qualify for the study, you will be invited to attend up to about 10 more sessions of about 1-2 hours. We expect you to complete these sessions within about 1-2 months, but if your schedule does not allow that, we will do our best to accommodate you.

Over the course of about three years, we will be conducting taste tests on many APIs and flavors. As long as you remain otherwise eligible, you are welcome to participate in as many or as few of these sessions as you wish. In total, we expect up to about 100 people to participate over the course of about three years.

What am I being asked to do?

First study visit:

- Read, discuss, and (if you agree) sign this consent form.
- We will ask some health questions to help decide if you qualify to participate. If you do not qualify based on the health questions, you will not be asked to do any of the procedures that are listed below.
- If you qualify according to the health questions, and you are able to become pregnant, we will give you a commercial pregnancy test to take to a nearby bathroom (the test requires a small amount of urine). We will ask you to bring the completed test to a private room where a study team member will record the result. If the test indicates that you may be pregnant, you will not be eligible to participate.
- If you qualify based on the health questions and (if applicable) the pregnancy test, we will begin training you to make taste ratings. We will give you instructions on the scales to be used and have you practice using the scales by rating the strength of some remembered or imagined sensations (for example, the brightness of a dimly lit room). Next, we will instruct you to rate the taste of some food-grade sweet and bitter experimental flavor ingredients, and also to rate the taste of an HIV medication. We will instruct you to taste about 25 samples in total. Each sample will be up to about 5 ml, or about a teaspoon. You will be instructed to spit out samples after tasting them and rinse your mouth with water. No samples should be swallowed, since that would increase your risk of harm.
- After you are finished with this first tasting session, we will look at your taste ratings to see if you are able to do the task. If not, we may remove you from the study at this point and pay you for that study visit. If you are able to do the task, we will invite you to continue training.

Further training sessions (study visits 2-3, with more visits possible if needed to complete training):

Over the next 2-3 visits, we will train you to recognize various sensations like bitterness, sourness, astringency, metallic taste, and pungency. We will do this by having you taste liquid samples (up to about 5 ml, or about 1 teaspoon) or foods (like unsweetened chocolate, carbonated water, a drop of hot sauce) that have these target sensation qualities. There will be a few examples that are not foods, like pickling alum to demonstrate astringency. We will instruct you to spit these samples out rather than swallowing them. We will first give you examples with labels identifying the target tastes, then later give you examples without labels to see how well you recognize the various sensations. This training will require at least 2 visits (1-2 hours each), but some people need more visits. We would not expect this training to take more than five sessions in total.

Subsequent tasting sessions (at least 4 visits, but you may participate in more visits if you remain interested and eligible):

After you are trained, we will move on to experiments in which you taste samples which contain various APIs (active pharmaceutical ingredients) of interest or other experimental flavor ingredients. In each of these sessions (1-2 hours each), we will instruct you to taste up to about 20 samples (about 5 ml, or about 1 teaspoon) each. Some will be liquids. Some may be thicker, like a gel. For all of them, we will instruct you to spit out samples after tasting them and to rinse your mouth with water. For each sample, you will be instructed to rate the strength of various target tastes.

Samples will contain one or more of the following: 1) an API, 2) standard flavoring ingredients, including (but not limited to) salts, sugars, or low calorie sweeteners (natural or artificial), 3) other ingredients used in foods or drugs, including thickeners, emulsifiers, stabilizers, ethanol (the alcohol in beer, wine, and spirits), or coloring, and 4) experimental flavor ingredients that are not standard flavor additives.

We may conduct some tasting sessions in a dimly lit room to minimize the impact of appearance (like color differences between samples). We will often instruct you to use plastic nose clips to pinch your nostrils shut while tasting samples so that smell does not influence your ratings. Tasting sessions will include breaks between samples to allow your palate to recover. To help clear the palate between samples, we may instruct you to rinse your mouth with saline (weak salt water) or take a bite of a bland food (like white bread or a soda cracker). You will be instructed to spit out palate cleansers rather that swallow them.

As you continue in the study, we may periodically repeat some training (as described above, though for ongoing training a single refresher session is often enough). We will also periodically ask you the same health questions as we did during the first study visit and (if applicable) repeat the pregnancy test to make sure that you have not become pregnant. If you become ineligible while you are participating, we will remove you from the study. You are welcome to continue in the study as long as you remain interested in eligible, but you are free to discontinue at any time for any reason.

Collection of saliva, from which we may extract DNA:

Before one of the tasting sessions, we will collect saliva by having you spit into a sample tube. We may get DNA (your genetic code) from cells in the saliva sample. If we do, we will determine if genetic differences between participants are related to differences in how they perceive bitterness.

As a participant, we expect you to 1) attend scheduled study visits, 2) follow study instructions, 3) not to eat, drink anything except for water, smoke, brush your teeth, or use other oral hygiene products for at least one hour before the start of a tasting session, 4) let us know right away if any procedure is too uncomfortable for you, or if you have any concerns, and 5) contact us as soon as possible if you experience any unusual feelings or symptoms.

What are the possible risks or discomforts?

We do not know of any likely risks of serious harm from tasting the samples as we will use them in the study. Some samples may contain low calorie sweeteners like those in Splenda™, Nutra-sweet™ and Equal™. Some may contain animal-based products like milk and gelatin. Some will contain other food, beverage, or pharmaceutical ingredients, including flavoring, thickeners, food coloring, or emulsifiers. Emulsifiers are substances added to help dissolve ingredients which do not dissolve well in water (we may also use ethanol, the alcohol in beer and wine, to help dissolve some substances). Some samples will contain active pharmaceutical ingredients, including 1) tenofovir alafenamide (brand name, Vemlidy®, used to treat HIV infection and hepatitis B), 2) rifampicin (brand names Rifadin® and Rimactane®, used to treat tuberculosis), 3) rifapentine (brand name Priftin®, used to treat tuberculosis), and 4) levofloxacin (brand name Levaquin®, used to treat various bacterial infections). Finally, some samples may include experimental flavor ingredients that are not typically added to foods at this time.

You will be instructed to spit out all samples after tasting, but if you swallow samples, you could be at increased risk of harm. Also, if you have food or drug allergies, you could be at increased risk of harm, and you should NOT participate. If you are pregnant, nursing, or plan to become pregnant, you should NOT participant since there could be risks to unborn or nursing babies. If you have any chronic or serious illness, you could be at increased risk of harm and you should NOT participate.

Known risks follow:

- Some samples will almost certainly taste bad to you. Some people experience temporary nausea or queasiness from bad tastes, though it usually passes quickly. If any samples taste too bad to you, please let us know and testing can be stopped if you prefer.
- In tasting food, ingredient, or drug samples, there is always some risk of bad reactions like allergy or sensitivity reaction. If you have any food or drug allergies or sensitivities, you should NOT participate since you could be at greater risk of harm.

- Contamination/food borne illness. Any time someone places something in the mouth, there is risk. We will reduce this risk by using samples prepared in a clean laboratory environment, storing samples under refrigeration as appropriate, and using prepared samples promptly.
- Other infection. Communicable illness (like a cold or flu) is always possible with human contact. Disposable materials will be used whenever possible. Tasting stations will be disinfected after use.
- Confidentiality. We will collect some potentially sensitive information, including limited health information. Should this information be released, it could cause personal embarrassment or affect hiring or insurance options. We will do our best to avoid disclosing any information (more information below), but these risks cannot be completely eliminated.
- API-specific risks. You will be instructed to spit out all samples after tasting, but trace amounts could be absorbed through the tissue in your mouth during tasting. It is also possible that you could swallow small amounts accidentally. We do not anticipate that this will cause serious harm, but you should know that patients taking the drugs we will study have experienced serious side-effects, including:
    - Severe allergic reaction (in the case of rifampicin, this can cause failure of the kidneys)
    - Severe liver damage (occasionally fatal)
    - Dangerous build-up of lactic acid in the blood
    - Drug resistance (in which drugs are no longer effective against the bacteria that cause TB or the HIV virus). You could have HIV or TB bacteria and NOT have any symptoms. So, if you have tested positive for HIV, TB, or hepatitis B, or you are at risk for these infections, you should NOT participate
    - Damage to your tendons or joints (levofloxacin)
    - Digestive problems (like severe diarrhea)
    - There could be other, milder symptoms like:
        - Cough,
        - Flu-like symptoms (fever, fatigue, soreness),
        - Headache,

- Milder digestive symptoms, or
- Other issues.

In general, if you have any doubts, we strongly suggest that you consult with your health care provider before deciding whether to participate. If, during the course of the study, you experience any unusual symptoms or feelings, please let us know right away. More generally, ***if any procedure causes you discomfort, please tell the study team right away.*** Testing can be paused, or stopped completely, at any time if you choose. You can withdraw from the study without losing any compensation earned up to the time you withdraw, and you will still be eligible to participate in any other study with the study site or Sponsor for which you would otherwise qualify.

Risks associated with collection and analysis of genetic material include:

- This research may include genetic analysis and will not include whole genome sequencing. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe that the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
- There can be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives. Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low, because your samples will be coded. We do not plan to share results of these tests with participants or their doctors.
- Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, it could make it harder for you to get or keep a job or insurance, or life insurance companies may charge a higher rate based on this information. We will take several steps to keep your genetic information confidential to prevent it from being misused in such a way. We will store saliva, DNA extracted from saliva, and electronic genetic information under

a Study ID code. Documents containing information with the Study ID Code will be stored separately from information which might be used to identify you. We will store your electronic genetic information on secure servers. We feel that risk of an unintentional release of your information is very low, but it is still possible.

- A federal law (Genetic Information Non-Discrimination Act, GINA) helps reduce the risk from health insurance or employment discrimination. The law does not include other types of misuse by life insurance or long-term care insurance. GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
    - Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
    - Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
    - Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law. Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

I am an employee (or one of my family members is an employee) of the Monell Chemical Senses Center. Do I have to be in this study?

No, participation in this research study is NOT required for employees or relatives of employees. Your decision to participate (or not to participate) will have no influence on hiring, retention, promotion, salary, employee evaluations, or any other interactions with Monell. If you have questions about employee participation in research studies at Monell, please contact our head of Human Resources, Nico Cook (Chief People and Operations Officer) at 267-519-4731.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

*Y*ou will not receive any direct benefit. In the future, knowledge gained in this study could lead to flavor formulations in drugs that make liquid drugs easier to take for people who cannot swallow pills or capsules, including children. If so, your participation might contribute to better health outcomes for patients in the future.

What other choices do I have if I do not participate?

The only alternative to participation in this study is not to participate. The procedures do not diagnose or treat any illness or condition, and all are purely for research purposes, so there is no loss of benefits or treatment options if you decide not to participate.

Will I be paid for being in this study?

Participants will receive $50.00 for a 2-hour visit, $35.00 for a 1.5-hour visit, and $25 for a 1-hour visit (rounding up). If you choose to stop participating, you will be paid for all sessions completed up to the time you leave the study. We pay by check (if you participate long-term we prefer to issue checks monthly, but if you want to make different arrangements we may be able to accommodate you).

We collect social security numbers (or IRS-issued taxpayer ID numbers) as part of the payment process (using an Internal Revenue Service Form W-9). If you are paid more than $600 in one calendar year, Monell will issue a 1099-MISC to you and the IRS. If you are a non-resident alien without a social security or IRS-issued taxpayer ID number, you may still be eligible to receive compensation. If you are a citizen of a country that has a tax treaty with the United States, you will need to fill out an IRS form 8233 instead

of a W-9. If you are a citizen of a country that does not have a tax treaty with the United States, or if you are unwilling to fill out the required tax forms, then you may still be eligible to participate in the research study, **but we will not be able to pay you** for participating.

Will I have to pay for anything?

There are no costs to participate. However, if your internet service provider or wireless provider charges you for data, you may be billed for communicating with study team regarding the study.

Will I receive the results of research testing?

We do not plan to return results of tests to you, but please note that results would not tell participants anything about their health in any case, and none of the tests are designed and validated to diagnose illness (all are for research purposes).

What happens if I am injured or hurt during the study?

If you are injured during the study, you should go to the nearest emergency room. There are no plans for the Monell Chemical Senses Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form. If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The principal investigator's name and phone number are listed on the first page in this consent form. You may also use the Emergency contact number listed on page one of this form.

When is the study over? Can I leave the study before it ends?

This study is expected to end after all participants have been evaluated, and all information has been collected. This study may also be stopped at any time by the Monell Chemical Senses Center, the Food and Drug Administration (FDA), The U.S. Office of Human Research Protections (OHRP), the Monell Human Subjects Committee, the Institutional Review Board, or by study sponsors.

In addition, the Principal Investigators may end your participation in the study if the Principal Investigators feel that 1) continued participation may be dangerous to your health or safety, or 2) you have not followed study directions. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.

You are free to leave the study anytime, for any reason. Withdrawal will not interfere with your future interactions with this institution.

How will my personal information be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. Paper forms with personal or identifying information will be kept in locked cabinets in rooms that require keyed access, in a building that requires keyed access. Electronic records with your information will be stored on secure servers protected by firewalls, with access protected by passwords and available only to study team.

We will not record any sessions, either by video or audio.

However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If taste test or other results of particular people are presented, the results will identify people only according to a random code number. The Institutional Review Board (IRB) and the US Food and Drug Administration may have access to your records. Representatives of the Sponsor and Members of the Monell Chemical Senses Center Human Subjects Committee may access your records to make sure the study was done properly.

Concerning privacy, some of your taste sessions may be conducted in a group setting with up to three other participants present, and you may see other participants when you come to Monell, so others may be aware you are participating in a Monell study.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

How long will you keep my data and what if I decide later that I want to opt out of the study database?

We will keep your information, saliva samples, and (if we get DNA from the saliva samples) your genetic code indefinitely. If you later decide that you do not want us to keep your data or saliva sample, you may send a request to have your data removed and saliva destroyed, either in writing or by e-mail to the principal investigator listed on the first page of this form. Upon receipt of such a request to opt out, we will delete/destroy all your study data, samples, and records we are not required by law or regulatory bodies to retain. We will not destroy records that you participated in the study (including this consent form), or records that you received compensation from Monell as a research participant. We may share de-identified study data or parts of your genetic code related to bitter taste with other researchers (and plan to share de-identified data with study sponsors). De-identified means that data from individual participants will not be attached to names or other identifying information. Once we share de-identified data outside Monell, we will not be able to remove you from those datasets already shared, but your data will not be included in any future data-sets shared outside Monell. We will NOT share your saliva samples outside of Monell. If you request that your data be removed from the study data-base, you will not be able to remain in the study.

Will information about this study be available to the public?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

We may also publish results in scientific journals and/or present results at scientific meetings. Results shared outside the study team in this way will have all identifiable information removed so no one will be able to identify participants. If individual participant results are published or presented, your results will be identified using a study ID code rather than your name or initials.

Future Use of Data

Your information will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. Your de-identified data may be shared with future researchers at the discretion of the principal investigators. However, it would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected in this study. Research results that are clinically relevant, including individual research results, will not be disclosed to you.

Whom to contact about this study?

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness.
- Payment or compensation for being in the study, if any.
- Your responsibilities as research participant.
- Eligibility to participate in the study.
- The Investigator's or study site's decision to withdraw you from participation.
- Results of tests and/or procedures.

Please contact the Principal Investigator

Paul Wise, Ph.D.

Telephone: **267-519-4799**
267-519-4900 (24 Hour)

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By mail:

  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call toll free: 877-992-4724
- or by email: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00083652.

When you sign this form, you are volunteering to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the Monell Chemical Senses Center to use your personal health information collected about you for research purposes within our institution. You are also allowing the Monell Chemical Senses Center to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you for your records.

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date
_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date

Witness Signature For Subjects Who Cannot Read (if applicable)

The study subject has indicated that he/she is unable tq`o read. The consent document has been read to the subject by a member of the study team, discussed with the subject by a member of the study team, and the subject has been given an opportunity to ask questions of the study team.

_____

Printed Name of Impartial Witness

_____	_____
Signature of Impartial Witness	Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include

- Representatives of Monell Chemical Senses Center
- Representatives of Advarra IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct and oversee the research, including for instance:

- To assess taste of experimental flavor ingredients and APIs.

- To compare the taste profiles of experimental flavor ingredients and APIs to others.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the principal investigator at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ _____

Name of Subject (Please Print) Signature of Subject Date

_____

Name of Person Obtaining Consent (Please Print) Signature Date

Witness Signature For Subjects Who Cannot Read (if applicable)

The study subject has indicated that he/she is unable to read. The Authorization document has been read to the subject by a member of the study team, discussed with the subject by a member of the study team, and the subject has been given an opportunity to ask questions of the study team.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date