Document Coversheet

Study Title: Regulation of Mucosal Healing in Inflammatory Bowel Disease

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	10/02/2025
NCT Number:	NCT04504136
IRB Number	56677
Coversheet created:	8/11/2026

Statistical Analysis Plan:

Statistical analyses were conducted using the evaluable participant population, defined as participants with available specimens or assessments for each specific outcome; therefore, sample sizes varied by assay because of sample availability, withdrawals, or use of samples in other prespecified analyses. Baseline demographic and clinical characteristics, molecular measures (mitochondrial DNA copy number and relative cMyc and PGC-1α expression), Ki67-positive cells per crypt, endoscopic scores, and fecal calprotectin levels were summarized descriptively by study group using the mean and standard error (SE) for continuous variables and counts and percentages for categorical variables. Comparisons between healthy controls and participants with inflammatory bowel disease were interpreted descriptively, given the small sample size and exploratory nature of the study; where formal comparisons were performed, two-sided independent-samples tests appropriate to data distribution (Student's t test or Wilcoxon rank-sum test) were used. Endoscopic outcomes were summarized separately for participants with ulcerative colitis (Mayo Endoscopic Score) and Crohn's disease (segmental SES-CD score), as these measures were not applicable to healthy controls. No imputation was performed for missing data, and results should be interpreted in the context of the limited, outcome-specific sample sizes.

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IRB Approval
10/2/2025
IRB # 56677
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.

CONTINUATION REVIEW/FINAL REVIEW

2 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

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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:

60

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

0

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:

15

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

15

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.

Subject #14 had initial colonoscopy performed bud did not have 2nd procedure performed as she cancelled and was later lost to follow-up. She has since been withdrawn. Subject 12's initial colonoscopy was deemed an incomplete procedure due to difficult anatomy. She did not tolerate the procedure well due to hypoxia. Stool based screening was recommended and subject was withdrawn.

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

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: 3

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
- [x] (HHS) Dept. of Health & Human Services
  - [x] (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.

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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.

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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
Ashe	Laura
Boggs	Lori

Last Name	First Name
Brown	Paul
Campbell	Donald
Dela Cruz	Anna
Flomenhoft	Deborah
Gao	Tianyan
Grigorian	Alla
Grigsby	Kaitlyn
Hassan	Syed
Kapur	Neeraj
Kota	Vamshi
Lohr	Kristine
Perry	Courtney
Schneider	Pamela
Spear	Terri
Stuffelbeam	Amy
Suljicic-Martinez	Minela
Turner	Sarah
Wempe	Lesley

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.

The study remains open to enrollment and should remain open with the IRB

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.):

We submitting one modification since the last CR and it did not affect subject safety and/or welfare

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).

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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				
Black or African American		2		
Latinx				
Native Hawaiian or Other Pacific Islander				
White	7	6		
American				

Arab/Middle Eastern/North African				
Indigenous People Around the World				
More than One Race				
Unknown or Not Reported				

If unknown, please explain why:

15. Research Sites

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

UK Sites

- ☐ 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

Regulation of mucosal healing in Inflammatory Bowel Disease

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.

Mucosal healing

Anticipated Ending Date of Research Project: 1/31/2026

Maximum number of human subjects (or records/specimens to be reviewed) 60

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 the 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*).

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:	Terrence	Room# & Bldg:	MN649 Med Science Bldg.
Last Name:	Barrett	Speed Sort#:	40536
Middle Name			
Department:	Internal Medicine - 7H350	Dept Code:	7H350
PI's Employee/Student ID#:	10954269	Rank:	Chief
PI's Telephone #:	8593234887	Degree:	MD
PI's e-mail address:	t.barrett@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	6/5/2024
		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.

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 to 90

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 are recruited from the Endoscopy Unit at the University of Kentucky Chandler Hospital or Good Samaritan Hospital. The subject population includes patients with known Crohn's disease and ulcerative colitis undergoing a colonoscopy. In addition, we will recruit non-IBD (rheumatoid arthritis/psoriatic arthritis) patients receiving anti-TNF Ab therapies and other healthy control patients. All participants will be undergoing endoscopy with biopsy for surveillance, screening or diagnosis. The subject goal is 20 subjects with IBD (Group 1), 20 non-IBD subjects receiving anti-TNF Ab therapies (Group 2) and 20 non-IBD healthy controls (Group 3).

General Inclusion Criteria:
1. 18 years of age or older
2. Able and willing to communicate in English
3. Able and willing to provide written informed consent to take part in the study
4. Availability to return for a study visit, barring unforeseen circumstances

Group 1 Inclusion Criteria:
1. Diagnosed UC or Crohn's Colitis
2. Biologic failure or naive to biologic treatment

Group 2 Inclusion Criteria:
1. Diagnosed rheumatoid arthritis or psoriatic arthritis
2. Receiving anti-TNF Ab therapy at the time of enrollment

General Exclusion Criteria:
1) Subjects classified in an anesthesia risk group, ASA Class = 4
2) History of bleeding diathesis or coagulopathy
3) Stroke or transient neurological attack within the last 6 months
4) Pregnancy
5) Receiving anticoagulants and anti-platelets medications (other than low does aspirin =325 mg)
6) Receiving steroid treatment
7) Subject is unable to consent
8) Subject is HIV-positive
9) Incarcerated
10) History of total proctocolectomy
11) History of systemic chemotherapy within 18 months of screening
12) Uncontrolled intercurrent illness that could compromise the study or contraindicate safe participation including, but not limited to, severe COPD, alcoholism, decompensated cirrhosis, opioid dependence) ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, chronic renal failure, chronic renal insufficiency, or psychiatric illness/social situations that would limit compliance with study requirements, or patients who would be unable to return for a second “research” endoscopy

Withdrawal Criteria:
The patient has the right to withdraw from the study at any time. This includes the right to request destruction of tissue samples provided.

Attachments

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:	0	0		
Asian:	1	1		
Black/African American:	3	3		
Latinx:	0	0		

Native Hawaiian/Pacific Islander:	0	0		
White:	26	26		
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:				

If unknown, please explain why:

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 Civilian Employees
- ☑ Patients
- ☐ Appalachian Population

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]
- 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

- ☐ 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/HIPAA Combined Form	Barrett Mucosal ICF v042722.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.

Prior to the patient endoscopy visit, a University of Kentucky endoscopy scheduler will inquire if the eligible patient is interested in hearing more about our ongoing research. If the patient is interested, research coordinators, or research staff will contact the individual, provide a brief review of the study and its rationale, and inquire as to whether or not the individual would like to participate. Subjects will be consented prior to the initial endoscopy procedure by a research coordinator in a neutral environment prior to entering the endoscopy suite where the study will be thoroughly explained and questions can be asked in a relaxed environment. The informed consent document will be reviewed and a signed informed consent will be obtained prior to the initial endoscopy. Patients will call or write to the PI if they have concerns or complaints. Contact information for the PI (phone and address) is provided in the informed consent paperwork. Additionally, patients are provided with the standard and toll-free numbers for the Office of Research Integrity at UK.

☑ 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.

The bare minimum requirements to screen patients will be viewed in AEHR. We will be viewing current/past medications including biologics/immunomodulators (methotrexate, infliximab, adalimumab, vedolizumab, ustekinumab, certolizumab, golimumab, azathioprine), anti-inflammatory/immune suppressants (prednisone, budesonide, decadron, methylprednisolone, 5-ASA agents), blood thinners/anti-platelet (xarelto, eliquis, aspirin, warfarin, plavix, brilinta), pain medications/opioids (oxycodone, norco, hydroxymorphone, NSAIDS). We will also be looking at healthcare diagnoses (UC/CD, rheumatoid/psoriatic arthritis), as well as underlying health conditions that could compromise study (Severe COPD, alcoholism, Decompensated Cirrhosis, Opioid dependence). In addition we will view lab results (Fecal Calprotectin, hemoglobin, albumin, CRP). Without viewing this baseline data,
we will be unable to identify who would be
eligible to complete the study. After eligibility has been determined an in-person informed consent session will occur prior to participation in the research study.

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

Information viewed to determine study eligibility will not be
recorded or stored. This is the only data that we
will view prior to contacting patients for study
entry. We will not compromise patient's rights or
welfare by viewing this information.

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

Without the ability to view healthcare diagnoses and medication, we will be unable to determine who is eligible to enter the study. We cannot appropriately investigate mucosal healing in IBD if we are unable to identify eligible patients, based on healthcare diagnoses, medication, and assessment of underlying health conditions that could make participation potentially unsafe.

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

Should any new and pertinent information become available regarding IBD treatment or safety of endoscopy then I will inform the study participants of this result.

e) If the research involves using or accessing identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

- Private information/specimens are “identifiable” if the investigator may ascertain the identity of the subject or if identifiers are associated with the information (e.g., medical records). This could be any of the 18 HIPAA identifiers including dates of service.
- If not using identifiable private information or identifiable biospecimens, insert N/A below.

As above, this study could not be practicably
conducted without the ability to identify eligible IBD patients, rheumatoid/psoriatic arthritis patients, and healthy controls. It is also critically important that we assess underlying health conditions that could compromise safe participation in our research. We will only view the bare minimum requirement to determine subject eligibility, and there is no other practical way to obtain this information without looking into the EMR.

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
Ashe	Laura	Project Assistance/Support	DP	N	Y		P	Y	06/05/2023	Y	N	07/07/2021	N	Y
Boggs	Lori	Project Assistance/Support	DP	N	Y		P	Y	08/22/2025	Y	N	12/17/2024	N	Y
Brown	Paul	Study Coordinator	DP	Y	N		P	Y	09/08/2023	Y	N	01/06/2023	N	Y
Campbell	Donald	Sub-Investigator	SP	Y	N	MD	P	Y	12/12/2024	Y	N	12/06/2021	N	Y
Dela Cruz	Anna	Project Assistance/Support	SP	N	N	MD	P	Y	02/29/2024	Y	N	08/10/2021	N	Y
Flomenhoft	Deborah	Sub-Investigator	SP	Y	N	MD	P	Y	10/24/2023	Y	N	01/23/2020	N	Y
Gao	Tianyan	Co-Investigator	SP	N	N		P	Y	07/22/2025	Y	N	04/02/2020	N	Y
Grigorian	Alla	Co-Investigator	SP	N	N		P	Y	04/26/2023	Y	N	04/02/2020	N	Y
Grigsby	Kaitlyn	Project Assistance/Support	SP	N	N		P	Y	09/12/2025	Y	N	04/20/2022	N	Y
Hassan	Syed	Project Assistance/Support	SP	Y	Y		P	Y	01/31/2025	Y	N	02/02/2023	N	N
Kapur	Neeraj	Data Analysis/Processing	DP	N	N	PhD	P	Y	07/17/2025	Y	N	01/06/2023	N	Y
Kota	Vamshi	Project Assistance/Support	SP	Y	N		P	Y	06/13/2024	Y	N	08/09/2024	N	Y
Lohr	Kristine	Co-Investigator	SP	N	N		P	Y	03/20/2023	Y	N	04/02/2020	N	Y
Perry	Courtney	Sub-Investigator	DP	Y	N	DO	P	Y	07/08/2025	Y	N	01/06/2023	N	Y
Schneider	Pamela	Project Assistance/Support	SP	N	N		P	Y	10/25/2024	Y	N	02/04/2022	N	Y
Spear	Terri	Project Assistance/Support	SP	N	N		P	Y	09/27/2024	Y	N	11/13/2024	N	Y
Stuffelbeam	Amy	Project Assistance/Support	SP	N	N		P	Y	07/01/2024	Y	N	01/20/2022	N	Y
Suljicic-Martinez	Minela	Data Analysis/Processing	DP	N	Y		P	Y	10/23/2023	Y	N	05/06/2021	N	Y
Turner	Sarah	Data Analysis/Processing	DP	N	N		P	Y	03/03/2025	Y	N	01/06/2023	N	Y
Wempe	Lesley	Data Collection	SP	Y	N		P	Y	03/07/2024	Y	N	04/26/2022	N	N
Abdelsalam	Mohammed	Data Analysis/Processing	SP	Y	N		P	N	06/19/2019		Y	04/09/2021	N	N
Abdelwahab	Ahmad	Data Collection	SP	Y	N		P	N	08/12/2020		Y	11/29/2023	N	N
Abomhya	Ahmed Abdelsatar	Data Analysis/Processing	SP	Y	N		P	Y	04/19/2025	Y	Y	04/09/2021	N	Y
Ahmed	Mohamed Elsayed Ahmed Elsayed	Data Collection	SP	Y	N		P	N	09/15/2022	Y	Y	08/21/2024	N	N

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Akanbi	Olalekan	Data Analysis/Processing	SP	N	N	MD	P	N	08/15/2018		Y	02/12/2020	N	N
Aslam	Bilal	Data Collection	SP	N	N	MD	P	N	10/17/2018		Y	02/12/2020	N	N
Auer	Joseph	Data Collection	SP	N	N	MD	P	N	01/25/2022	Y	Y	05/06/2021	N	Y
Avdiushko	Margarita	Data Analysis/Processing	DP	N	N		P	N	07/23/2021	Y	Y	12/14/2023	N	Y
Beswick	Ellen	Data Analysis/Processing	SP	N	N	PhD	P	Y	01/18/2024	Y	Y	01/09/2024	N	N
Beyer	Ryan	Sub-Investigator	SP	N	N	MD	P	N	07/07/2021	Y	Y	01/09/2023	N	N
Broadbent	Mary	Project Assistance/Support	SP	N	N		P	N	01/23/2022	Y	Y	09/19/2025	N	Y
Chaiswing	Luksana	Co-Investigator	SP	N	N		P	Y	02/26/2023	Y	Y	02/23/2023	N	Y
Dawoud	Nabila	Data Collection	SP	Y	N		P	N	12/06/2020	Y	Y	06/23/2023	N	N
Elkammar	Mahmoud	Data Collection	SP	Y	N		P	N	08/13/2020		Y	07/06/2022	N	N
Elkheshen	Ahmed	Sub-Investigator	SP	Y	N		P	N	07/25/2019		Y	04/09/2021	N	N
Elmoursi	Ahmed	Data Collection	SP	Y	N		P	N	04/26/2019		Y	04/09/2021	N	N
Elsaadani	Mohamed	Data Collection	SP	Y	N		P	N	07/11/2022	Y	Y	06/23/2023	N	N
Elsayed	Ahmed	Project Assistance/Support	SP	N	N		P	N	08/29/2021		Y	08/27/2021	N	N
Eltaher	Mohamed	Data Collection	SP	Y	N		P	N	09/20/2021	Y	Y	06/23/2023	N	N
Emhmed Ali	Saad	Sub-Investigator	SP	N	N	MD	P	N	12/27/2016		Y	02/12/2020	N	N
Evers	Bernard	Sub-Investigator	SP	N	N		P	Y	07/02/2025	Y	Y	08/26/2021	N	Y
Goretsky	Tatiana	Data Analysis/Processing	SP	N	N	PhD	P	Y	02/17/2025	Y	Y	11/25/2024	N	Y
Harris	Olivia	Project Assistance/Support	SP	N	N		P	N	02/08/2022	Y	Y	09/19/2025	N	Y
Harrison	Douglas	Co-Investigator	SP	N	N		P	N	07/09/2020	Y	Y	01/09/2024	N	Y
Harrod	Susan	Project Assistance/Support	SP	N	N		P	N	02/08/2022	Y	Y	09/19/2025	N	Y
Hartman	Ellen	Project Assistance/Support	DP	N	N		P	Y	12/10/2024	Y	Y	11/13/2024	N	Y
Holt	Elizabeth	Data Collection	SP	Y	N	MD	S	N	08/07/2020		Y	08/02/2021	N	N
Hussein	Mohamed Sabry Tawfik	Sub-Investigator	SP	Y	N		P	Y	08/14/2023	Y	Y	08/19/2021	N	Y
Kasem	Ahmad	Data Collection	SP	Y	N			Y	10/30/2022	Y	Y	11/15/2024	N	N
Lee	Goo	Sub-Investigator	SP	N	N	MD PhD	N	Y	03/03/3000		Y	12/06/2021	N	Y
Liu	Jinze	Co-Investigator	SP	N	N		P	N	01/16/2020		Y	02/23/2023	N	N
Makowski	Kristen	Project Assistance/Support	SP	N	N		P	Y	07/19/2025	Y	Y	06/24/2024	N	Y
Mandal	Prabin	Study Coordinator	SP	Y	N		P	N	06/27/2022	Y	Y	10/30/2023	N	N
Mayne	Casie	Project Assistance/Support	SP	N	N		P	N	02/02/2022	Y	Y	09/19/2025	N	Y
Mohamed	Rana	Data Collection	SP	Y	N		P	N	07/18/2021		Y	07/06/2022	N	Y
Pekez	Marijeta	Sub-Investigator	SP	Y	N	MD	P	N	11/23/2021	Y	Y	11/25/2024	N	Y
Ross	Zachary	Project Assistance/Support	DP	N	Y			Y	11/03/2023	Y	Y	06/24/2024	N	N
Schneider	Brittany	Project Assistance/Support	SP	N	N		P				Y	02/04/2022	N	Y
Stromberg	Arnold	Co-Investigator	SP	N	N			N	09/07/2021	Y	Y	11/13/2024	N	N
Sullivan	Patrick	Co-Investigator	SP	N	N		P	Y	02/01/2024	Y	Y	01/09/2024	N	Y
Tadisetty	Sindhura	Project Assistance/Support	SP	Y	N		P	N	01/10/2022	Y	Y	04/26/2022	N	N
Thomas	Justin	Study Coordinator	DP	Y	Y	PhD	P	Y	11/09/2024	Y	Y	07/01/2021	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).

Induction of mucosal healing in IBD is associated with reduced hospitalizations, surgeries (van Assche G et al, Curr Drug Targets. 2010, 11:227-33), and reduced cancer risk. However, previous studies have shown that 54-69% of UC patients fail to heal ulcers after several weeks of treatment, and roughly half do not maintain remission at one year. The single most important factor in preventing severe medical consequences, like colon removal surgery or cancer, is treatment to completely heal the top layer of the intestine as quickly as possible. Utilizing new techniques, we have discovered that single cell RNA sequencing has opened a new, powerful method to interrogate mechanisms of ulcer healing. The mechanism of healing is a complex process and the dysfunction observed in colitis can only be fully understood by comparison to healing in non-IBD patients. Based on our ongoing findings we believe it is critical to focus on early events in the healing process. Thus, we are conducting a prospective trial involving three groups of patients where biopsies will be collected at baseline during standard of care endoscopy, and for two of the three groups, at a follow-up research endoscopy. The three patient groups include: 1) IBD patients with active disease, newly induced with anti-TNF therapy (biologic failure or naïve), 2) non-IBD (RA/psoriatic arthritis) patients receiving anti-TNF therapies, and 3) healthy control patients.
In addition to our interest in healing, we are interested in investigating the relationship between IBD endoscopic evaluation and fecal calprotectin level and the effect of biopsy collection on fecal calprotectin levels. Fecal calprotectin testing is an important non-invasive biomarker used to investigate disease severity in IBD patients. IBD patients undergo frequent endoscopies to rule out infection, or determine diagnosis or severity. Despite the value of endoscopy, it has increased expense and risk, as well as patient burden. Thus, fecal calprotectin has become an important diagnostic tool. In the current study we will investigate the relationship between fecal calprotectin level and the IBD severity observed endoscopically. In addition, the effect of biopsy collection on Fecal Calprotectin measures will be investigated.

Objectives

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

The objective of the current study is to compare the dysfunctional non-healing UC and CD colonic ulcers with normal healing. We will compare single cell RNA sequencing (scRNAseq) analyses of intestinal epithelial cells (IEC) from normal healing ulcers (Bx/Bx), active IBD patients before and after anti-TNF therapy, and non-IBD (rheumatoid arthritis/psoriatic arthritis) patients receiving anti-TNF therapy (Bx/Bx) to interrogate levels of mitochondrial gene transcription. We posit that this will unveil essential elements of normal ulcer healing that are impaired in IBD thereby providing novel insights into IBD pathogenesis. We will also be able to investigate the mechanisms leading to dysfuctional healing in IBD patients who are not responding to anti-TNF therapy. Findings from this research will offer unique directions to therapeutic intervention.

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.

We are conducting a prospective, un-blinded trial where biopsies will be collected at baseline during a standard of care endoscopy, and at a follow-up research endoscopy (groups 2 and 3 only). All patients will receive the same research procedures at the standard of

care endoscopy. The follow-up endoscopy for groups 2 and 3 will occur 3-6 days after the initial procedure. Additionally, participants in group 2 and 3 can opt in to provide two stool samples, first at the research endoscopy and second at a follow up visit 4-5 weeks later.

Attachments

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 are recruited from the Endoscopy Unit at the University of Kentucky Chandler or Good Samaritan Hospital. Researchers will be made aware of eligible IBD patients by Gastroenterology clinicians or by the Endoscopy schedule. Researchers will be made aware of eligible rheumatoid/psoriatic arthritis patients by Rheumatology clinicians or by the Endoscopy schedule. Researchers will be made aware of non-IBD/non-arthritis controls by Gastroenterology clinicians or by the Endoscopy schedule. All participants will be undergoing endoscopy with biopsy for surveillance, screening or diagnosis. Prior to the patient endoscopy visit, someone involved in the patients routine clinical care, or a University of Kentucky endoscopy scheduler, will inquire if the eligible patient is interested in hearing more about our ongoing research. If the patient is interested, research coordinators, or research staff will contact the individual, provide a brief review of the study and its rationale, and inquire as to whether or not the individual would like to participate or discuss participation further in person. Participants will be consented by the research coordinator prior to the initial endoscopy procedure in a neutral environment before entering the endoscopy suite where the study will be thoroughly explained and questions can be asked in a relaxed environment (preferably with a companion). The informed consent document will be reviewed and a signed informed consent will be obtained prior to the initial endoscopy. No research biopsies will be taken unless clinically indicated biopsies are required. If no biopsy specimens are taken from subjects for standard of care, participants will be withdrawn from the research study.
None

Attachments

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.

During the initial routine clinical care colonoscopy, 16-20 biopsies will be collected in addition to biopsies/polyp removal that will be taken for standard of care (typically, between 1 and 40 biopsies are taken during a standard colonoscopy). The area around these additional biopsies will be marked with a tattoo (1 proximal and 1 distal). The additional samples that will be taken may increase the time of the procedure up to 30 minutes. Subjects in groups 2 and 3 will be asked to return for a follow-up research colonoscopy 3-6 days after their standard of care procedures. The tattooed area will be examined and 16-20 biopsies will be taken at the additional endoscopy. Subjects in groups 2 and 3 will also have a cold snare applied to the edge of the biopsy site. The additional scope will take approximately 1 hour. Samples will be de-identified and stored indefinitely. To compensate for time and travel, subjects in groups 2 and 3 will be compensated $400 for the additional procedure. This will be paid after the completion of the follow-up endoscopy. Participants in group 1 will not be compensated because the research procedures occur during a standard of care procedure. The medical record will be reviewed for related information for the study such as medication usage and current medical conditions. After completion of the study protocol, a survey will be given to each subject seeking feedback about their research experience.
Biopsies from these subjects will be collected into formalin or OCT (histology or LCM), AllProtect (mRNA) or ice-cold PBS for IEC isolation and protein analysis. Samples may also be stored in a DMSO-FBS solution for cryopreservation. These samples will be used to analyze ulcer healing and gene expression analysis (stem and differentiation markers).
In addition to above, we will also ask research participants in groups 2 and 3 if they would be willing to collect and submit a stool sample at there research endoscopy and at a follow-up visit 4-5 weeks after the research endoscopy for measurement of Fecal Calprotectin. Participation in this aspect of the study is not required and does not impact participation in the remainder of the study protocol. If subjects decide they would like to complete this portion of the study they will be compensated $25 for the first stool sample submitted and $50 for the second sample (maximum of $75 additional compensation if two stool samples are submitted).

Attachments

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.

All patient data are coded. Information relevant to the patient's medical history will be collected and stored on secured and password protected servers using password protected devices. Data may also be collected using Research Electronic Data Capture (REDCap). Data includes age, sex, diagnosis, chronic medical conditions, pathology reports, endoscopy reports, disease activity indices, medication list, lab results, smoking history and BMI.

Attachments

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.

The PI has a fully funded research laboratory at the University of Kentucky, which includes access to histology and immunohistochemistry equipment and reagents, real time PCR machines, access to a laser capture microscope, as well as access to flow cytometry equipment and 10x single cell RNA sequencing. An experienced research team will process and analyze the biopsies. Dr. Barrett works with a team of GI doctors and nurses and has at his disposal an experienced team of Clinical Research Coordinators.

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.

Patients that have a known diagnosis of Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriatic arthritis, or who are healthy control patients, will undergo endoscopy for assessment of disease, surveillance, or screening, utilizing regular biopsy forceps. Participation in the study will involve the collection of 16-20 research biopsies during the standard of care procedure and may add up to 30 minutes to this procedure. Because of this added time, patients may experience more discomfort including abdominal pain/bloating secondary to air used during the colonoscopy. To mitigate this discomfort, we will use CO2 gas during endoscopy as it is associated with less post-procedural distention and discomfort. There may also be an increased risk of bleeding or perforation. In one study assessing the safety of surveillance colonoscopy in long-standing ulcerative colitis using multiple biopsies, no episodes of bleeding, infection, or death resulted from the 384 procedures that were completed (A). The risk of complications, such as perforation and bleeding, due to diagnostic/symptomatic colonoscopies has been reported to be 0.02-0.38% (B).

The research subjects in groups 2 and 3 will also return for a follow-up shortened colonoscopy. A tattooed area will be examined and 16-20 biopsies will be taken at the additional endoscopy. A cold snare will be utilized in the collection of this additional biopsy. There may be some abdominal discomfort and there may be some risk of bleeding or perforation with this procedure and technique. The additional scope will take approximately 1 hour. The potential risks will be minimized by utilizing an experienced team of gastroenterologists and nurses during both procedures.

(A) Koobatian G.J., Choi P. Safety of Surveillance Colonoscopy in Long-standing Ulcerative Colitis. American Journal of Gastroenterology 1994; 89:1472-1475.
(B) Kim S.Y., Kim H., Park H.J. Adverse events related to colonoscopy: Global trends and future challenges. World Journal of Gastroenterology 2019; 25: 190-204.
The information gathered in this study will provide additional insight into the dysfunctional mechanism of healing in patients with inflammatory bowel disease. Also, the study will provide information regarding the mechanism of healing in non-IBD patients. The potential benefit of gaining insight into the mechanism of ulcer healing in patients with and without IBD outweighs the risks of the procedures. In those patients who participate, research biopsies will be collected and a follow-up colonoscopy will be performed, possibly resulting in additional risk of bleeding, perforation or effects of prolonged sedation.

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).

The alternative is to choose not to participate in this study. No therapies will be administered as part of this study so there are no therapeutic alternatives.

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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

Patient biopsy samples will be coded only for the purpose of confidentiality and organization. Patient identification is not necessary for results. However, identification will be kept in a code book which will be locked in the PI's office.
Results from the fecal calprotectin testing will be added to the coded electronic database on the password protected server.
Subject biopsy samples will be coded for the purpose of confidentiality and organization and will be stored in the PI's laboratory, which remains locked when not in use. To accomplish this, the subject name and sample will be assigned a number at the time of biopsy. Coded patient samples may be stored indefinitely in the form of paraffin blocks or frozen RNA/protein preparations. Information relevant to the patient's medical history will be collected and stored on secured and password protected servers using password protected devices. Data may also be collected using Research Electronic Data Capture (REDCap). Only members of the research team will have access to samples. Since identification is not necessary to obtain results for the study, identification codes will be kept in a book which will be locked in the PI's office. This will be done in the event that a sample is found to have evidence of worsening disease process.
Biopsy procedures are performed at the University of Kentucky Hospital and Good Samaritan hospital, utilizing an experienced team of gastroenterologists and nurses. In the event of bleeding or perforation, patients will be treated using standard procedures available during all endoscopy procedures at the hospital. To ensure that sample identification codes remain private from patient information, the code book linking samples to patient information will remain locked in the PI's office. Collected medical information is kept in an electronic database on a secure (password-protected) UK server or stored using Research Electronic Data Capture (REDCap) on secured and password protected servers. Only personnel involved with the study will have access to this private information and it will be used in a restricted manner.

☑ **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.

Subjects in groups 2 and 3 will be paid $400 for the research endoscopy visit, which will occur 3-6 days after initial standard of care endoscopy. This money is intended to compensate subjects for time and travel expenses incurred. Patients who disenroll, for medical or non- medical reasons before the follow-up research endoscopy will not be compensated. Subjects will receive no payment for the initial clinical care visit, and the research team will not cover the costs incurred in this initial visit.
Subjects will be paid $25 for the stool sample submitted at the research endoscopy and $50 for the second sample submitted 4-5 weeks later (maximum $75). This amount will be paid after the completion of the follow up visit.

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.

None

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.

1. Monitoring the progress of clinical investigations and the safety of participants:
Procedures for promptly detecting harm and mitigating potential injuries: Throughout the colonoscopy, patients will be monitored for signs of bleeding or bowel perforation, consistent with the procedures already in place for routine colonoscopies (direct view of bleeding through the endoscope and vital sign monitoring by the physician and nurses). After the procedure, patients are observed for approximately 1 hour for signs of adverse consequences, including abdominal pain, tachycardia, etc. Patients are also provided information on how to contact the on-call physicians as well as Terrence Barrett, M.D. in the event of any delayed signs of bleeding or perforation.

What the monitors look for: Monitors will look for signs of bleeding or bowel perforation during the procedure, including obvious bleeding. Patients will be asked to report abdominal pain, abdominal distention or tenderness, fever and tachycardia as potential indicators of perforation after the procedure.

Procedures to ensure adequate feedback of information to researchers and medical decision-makers: All occurrences of bleeding or perforation will be reported to Terrence Barrett, M.D. within 24 hours of notification of the occurrence.

Process for avoiding conflict of interest: Tina Dela Cruz, M.D., an attending physician in the Division of Gastroenterology, will serve as a data safety monitoring officer (DSMO) in this trial. Dr. Dela Cruz has experience in endoscopy; however she is not a co-investigator on this trial. Each quarter, records from 10 subjects will be selected randomly and reviewed by Dr. Dela Cruz to determine that the subjects met the selection criteria. Dr. Dela Cruz will then report her findings to the PI and
research staff. Review of the data in this manner will avoid any potential conflict of interest.

2. Assuring compliance with the requirements regarding the reporting of unanticipated problems or adverse experiences:
Procedures for ensuring appropriate reporting of findings to the IRB: Study coordinators and sub-investigators have been trained in the IRB criteria for the prompt reporting of adverse experiences to the IRB. All adverse experiences meeting the criteria for prompt reporting will be filed following the time frame outlined by the IRB.

Reporting of findings to other entities: All adverse events reported to the principal investigator, Terrence Barrett, M.D., will be reported to Dr. Dela Cruz (the DSMO) and the IRB as necessary.

3. Assuring that temporary or permanent suspension of the study is reported to the appropriate entities:
If this study is suspended, the IRB will be notified.

4. Assuring data accuracy and protocol compliance:
What will be reported and how: De-identified data (e.g. histology scores, protein and genomic analyses) will be compiled by laboratory researchers.
Since these data are simply investigative, they will be reported as compiled study results in scientific literature and presentations.
Original source documents and other study documentation will be maintained at the study site.

What procedures are in place to ensure protocol adherence: All of the physicians, nurses, study coordinators, and lab personnel are aware of the study protocol. The endoscopy nurses, who assist with routine colonoscopies and who are not listed on the protocol, are also aware of the protocol and will contribute to adherence. Additionally, the study will be monitored by Dr. Dela Cruz (DSMO) at regular intervals to ensure protocol adherence.

5. Assuring communication among multi-center sites (if PI or UK is coordinating institution):
This section is not applicable since this is not a multi-center site

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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

POTENTIAL FUTURE USE
STORING AND SHARING THEIR INFORMATION OR SPECIMEN SAMPLES FOR FUTURE USE:
Terrence Barrett, M.D. would like to store, use, and share the participants' identified health information and some of the biopsies collected during the participants' procedures for future research. However, specimens and private health information will be de-identified before they are shared. No additional tissue will be taken. If the participants agree, these biopsies may be used in future research on inflammatory bowel disease (IBD) or other diseases of the gastrointestinal tract. Researchers may also need health information about the people who provide specimens. The researchers are also asking for the participants' consent to place information from the participants' medical record and/or research record in a database to be used for research. The participants' name and address will not be placed in the database. Having access to tissue samples and corresponding clinical data from the health

record from many people helps researchers identify trends and discover better ways to diagnose, prevent, and treat many conditions. The researchers can use the stored samples and health information to assist us with learning more about IBD or other diseases of the gastrointestinal tract.
The participants' complete set of genetic information is called their "genome". The participants' genomes are completely unique to each participant. Researchers may analyze sections or all of the participants' genome. They may also analyze genomes from many different people to look for differences which may help predict what makes people more or less likely to inherit a trait or get a certain disease or condition. Researchers can do studies that are more powerful when they share with each other the data or information they get from studying human genomes. Data obtained from analyzing the participants' genomic information and the participants' medical information may be put into scientific databases along with information from other research participants. The participants' name and other information that could identify the participants will not be included. Therefore, no one would know just from looking at the data that the information came from the participants.
The information from this study will be freely available in a public, unrestricted database that anyone can use. The public database will include information on hundreds of thousands of genetic variations in the participants' DNA code, as well as the participants' ethnic group and sex and pertinent health diagnoses. This public information will not be labeled with the participants' name or other information that could be used to easily identify the participants. However, it is possible that the information from the participants' genome, when combined with information from other public sources could be used to identify the participants, though the researchers believe it is unlikely that this will happen.
WHERE WILL INFORMATION OR SPECIMEN SAMPLES BE STORED AND FOR HOW LONG?
The samples and health information will be stored in Dr. Barrett's laboratory indefinitely.
ARE THERE RISKS FROM ALLOWING THEIR INFORMATION OR SPECIMEN SAMPLES TO BE STORED FOR FUTURE RESEARCH?
There is a risk that someone could get access to the stored information or samples. In spite of the security measures and safeguards the researchers will use, the researchers cannot guarantee that the participants' identity will never become known.
When the researchers collect extra tissue during the participants' procedure, the researchers will limit the amount so that there is no significant increase in risk to the participants
Even without the participants' names or identifiers, genetic information is unique to the participants making it possible for someone to trace it back to the participants. The results of genetic research apply to both the participants and the participants' family members. Genetic information used improperly to discriminate or support negative stereotypes could cause the participants or the participants' family distress.
There is a federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against the participants based on the participants' genetic information. Be aware that GINA does not protect the participants against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of an already known genetic disease.
There may be risks that at this time are unknown. As technology advances, there may be new ways of linking information back to the participants that the researchers cannot foresee now.
HOW WILL THEIR PRIVACY AND CONFIDENTIALITY BE PROTECTED?
Researchers will remove the participants' name or other direct identifiers from the participants' information or samples. The researchers will label the participants' information or samples with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to the participants.
HOW WILL THE RESEARCHERS SHARE THEIR INFORMATION OR SPECIMEN SAMPLES WITH OTHER RESEARCHERS?
The participants' de-identified information, as well as specimens may be shared with other researchers without the participants' additional informed consent, provided an Institutional Review Board (IRB) has approved this action. If that is the case, the data/specimens will not contain information that can identify the participants unless the participants give the participants' consent/authorization or the UK IRB approves the research.
An IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human participants. If a researcher requests the participants' information or samples with identifiable information, an IRB will decide if the research may be conducted with or without the participants' additional consent.
WHAT IF PARTICIPANTS CHANGE THEIR MIND AND WANT TO WITHDRAW THEIR INFORMATION OR SPECIMEN SAMPLES?
The participants' may withdraw their permission to allow their information or samples to be used for future research. To do so, the participants must send a written withdraw request to Terrence Barrett, M.D., University of Kentucky, GI Division, 800 Rose St. MN649, Lexington, KY 40536.
Any remaining information and samples will be destroyed. In addition, it may be possible to destroy the code that links the participants with the participants' information and specimen samples. However, the information and samples that have already been used or shared may not be withdrawn.
WILL PARTICIPANTS RECEIVE ANY COMMERCIAL PROFIT FROM FUTURE RESEARCH DISCOVERIES?
The information and samples that the participants provide will no longer belong to the participants. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to the participants or the participants' relatives should this occur.
WILL PARTICIPANTS BE GIVEN INDIVIDUAL RESULTS FROM THE FUTURE RESEARCH TESTS?
Tests done for research purposes are not meant to provide clinical information or help care for the participants. The results are only important for research. Therefore, the results of tests done with the participants' information and samples will not be provided to the participants. In the rare event that a finding might affect the health of the participants or the participants' family, the researchers will contact the participants and the participants can choose whether to receive or refuse the information.

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

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

Attach Type	File Name
Waiver	UK BxBx study - HIPAA Waiver Form K 7-9-2020 Signed.pdf

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

- ☐ 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, at jhesk2@uky.edu.

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?
◉ 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*

- [x] 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.):

R01 Grant awarded from NIH NIDDK titled "The Role of Crypt Fissioning in IBD Ulcer Healing"

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	Full R01 Submission.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

- ☑ 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)

Additional Information

- 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

Attach Type	File Name
OtherReviewCommittees	Barrett Biosafety Protocol.pdf

**** 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.**

SN 024 and 024.1 Continuation review

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	LB RCR online exp 12.17.26.pdf
Other	SN 024 cover memo.pdf
Other	SN 024.1 cover memo.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	
David	Moliterno	Department Authorization	Internal Medicine		04/13/2020 07:26 AM	View/Sign
Terrence	Barrett	Principal Investigator	Internal Medicine		05/08/2020 12:32 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		0.090	ovmo223	10/3/2025 8:47:28 AM
	Stamped Consent Form	Barrett Mucosal ICF v042722.pdf		0.337	ovmo223	10/3/2025 8:47:27 AM
	AddInfoProduct	SN 024.1 cover memo.pdf	Sn 024.1 Cover memo	0.108	llashe2	9/19/2025 7:56:54 AM
	AddInfoProduct	SN 024 cover memo.pdf	SN 024 cover memo	0.180	llashe2	9/18/2025 11:33:30 AM
	AddInfoProduct	LB RCR online exp 12.17.26.pdf	RCR Online training certificate	0.073	llashe2	12/17/2024 4:18:05 PM
	Informed ConsentHIPAA Combined Form	Barrett Mucosal ICF v042722.pdf	Barrett Mucosal ICF v042722	0.285	zsro223	4/27/2022 3:59:27 PM
	GrantContract	Full R01 Submission.pdf	Full Barrett R01 submission March 2020 NIH NIDDK	8.446	jmthomg	4/15/2021 10:08:49 AM
	Waiver	UK BxBx study - HIPAA Waiver Form K 7-9-2020 Signed.pdf	HIPAA Waiver Form K	0.089	jmthomg	7/10/2020 9:58:18 AM
	AdditionInfoConsiderations	Patient Research Survey UKY Mucosal Healing Study.pdf	Post-Participation Survey	0.222	jmthomg	4/8/2020 3:27:30 PM
	OtherReviewCommittees	Barrett Biosafety Protocol.pdf	Biosafety Protocol Approval	0.529	jmthomg	4/7/2020 3:54:34 PM

Protocol Changes

Protocol Number: 56677

Click link to sort Changed Date
Additional Information/Materials AdditionalInformation changed by llashe2 on 9/19/2025 7:57:10 AM
SN 024 and 024.1 Continuation review
Additional Information/Materials AdditionalInformation changed by llashe2 on 9/15/2025 3:54:00 PM
SN 023~~: Adding Boggs, RCR Online Training certificate~~1 Continuation review
Project Information ProjectEndDate changed by llashe2 on 9/15/2025 3:50:48 PM
12~~/~~31/2026 12:00:00 AM

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	1102915	107879	10165632	SP	N	Mayne	Casie	casie.mayne@uky.edu						N	Project Assistance/Support			P	Y	llashe2	9/19/2025 7:55:12 AM	N		
Deleted	1102916	107879	10166169	SP	N	Broadbent	Mary	mcbens2@uky.edu						N	Project Assistance/Support			P	Y	llashe2	9/19/2025 7:51:53 AM	N		
Deleted	1102929	107879	10936515	SP	N	Harris	Olivia	olivia.colliver@uky.edu						N	Project Assistance/Support			P	Y	llashe2	9/19/2025 7:52:11 AM	N		
Deleted	1102951	107879	12540583	SP	N	Harrod	Susan	Susan.Harrod@uky.edu						N	Project Assistance/Support			P	Y	llashe2	9/19/2025 7:52:24 AM	N		

Protocol Type Comment by Laura Ashe - PI to PI on 9/18/2025 2:25:13 PM
I have reached out to the study team and asked for the updated HSP training certificates.

Continuation/Final Review Comment by Beverly Raisor - ORI to IRB/PI on 9/19/2025 7:49:29 AM
PI/staff have requested that the CR be returned to addressed lapsed SP.

Continuation/Final Review Comment by Beverly Raisor - ORI to IRB/PI on 9/18/2025 1:32:15 PM
2025 CR
Mary Broadbent, Olivia Harris, Susan Harrod and Casie Mayne have allowed their mandatory human subject protections training to lapse. They must retrain asap or they will be removed from the study when it is reviewed by the IRB. Information about the mandatory training can be found by copying and pasting the following link into your web browser: https://research.uky.edu/office-research-integrity/training-education

Please respond to this request at your earliest convenience.

KEY INFORMATION FOR REGULATION OF MUCOSAL HEALING IN INFLAMMATORY BOWEL DISEASE:

We are asking you to choose whether or not to volunteer for a research study investigating the dysfunctional healing in patients with inflammatory bowel disease (IBD). We are asking you because you are having a colonoscopy for screening, surveillance, or diagnostic purposes. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study we hope to learn why people with IBD are unable to effectively heal their intestine. Your participation in this research will last between 1 day to 2 months, depending on which research group you are in (1 day if you have IBD or 2 months if you are a rheumatoid/psoriatic arthritis patient or a patient without these conditions).

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Your participation in this study may aid in our understanding of Crohn's Disease and Ulcerative Colitis.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Risks that could occur as a result of endoscopy and biopsy (obtaining a small tissue sample) include bleeding, bloating, abdominal pain, and possible puncture of the bowel (perforation). For a complete description of risks, refer to the Detailed Consent

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Terrence Barrett, M.D. of the University of Kentucky, Department of Internal Medicine and Gastroenterology at 859-323-4887. Questions can also be directed to Matt Thomas, PhD at 270-402-2214.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You should not take part in this study if you are under 18 years of age, if you are pregnant, if you have a history of bleeding, if you are on therapeutic anticoagulants and anti-platelet medications (e.g. Warfarin, Eliquis, Plavix) other than low does aspirin (≤325 mg), if you have had a stroke within the last 6 months, if you are HIV-positive, if you have any chronic medical conditions that potentially make your participation more risky, such as decompensated liver disease, alcohol dependence, or decompensated heart failure, or if you are unable to consent.

WHAT IS THE PURPOSE OF THIS STUDY?

Inflammatory bowel disease (IBD), which includes both Crohn's Disease and Ulcerative Colitis, is a debilitating disease that can affect patients' small and large intestines. The inflammation is a result of a complex group of cells in the immune system sending chemical signals to the lining of the intestine and causing damage. This results in abdominal pain, diarrhea, and blood in the stool and weight loss. IBD patients can develop chronic ulcers within the intestines that, without effective treatment, fail to heal resulting in continued disease progression. The single most important factor in preventing severe medical consequences, like colon removal surgery or cancer, is treatment to completely heal the top layer of the intestine as quickly as possible. Intestinal healing is a complex process and very little is known about the critical mechanisms. In the current study, researchers are trying to understand how mechanisms of intestinal healing are different for IBD patients compared to non-IBD.

This study requires patients to return to the hospital for an additional procedure after the initial visit to check on the progress of healing from previous colon biopsies. The patient will be compensated for this additional visit to account for their time and travel. By doing this study, we hope to understand how the colon heals in normal patients so that we can improve treatment for patients with IBD.

In addition, the current study seeks to understand the relationship between a biological marker, called fecal calprotectin and disease severity observed during the colonoscopy. IBD patients undergo frequent colonoscopies to rule out infection or investigate disease progression. Despite the value of endoscopy, it has risks, along with expense, and is a burden to the patient. In the current study, researchers are trying to understand how fecal calprotectin levels are related to the endoscopic evaluation as well as how biopsy collection affects fecal calprotectin levels.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The procedures will be conducted at UK Chandler Hospital or Good Samaritan Hospital. The additional tissue samples that will be taken during the initial procedure may increase the time of the procedure up to 30 minutes. If you are in one of the two research groups of participants without IBD then you will be asked to participate in one follow-up procedure after your initial endoscopy. The follow-up colonoscopy procedure will take about 1 hour and will occur within 3-6 days of your standard of care procedure.

WHAT WILL YOU BE ASKED TO DO?

1. Should you participate, your participation begins on the day of your endoscopy, and will require one additional procedure if you are a participant who does not have IBD.
2. During both procedures (only one if you have IBD) you will be under sedation (medication given to you throughout your procedure that will make you feel relaxed and drowsy).
3. On your initial colonoscopy, you will provide 16-20 biopsies in addition to biopsies/polyp removal that will be taken for your standard of care. Typically, between 1 and 40 biopsies are taken during a standard colonoscopy. The additional samples that will be taken may increase the time of the procedure up to 30 minutes. The area around these additional biopsies will be marked with a tattoo. These small tattoos will be placed just above and just below the research biopsies. Specifically, a small amount of ink (1/10 of a teaspoon) will be injected into the colon to form a dark spot (1/4 inch). GI tattoos are commonly placed during endoscopic procedures to mark locations for later evaluation. These small tattoos will be placed in the colon to mark the location of the biopsies and will make it easier to locate your biopsy sites at the follow-up research colonoscopy visit.
4. If you are a rheumatoid/psoriatic arthritis patient or a patient without these conditions you will return for a shortened colonoscopy 3-6 days after your initial procedure. The tattooed area will be examined and 16-20 biopsies will be taken at the additional endoscopy. There will also be a cold snare applied to the edge of the biopsy site. A cold snare is a mechanical method that uses a wire looped end to take/retrieve tissue samples without electrical current. Clinical studies have also shown lower rates of delayed bleeding with the use of this method. The additional scope will take approximately 1 hour.
5. Your medical record may be reviewed for related information for the study such as medication usage and current medical conditions. Your information will remain confidential and any information that could identify you such as name, address and medical record number, will be removed before your data and samples are shared with other researchers.
6. Tissues samples will be used to analyze sections or all of your genome to assess which genes are important for healing the colon. They may also analyze genomes from many different people to look for differences which may help predict what makes people more or less likely to inherit a trait or get a certain disease or condition.
7. For non-IBD participants we will also ask if you will be willing to collect and submit a stool sample at your follow-up endoscopy visit and at an additional visit 4-5 weeks after for the measurement of Fecal Calprotectin. Participation in this additional procedure is not required and does not impact your participation in the remainder of the study protocol.
8. After completion of the study protocol, you will be given a survey seeking feedback on your experience. You will be allowed to fill out this survey in a private setting without research personnel present. Your responses will be kept anonymous.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some or none of the risks or side effects listed. Rare, unknown, or unforeseeable (unexpected) risks also may occur.

Risks that could occur as a result of endoscopy and biopsy (obtaining a small tissue sample) include bleeding when taken, which usually stops on its own without treatment. Other risks include bloating and abdominal pain as well as possible puncture of the bowel (perforation). It is reported that risk of perforation of the bowel is approximately 6 per 10,000 colonoscopies performed. This risk can be higher in IBD patients. The effect of biopsy collection on the risk of perforation is not well established. However, any inherent risk of biopsy collection may be higher if research biopsies are collected in addition to standard of care. The risk of infection is very low during endoscopy; it is reported that 1 in 1.8 million acquire an infection because of endoscopy. Death is a very serious but rare complication of endoscopy. Extending the time of the initial colonoscopy and participating in a follow-up research colonoscopy increases the risk of any complications.

Complications resulting from a colon tattoo are quite rare but includes self-limited inflammation (redness) at the injection site. This is painless and could last approximately 24 hours. The risks, although small, associated with sedation (medication given to you throughout your procedure that will make you feel relaxed and drowsy) include low blood pressure, decreased breathing rate, and other than normal heart rhythm. If you are in either the non-IBD or control group of patients, the use of a cold snare in the collection of your additional biopsy may cause some abdominal discomfort and there may be some risk of bleeding or perforation with this procedure and technique.

There is always a chance that any medical treatment can harm you, and the investigational treatment(s) including those associated with additional biopsies in this study is/are no different. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. However, your participation in this study may aid in our understanding of Crohn's Disease and Ulcerative Colitis.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study your endoscopy will be performed as it normally would (without the follow-up procedure or additional biopsies for research purposes or stool sample collection).

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare or Medicaid will be responsible for the costs of the care and treatment you receive during this study that you would normally receive for any condition you may have. These are costs that are considered medically reasonable and necessary and will be part of the care you receive if you do not take part in the study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare or Medicaid for the medical procedures done strictly for research.

You will not be charged for any part of the research study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study.

When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of the study; however, we will keep your name and other identifying information private. Your social security number will be collected for payment purposes.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. At the time the biopsies are taken, samples used for research will be assigned a number, which corresponds to the number assigned to this consent form. Information identifying you will then be removed from your research biopsy samples. The consent form containing your identifying number will then remain locked in the researcher's office. All electronic data will be stored on an electronic database on a secure (password-protected) UK server or stored using Research Electronic Data Capture (REDCap) on secured and protected devices. Only investigators involved in this study will have access to the data stored.

You should know, however, there are circumstances in which we may have to share your information with other people. For example, the law may require us to show your information to a court or to tell authorities if you have a reportable disease/condition or if you report information about a child being abused or if you pose a danger to yourself or someone else.

Officials of the National Institutes of Health, the University of Kentucky, the Office of Research Integrity, and the research team may look at or copy pertinent portions of records that identify you.

Certificate of Confidentiality (CoC):

To help us protect your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;
- to the sponsor (e.g., National Institutes of Health) or agency auditing the research (e.g., Food and Drug Administration);
- about child or elder abuse, neglect, or harm to yourself or others; and
- about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study, depending on what that study is. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Terrence Barrett, M.D. at 859-323-4887 or via cell at 312-479-4122 immediately. Dr. Barrett will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

The medical costs related to your care and treatment because of research related harm will be your responsibility.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

Participants without IBD receive $400 for the additional research endoscopy visit, which will occur after your initial standard of care endoscopy. Participants with IBD will not be compensated, because they are participating in a standard of care procedure. This money is not intended to influence your decision to enroll in the research study, rather, it is to compensate you for your time and travel expenses incurred, specifically your time away from other activities, and is consistent with the invasiveness of the procedure. Individuals who disenroll, for medical or non-medical reasons before the follow-up research endoscopy will not be compensated. You will receive no payment for your initial clinical care visit, and the research team will not cover the costs incurred in this initial visit. Research studies using your biopsies may lead to the development of future treatments for IBD. You will not be compensated for these treatments now or in the future.

Participation in the additional procedure, involving the collection and submission of a stool sample, is not required and does not impact your participation in the remainder of the study protocol. If you decide you would like to complete this portion of the study you will be compensated $25 for the first stool sample and $50 for the second stool sample for a possible total of $75 for submitting both samples.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE FUTURE RESEARCH TESTS?

Tests done for research purposes are not meant to provide clinical or health care information for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family we will contact you and you can choose whether to receive or refuse the information.

WHAT ELSE DO YOU NEED TO KNOW?

A description of this clinical trial will be available on ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

The biopsy samples that you are giving will no longer belong to you and might be used for studies that lead to new products for research, diagnosis, or treatment. These products might have some commercial value. There are no plans to provide financial compensation to you should this occur.

National Institutes of Health (NIH) is providing financial support for this study.

POTENTIAL FUTURE USE

STORING AND SHARING YOUR INFORMATION OR SPECIMEN SAMPLES FOR FUTURE USE:

Terrence Barrett, M.D. would like to store, use, and share your identified health information and some of the biopsies collected during your procedures for future research. However, specimens and private health information will be de-identified before they are shared. No additional tissue will be taken. If you agree, these biopsies may be used in future research on inflammatory bowel disease (IBD) or other diseases of the gastrointestinal tract. Researchers may also need health information about the people who provide specimens. We are also asking for your consent to place information from your medical record and/or research record in a database to be used for research. Your name and address will not be placed in the database. Having access to tissue samples and corresponding clinical data from the health record from many people helps researchers identify trends and discover better ways to diagnose, prevent, and treat many conditions. We can use the stored samples and health information to assist us with learning more about IBD or other diseases of the gastrointestinal tract.

Your complete set of your genetic information is called your “genome”. Your genome is completely unique to you. Researchers may analyze sections or all of your genome. They may also analyze genomes from many different people to look for differences which may help predict what makes people more or less likely to inherit a trait or get a certain disease or condition. Researchers can do studies that are more powerful when they share with each other the data or information they get from studying human genomes. Data obtained from analyzing your genomic information and your medical information may be put into scientific databases along with information from other research participants. Your name and other information that could identify you will not be included. Therefore, no one would know just from looking at the data that the information came from you.

The information from this study will be freely available in a public, unrestricted database that anyone can use. The public database will include information on hundreds of thousands of

genetic variations in your DNA code, as well as your ethnic group and sex and pertinent health diagnoses. This public information will not be labeled with your name or other information that could be used to easily identify you. However, it is possible that the information from your genome, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen.

WHERE WILL INFORMATION OR SPECIMEN SAMPLES BE STORED AND FOR HOW LONG?

The samples and health information will be stored in Dr. Barrett's laboratory indefinitely.

ARE THERE RISKS FROM ALLOWING YOUR INFORMATION OR SPECIMEN SAMPLES TO BE STORED FOR FUTURE RESEARCH?

There is a risk that someone could get access to the stored information or samples. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known.

When we collect extra tissue during your procedure, we will limit the amount so that there is no significant increase in risk to you

Even without your name or identifiers, genetic information is unique to you making it possible for someone to trace it back to you. The results of genetic research apply to both you and your family members. Genetic information used improperly to discriminate or support negative stereotypes could cause you or your family distress.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of an already known genetic disease.

There may be risks that at this time are unknown. As technology advances, there may be new ways of linking information back to you that we cannot foresee now.

HOW WILL YOUR PRIVACY AND CONFIDENTIALITY BE PROTECTED?

Researchers will remove your name or other direct identifiers from your information or samples. We will label your information or samples with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to you.

HOW WILL WE SHARE YOUR INFORMATION OR SPECIMEN SAMPLES WITH OTHER RESEARCHERS?

Your de-identified information, as well as specimens may be shared with other researchers without your additional informed consent, provided an Institutional Review Board (IRB) has approved this action. If that is the case, the data/specimens will not contain information that can identify you unless you give your consent/authorization or the UK IRB approves the research. An IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human participants. If a researcher requests your information or

samples with identifiable information, an IRB will decide if the research may be conducted with or without your additional consent.

WHAT IF YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR INFORMATION OR SPECIMEN SAMPLES?

You may withdraw your permission to allow your information or samples to be used for future research. To do so, you must send a written withdraw request to *Terrence Barrett, M.D., University of Kentucky, GI Division, 800 Rose St. MN649, Lexington, KY 40536.*

Any remaining information and samples will be destroyed. In addition, it may be possible to destroy the code that links you with your information and specimen samples. However, the information and samples that have already been used or shared may not be withdrawn.

WILL YOU RECEIVE ANY COMMERCIAL PROFIT FROM FUTURE RESEARCH DISCOVERIES?

The information and samples that you provide will no longer belong to you. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives should this occur.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE FUTURE RESEARCH TESTS?

Tests done for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information.

OPTIONAL FUTURE USE:

Do you give permission for your collected specimen and health information to be stored, used, and shared for future research on inflammatory bowel disease (IBD) or other diseases of the gastrointestinal tract for future research?

☐ Yes ☐ No Initials _____

Remember, you can still be in the main study even if you even if you do not wish to allow your information and/or specimens stored or shared for future research.

EXTRA SAMPLES:

If you require surgery, either following a referral or as a result of your scope procedure, the tissue removed in your surgery may be useful for research purposes. Please initial whether you agree to allow extra samples to be taken. Do you agree to allow tissue to be taken during your surgery (if needed), which may or may not be used for this study?

☐ Yes ☐ No Initials _____

Remember, you can still be in the main study even if you even if you do not wish to allow extra surgical samples to be collected.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Name
- Address
- Medical record number
- Telephone number
- Medical history
- Allergies
- Current and past medications or therapies
- Current symptoms
- Pathology reports
- Previous endoscopy
- Social security number

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.
- Law enforcement agencies when required by law.
- University of Kentucky representatives.
- UK Chandler and Good Samaritan Hospitals
- National Institutes of Health (NIH)
- University of Kentucky Research Coordinators

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You will not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect your:

- **Current or future healthcare at the University of Kentucky**
- **Current or future payments to the University of Kentucky**
- **Ability to enroll in any health plans (if applicable)**
- **Eligibility for benefits (if applicable)**

After signing the form, you can change your mind and NOT let the researcher(s) release or use your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: *Terrence Barrett, M.D., University of Kentucky, GI Division, 800 Rose St. MN649, Lexington, KY 40536* to inform him of your decision.

- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).
- You may not be allowed to participate in the study.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer at: (859) 323-1184.

You are the subject and have read this information. You will receive a copy of this form after it is signed.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of research subject Date

_____

Printed name of research subject

_____ _____

Printed name of (of authorize) person in obtaining consent and HIPA Authorization Date

_____

Signature of Investigator