Reply all Delete Junk Block ...

IRB: Study Correspondence Letter

U **umcirb@ecu.edu**
Fri 10/18/2019 9:27 AM
Samuel, Gbeminiyi Olanrewaju

EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Boa
4N-64 Brody Medical Sciences Building· Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office **252-744-2914** · Fax **252-744-2284** · **rede.e**

Notification of Initial Approval: Exped

From: Biomedical IRB
To: Gbeminiyi Samuel
CC: Eslam Ali
Date: 10/18/2019
Re: UMCIRB 19-000848
The barriers and facilitators of Colorectal Cancer Screening in an Outpa and prospective study

I am pleased to inform you that your Expedited Application was approved. Approv form(s) occurred on 10/17/2019. The research study is eligible for review under e Chairperson (or designee) deemed this study no more than minimal risk.

Changes to this approved research may not be initiated without UMCIRB review ex eliminate an apparent immediate hazard to the participant. All unanticipated prob participants and others must be promptly reported to the UMCIRB. The investigat application to the UMCIRB prior to the Expected End Date provided in the IRB appl completed by this date, an Amendment will need to be submitted to extend the Ex Investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the documer participants (consent documents with the IRB approval date stamp are found unde study workspace).

East Carolina University

Date: Wednesday, November 13, 2019 6:30:42 PM Print Close

Study Identification Information

This is the first step in your Human Research Application. You will automatically be guided to the appropriate page views needed to complete your submission. If a question is not applicable to your study, you may state this as your response. Please read the help text located on the right side of the page throughout this application.

1.0 * Study Name (Short):
The barriers and facilitators of Colorectal Cancer Screening in an Outpatient Setting: A retrospective and prospective study

2.0 Study Name (Long):

3.0 * Summary of Research in Lay Terms:
Introduction:
Colorectal cancer (CRC) is the third most common cancer and the second leading cause of cancer-related deaths in the United States. Colonoscopy, the preferred modality for CRC screening, has been studied to reduce incidence and mortality. Despite this, the screening rates remain low with less than half of adults in the United States undergoing colonoscopy at the recommended interval. Screening rates are even lower in African Americans compared to White Americans contributing to 20% higher CRC incidence and 40% higher CRC mortality rate. Although colonoscopy is the preferred screening modality due to its diagnostic and therapeutic advantage, the CRC screening guidelines involve various modalities: Current screening recommendations for individuals aged 50 to 75 years include colonoscopy every 10 years, flexible sigmoidoscopy every 5 years, CT colonography every 5 years, or annual stool-based testing. Stool-based testing, including fecal immunochemical tests (FITs), are cost effective, easy to perform at home, and noninvasive.
Nevertheless, approximately 4 in 10 patients are not appropriately screened. We hypothesize that the screening rate in our IM clinic is about the same or even much lower.

Barriers to screening are multifactorial, racial status(minorities) and socioeconomic status 'SES' (lack of insurance and low-income) are known factors that can influence screening utilization. These groups show some of the lowest rates of screening, which has been associated with later stages of detection and worse outcomes. Furthermore, multiple patient-level barriers have been identified as barriers to CRC screening including fear, embarrassment, bowel preparation, lack of provider recommendation, and logistical barriers, such as cost and lack of transportation, lack of awareness, low perceived susceptibility, and attitudes about the futility of treatment also affect screening.

Given the disparities in screening, it is essential to determine what screening barriers are most important to our patient population and "what gets in the way" of CRC screening for lower-income, under- and uninsured patients. Our objective is to describe self-identified barriers to CRC screening in our patients and to assess the association of these barriers and specific SES challenges (income, education, insurance, employment).

Study design
Chart review and data collection will be performed retrospectively by identifying all age-eligible patients for colonoscopy in the past 1 year. Inclusion criteria: patients between the ages of 50-75 at the time of 'follow-up' or 'establishing care' clinic encounters. Exclusion criteria: patients who require a colonoscopy for other diagnostic purposes. or

The investigators (residents and fellow) will contact those patients via telephone, in a private setting, after developing a standardized questionnaire (see attached). Baseline demographics (age,

race/ethnicity, gender, zip-code, employment status, monthly income, years of education, insurance status) will be included. The discussion will include the reason(s) for declining or accepting colonoscopy or another acceptable screening method. assessing if other CRC screening modalities were offered, and explaining the risks/benefits of other CRC modalities (such as FIT, FOBT, Flexible sigmoidoscopy, CT colonography). Participants will be asked if they had ever had each test and when they completed their most recent test. The up-to-date screening is defined as an FOBT within the last year, Ct Colonography or sigmoidoscopy/colonoscopy within the last 5 years. Responses will be categorized as never screened, screened but not up-to-date, and screened and up-to-date. Barriers to CRC screening were assessed for all participants with an open-ended question: "What barriers/things got in the way of being screened?". For non-English speaking patients, the service of a hospital interpreter will be employed. We will also ask whether they have delayed or not obtained care because of cost, lack of transportation, or because of the way they thought they would be treated.

For those who are not up-to-date on screening, we will document reasons why they are not up-to-date, and if possible, make arrangements for a visit with Vidant Gastroenterology faculty, Dr. Ali, to schedule an appointment and/or order the preferred screening modality.

Data analysis
Descriptive statistics will be used to summarize participant demographics and CRC screening rates using SPSS or STATA. Differences between those who reported barriers and those who did not will be determined using chi-square tests. Responses will be reviewed by the primary coder and organized based on inductive and deductive coding. Pre-determined codes from the literature (such as fear, embarrassment, bowel preparation, lack of provider recommendation, and logistical barriers) will be used. and additional codes were added based on the preliminary review of the qualitative data. Responses that addressed multiple topics will be double coded. Three investigators will review topics and coding to check agreement; discrepancies will be resolved through consensus. We will then code barriers or facilitators as categorical variables to analyze bivariate associations with socioeconomic variables and CRC screening status using chi-square tests.

Objectives:
We aim to assess the barriers and facilitators of CRC screening in our Internal Medicine clinic. In turn, we hope to raise awareness of the various CRC screening modalities with the goal of increasing CRC screening rate.

Project Aims:
1. To determine if there is non-adherence in the ECU Internal Medicine Clinic to the CRC screening guidelines among healthcare providers and patients
2. To determine reasons for non-adherence among healthcare providers and patients
3. To raise awareness of non-adherence to the CRC screening guidelines among healthcare providers (through lectures by Vidant Gastroenterology fellows) and patients (via telephone patient surveys).
4. To schedule patients (through the Vidant Gastroenterology Clinic) for CRC screening by preferred modality
5. To determine if a strategy (such as implementing other CRC modalities in the electronic medical records 'best practice advisory') is indicated to increase adherence of CRC screening.

4.0

*** Principal Investigator:**
Gbeminiyi Samuel

5.0 **Faculty Investigator** (Serving as the responsible individual in the oversight of the research study when the PI is a student, resident, fellow or visiting faculty.)
Eslam Ali

Faculty Investigator IRB Certification Renewal Deadline: 3/25/2022

6.0 **Study Coordinator or Contact Individual:**

7.0 **Contact Individual(s) (if different from Study Coordinator or Principal Investigator):**

Last Name First Name Organization Profile IRB Certification Renewal Deadline

There are no items to display

8.0 **Sub-Investigators:**

Last Name	First Name	Organization	Profile	IRB Certification Renewal Deadline
Hamed	Ahmed	Internal Medicine, Department of	ahmed hamed's Profile	12/20/2019
Lambert	Karissa	Internal Medicine, Department of	Karissa Lambert's Profile	8/30/2021
Poola	Shiva	Internal Medicine, Department of	Shiva Poola's Profile	10/11/2021
Smalls	Jackie	Internal Medicine, Department of	Jackie Smalls's Profile	9/26/2020
Udom	Jennifer	Internal Medicine, Department of	Jennifer Udom's Profile	3/31/2022

9.0

Other Study Staff - (Read-Only):

Last Name First Name Organization Profile IRB Certification Renewal Deadline

There are no items to display

Study Staff Roles and Responsibilities

1.0 *** Click on the UPDATE button beside each person's name to provide the responsibilities for each study staff member:**

	Name	Role	Responsibilities
View	Gbeminiyi Samuel	Principal Investigator	Screens potential participants, Obtains Informed Consent, Conducts physical exams, Enters data on paper research records, Data management, Collects data/specimens, Communicates with IRB,

	Name	Role	Responsibilities
			Prepares Study initiation activities, Educates participants, families, or staff, Conducts surveys/interviews, Administers tests/study interventions, Performs observations, Trains research team members
View	Eslam Ali	Faculty Supervisor	Screens potential participants, Obtains Informed Consent, Conducts physical exams, Enters data on paper research records, Data management, Collects data/specimens, Prepares Study initiation activities, Enters patient data into electronic research records, Educates participants, families, or staff, Conducts surveys/interviews, Administers tests/study interventions, Performs observations
View	Shiva Poola	Sub-Investigator	Screens potential participants, Obtains Informed Consent, Data management, Collects data/specimens, Prepares Study initiation activities, Enters patient data into electronic research records, Educates participants, families, or staff, Conducts surveys/interviews, Administers tests/study interventions, REDCap
View	Karissa Lambert	Sub-Investigator	Screens potential participants, Obtains Informed Consent, Conducts physical exams, Enters data on paper research records, Data management, Collects data/specimens, Prepares Study initiation activities, Enters patient data into electronic research records, Educates participants, families, or staff, Conducts surveys/interviews, Performs observations, REDCap
View	Jackie Smalls	Sub-Investigator	Screens potential participants, Obtains Informed Consent, Data management, Collects data/specimens, Prepares Study initiation activities, Enters patient data into electronic research records, Educates participants, families, or staff, Conducts surveys/interviews, Administers tests/study interventions, REDCap
View	Ahmed Hamed	Sub-Investigator	Screens potential participants, Obtains Informed Consent, Conducts physical exams, Enters data on paper research records, Data management, Collects data/specimens, Prepares Study initiation activities, Enters patient data into electronic research records, Educates participants, families, or staff, Conducts surveys/interviews, Performs observations, REDCap
View	Jennifer Udom	Sub-Investigator	Screens potential participants, Obtains Informed Consent, Enters data on paper research records, Data management, Collects data/specimens, Prepares Study initiation activities, Enters patient data into electronic research records, Conducts surveys/interviews, REDCap

IRB Researcher Training Records

The following information is taken from your researcher profile.

1.0 Principal Investigator's Training

IRB CITI Modules Completion Date:
3/29/2019

IRB CITI Modules Renewal Deadline:
3/29/2022

2.0 **Study Coordinator IRB CITI Modules Renewal Deadline:**

3.0 **Other Relevant Training:**

Study Funding Information

1.0 *** Select the appropriate funding type for this study:**

Funding Type	
☐	Federal Funding
☐	Industry
☐	Non-Profit
☐	State or Local Funding
☐	Internally Funded (ECU)
☐	Other University or College
☑	**No Funding**
☐	Other
☐	International Funding

If other, provide the name of the type of funding source:

2.0 **Provide your RAMSeS application number, if applicable:**

3.0 *** Does the research include any monetary inducements, compensation or reimbursement for participation in this research study?**

○ **Yes** ● **No**

4.0 **Will the sponsor/funding agency reimburse the participant for any items or procedures or supply any items at no cost involved in this research study?**

○ Yes ● No

Disclosing Real or Perceived Conflict of Interest (COI)

Principal Investigator (PI)

The PI must answer the following questions:

1.0 *** Do you or a member of your immediate family have a financial interest consisting of consulting fees, honoraria, royalties, salaries or other payments, ownership of stocks or other interests in any external entity related to this research?**

○ Yes ● No

2.0 *** Do you or a member of your immediate family have an executive position or serve as a board member of any external entity related to this research?**

○ Yes ● No

3.0 *** Do you hold or plan or hold any claims to intellectual properties, licenses or pending patents on technology that will result from conducting this research study?**

○ Yes ● No

4.0 *** Will you receive any incentives or bonuses based on the number or speed in which you enroll human subjects?**

○ Yes ● No

5.0 *** Will you or any key study personnel receive any incentives or bonuses, based on the outcome of the research study?**

○ Yes ● No

6.0 *** Will any related persons participate on the project?**

○ Yes ● No

7.0 **If you have answered "Yes" to any of the questions above, you may have either a real or perceived COI. If you have not already done so, you must contact the** Office of Research Integrity & Compliance (ORIC) **for a determination of whether there is a COI. Please upload ORIC's COI determination and/or, if required, a fully executed COI management plan below.**

Name	Version	Document

There are no items to display

Provide any additional details regarding the financial or intellectual relationship:

Key Study Personnel Other Than the PI (Study Coordinators, Sub-Investigators, Other Study Team Members, etc.)

1.0 *** Do any of the key study personnel (or their immediate family/significant other) have a financial and/or intellectual property interest in the sponsor or products used with this project?**

○ Yes ● No

2.0 **If you have answered "Yes" to the question above for any of the key study personnel (KSP) they may have either a real or perceived COI. Each East Carolina University KSP for whom this response is "Yes" must complete a project specific COI disclosure in AIR at** ecu.myresearchonline.org/air/. **If ORIC determines a COI exists, ORIC will notify the respective KSP of the need for a management plan. A fully executed management plan, if required, must be uploaded below for each KSP for whom a COI is identified.**

Name	Version	Document

There are no items to display

Study Locations

1.0 **Select the Research Facilities where this study will be conducted locally:**

	Name
☐	Carolina East Medical Center
☐	Vidant East Carolina Health-Beaufort, Inc.
☐	Physicians East, PA
☐	Vidant Medical Group
☐	Orthopaedics East, Inc.
☑	**East Carolina University**
☐	Vidant Medical Center
☐	Albemarle Hospital Authority
☐	Vidant Duplin Hospital
☐	Vidant Bertie Hospital

Name
☐ Vidant Chowan Hospital
☐ Vidant Edgecombe Hospital
☐ Vidant Health Access, Inc.
☐ Vidant Surgicenter Services of Pitt, Inc.
☐ Vidant Roanoke Chowan Hospital

2.0 **Other Study Locations (if not captured in the list above):**

Name
There are no items to display

3.0 **Upload letter(s) of support/agreement from the research facility/site/school unless research will be conducted at ECU or Vidant Medical Center.**

Name	Version Number
There are no items to display	

4.0 *** Describe the research setting, listing any safeguards in place for participant safety:**
All data will be maintained in a password protected computer. REDCap will be utilized

5.0 *** Is this a multi-site study being conducted at other sites national or internationally?**
○ Yes ● **No**

6.0 *** Will an external IRB act as the IRB of record for this study?** ○ Yes ● **No**

Required Reviews

1.0 *** Requested Review Type:**

Name
○ Exempt

Name

● **Expedited**

○ Full IRB Review

2.0 Required Department Approvals:

Department/School	College/School	Division/Institution
Internal Medicine, Department of	Brody School of Medicine	Health Sciences

3.0 Research Type:

☐ Clinical Trial

☑ **Qualitative Research**

☐ Quantitative Research

Study Population

1.0 * Indicate what your primary targeted population will be:

Study Population

☐ Children (participants under 18 years of age)

☑ **Adults (18 years of age and older)**

☐ Normal Volunteers

☐ Employees

☐ Students

☐ Inpatient Patients

☑ **Outpatient Individuals**

☐ Desperately/Terminally Ill Participants

☐ Traumatized/Comatose Participants

Study Population

- [ ] Prisoners
- [ ] Institutionalized Participants
- [ ] Cognitively or emotionally impaired
- [ ] Pregnant Participants
- [ ] Embryos, Human Fetuses, or Neonates
- [ ] Wards
- [ ] Non-English Speaking
- [ ] International populations
- [ ] Other

If other, list below:

2.0 *** Indicate the inclusion criteria for enrollment:**
Patients between 50 and 75 years at the time of 'follow-up' or 'establishing care' clinic encounters who are considered the average risk for CRC

3.0 *** Indicate exclusion criteria for enrollment:**
Patients with a diagnosis of CRC will be excluded

4.0 *** Provide justification if this study excludes a population who might benefit.**
Patients with a diagnosis of CRC will be excluded as they need a colonoscopy for diagnostic and therapeutic benefits

Patient Participants

1.0 *** Please check the box(es) below that best reflect how patients will be identified and recruited for participation.**

- [x] **Potential participants will be identified after a review of medical records of patients under the care of one or more of the study investigators.**
- [ ] Potential participants will be identified by their treating physicians and referred to the researchers. Patients' private and identifiable information will not be shared prior to receiving permission from the patient to do so.
- [ ] Medical records and/or other institution sources (databases, billing records, pathology reports, admission logs, etc.) will be reviewed to identify potential participants. May involve access of records by individuals not involved in the patient's care.

- ☐ Potential participants will be identified from a registry of individuals interested in research opportunities.
- ☐ Participants will roll-over from another research study.
- ☐ Potential participants will self-refer in response to advertisements.
- ☐ Other

2.0 Describe other plans to recruit or identify participants who may also be patients:

3.0 * Do you assure the IRB that you acknowledge the need to address the potential for coercion with this population and that you will employ reasonable and appropriate steps to emphasize the voluntary nature of participation? ● Yes ○ No

4.0 Describe your plan to receive approval for the patients participation from their attending physician (if not listed as an investigator on this study).

5.0 If you plan to approach patients of other attending physicians who are not participating as investigators in this study and you know who these physicians will be, you should obtain their signatures on the Attending Physician Signature Form and upload that document here:

Study Population Summary

1.0 * What is the maximum number of participants you plan to recruit for this site? For record/chart reviews, please provide the number you plan to review.

1000

2.0 If you are enrolling human participants, provide the number of individuals you may need to approach for recruitment in order to enroll the number above:

3.0 If this is a multi-site study, indicate the projected total participant accrual:

4.0 Provide any additional comments regarding proposed number of participants:

5.0 * Justification for Sample Size:
Projected sample size appears to be large enough for statistical analysis

6.0 * Describe the safeguards in place to protect the rights and welfare of any vulnerable participants enrolled in this research study.
Data of participants will be secured via RedCap

Expedited Qualification

If you check any of the items below, the study is qualified for EXPEDITED review status under federal guidelines.

1.0 * Select all that apply:

Question

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

(a) Research on drugs for which an investigational new drug application **(21 CFR Part 312)** is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).

(b) Research on medical devices for which **(i)** an investigational device exemption application **(21 CFR Part 812)** is not required; or **(ii)** the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

(a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) From other adults and children, considering the age, weight, and health of subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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

(a) hair and nail clippings in a nondisfiguring manner;

(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

(c) permanent teeth if routine patient care indicates a need for extraction;

(d) excreta and external secretions (including sweat);

(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

(f) placenta removed at delivery;

(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(j) sputum collected after saline mist nebulization.

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

(a) physical sensors that are applied either to the surface of the body or at a distance and do

Question

not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

(b) weighing or testing sensory acuity;

(c) magnetic resonance imaging;

(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☑ **5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101 (b)(4). This listing refers only to research that is not exempt.)**

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

☑ **7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt)**

Study Summary

1.0 *** Expected Start Date:**
7/15/2019

2.0 *** Expected End Date:**
4/1/2020

3.0 *** Describe the study objectives.**

Objectives:

We aim to assess and improve CRC screening adherence in average risk patients. In turn, we hope to raise awareness of the various CRC screening modalities with the goal of increasing CRC screening rate.

Project Aims:

1. To determine if there is non-adherence in the ECU Internal Medicine Clinic to the CRC screening guidelines among healthcare providers and patients
2. To determine reasons of non-adherence among healthcare providers and patients

3. To raise awareness of non-adherence to the CRC screening guidelines among healthcare providers (through lectures by Vidant Gastroenterology fellows) and patients (via telephone patient surveys).

4. To schedule patients (through the Vidant Gastroenterology Clinic) for CRC screening by preferred modality

5. To determine if a strategy (such as implementing other CRC modalities in the electronic medical records 'best practice advisory') is indicated to increase adherence of CRC screening

4.0 *** Describe the rationale for the type of research design chosen for this study.**

Assess the compliance of our patient population with health maintenance guidelines

5.0 *** Describe the uncertainty to be addressed by this research study (this is the research question).**

Our objectives are to describe self-identified barriers to colorectal screening in our patients and to assess the association of these barriers and specific 'socioeconomic status' challenges (income, education, insurance, employment).

6.0 *** Describe the current state of knowledge surrounding the research questions to be addressed in this study. Include any relevant citations to support your discussion (if not already included in the protocol).**

Colonoscopy, the preferred modality for colorectal cancer screening, has been studied to reduce incidence and mortality. Despite this, the screening rates remain low with less than half of adults in the United States undergoing colonoscopy at the recommended interval. Screening rates are even lower in African Americans compared to White Americans contributing to 20% higher CRC incidence and 40% higher CRC mortality rate. There are other CRC screening modalities that are less invasive, however, approximately 4 in 10 patients are not appropriately screened. And still, CRC remains the third most common cancer and the second leading cause of cancer-related deaths in the United States (from protocol). Barriers to screening are multifactorial, whether racial status, socioeconomic status, patient level barriers, such as fear or embarrassment, lack of transportation, or provider level barriers, such as lack of communcation and limited provider knowlegde on other screening modalities.

7.0 **UPLOAD your study protocol or grant application here. A protocol is required for review by the convened IRB committee.**

For student projects, UPLOAD your professional paper proposal, thesis, or dissertation proposal.

Name	Version	Document
Facilitators and Barriers for Colon Cancer screening In Internal Medicine Clinic	0.01	Facilitators and Barriers for Colon Cancer screening In Internal Medicine Clinic(0.01)

8.0 **If applicable, UPLOAD your Clinical Investigator's Brochure:**

Name	Version	Document

There are no items to display

Recruitment Methods

1.0 * Select recruitment methods used on this study:

- [ ] Advertising such as flyers, letters, or ads (newspaper, TV, radio)
- [ ] Email Campaign (provide language to be used in email)
- [ ] Web Site (provide language to be used on website)
- [ ] Phone Solicitations
- [ ] Referral by independent source
- [ ] Pre-existing relationship with participants
- [x] **Selected from pre-existing records**
- [x] **Selected from investigators clinic/patient population**
- [ ] Treating provider will share PHI of potential participants with study team (also requires Application for Alteration of Authorization form)
- [ ] Treating provider shares contact information of study team with potential participants to allow self-referral, no PHI is shared and no form required.
- [ ] Social Media (Facebook, Twitter, Blogs, Forums, etc)
- [ ] Other

2.0 What are the "other" methods selected above:

3.0 Upload all recruitment documents or scripts that need approval:

Name	Version Number

There are no items to display

4.0 If recruitment will use PHI from a designated health care component of ECU or Vidant Health, please describe how the PI and/or study team members are affiliated with that health care component (check all that may apply).

1. PI and/or members of the study team are workforce members of a designated health care component of ECU
2. PI and/or members of the study team are workforce members of Vidant Health

If any study team member accessing or using PHI for recruitment is not a workforce member of the health care component from which the PHI will be accessed, or as noted above in Question 1.0, please upload the Application for Alteration of Authorization for Recruiting by Research Team Members Who Are Not Health Care Component Workforce Members.

There are no items to display

Methods & Procedures: Behavioral Methods/Data Collection

1.0 **Select all behavioral/data collection methods and procedures which apply to this study:**

Procedure	
☑	**Surveys/Questionnaires**
☐	Interview/Focus Groups
☐	Videotaping/Audio Recording/Photography
☐	Intervention or Experimental Procedure
☐	Public Observation
☐	Standardized/Non-standardized tests
☐	Deception
☐	Creating a Databank
☐	Use of Existing Datasets
☐	Teacher Inquiry
☑	**Chart Review**
☐	Other social science, behavioral, or educational procedures

Surveys & Questionnaires

1.0 * Upload Surveys or Questionnaires that will be used in this study:

Name	Description
Telephone survey	Surveys and Questionnaires

Use of Existing Datasets

1.0 * Specify what data will be used, where the data will come from and any dates associated with when that data was originally collected (i.e. data set from 2010 census, chart review of clinic records from 2003-2005, etc):
This is a retrospective and prospective study that will capture age-eligible patients for colon cancer screening between July 1, 2018 - June 30, 2019. Chart review and data collection will be performed retrospectively by identifying those patients who are eligible for CRC screening at ECU Internal Medicine Clinic. Inclusion criteria: patients between 50 and 75 years at the time of 'follow-up' or 'establishing care' clinic encounters who are considered the average risk for CRC. Exclusion criteria: patients who require colonoscopy for other diagnostic purposes. The investigators (residents and fellow) will contact those patients via telephone, in a private setting, after developing a standardized questionnaire (see attached). Baseline demographics (age, race/ethnicity, gender, zip-code, employment status, insurance status) will be included. The discussion will include reasons for accepting or declining colonoscopy, for those who decline, we will assessing if other CRC screening modalities were offered, and explaining the risks/benefits of other CRC modalities (such as FIT, FOBT, Flexible sigmoidoscopy, CT colonography). For non-English speaking patients, a hospital interpreter will be used. After a decision is made, the investigator will send a message (via EPIC) to the Vidant Gastroenterology faculty, Dr. Ali, to schedule an appointment and/or order the preferred screening modality. And with those patients who decline, the investigator will document the reason.

2.0 * Describe the method of obtaining this data set:
This is a retrospective and prospective study that will capture age-eligible patients for colon cancer screening between July 1, 2018 - June 30, 2019. Chart review and data collection will be performed retrospectively by identifying those patients who are eligible for CRC screening at ECU Internal Medicine Clinic. Inclusion criteria: patients between 50 and 75 years at the time of 'follow-up' or 'establishing care' clinic encounters who are considered the average risk for CRC. Exclusion criteria: patients who require colonoscopy for other diagnostic purposes. The investigators (residents and fellow) will contact those patients via telephone, in a private setting, after developing a standardized questionnaire (see attached). Baseline demographics (age, race/ethnicity, gender, zip-code, employment status, insurance status) will be included. The discussion will include reasons for accepting or declining colonoscopy, for those who decline, we will assessing if other CRC screening modalities were offered, and explaining the risks/benefits of other CRC modalities (such as FIT, FOBT, Flexible sigmoidoscopy, CT colonography). For non-English speaking patients, a hospital interpreter will be used. After a decision is made, the investigator will send a message (via EPIC) to the Vidant Gastroenterology faculty, Dr. Ali, to schedule an appointment and/or order the preferred screening modality. And with those patients who decline, the investigator will document the reason.

3.0 * Will the dataset include any information that could identify the individual from which the data came? ● Yes ○ No

4.0 If applicable, upload the approval/permission letter that allows you access to this existing data.

Methods & Procedures: Bio-Medical Research

1.0 Select all appropriate Bio-Medical methods and procedures for this study:

Methods/Procedure

- [ ] Investigational Drugs & Biologics
- [ ] FDA Approved Drugs & Biologics
- [ ] Investigational Medical Devices/Humanitarian Use Devices
- [ ] Approved Medical Devices (being used according to their FDA approval)
- [ ] Randomization
- [ ] Placebo or No-Treatment Arm
- [ ] Washout of Previous Medications
- [ ] Diagnostic Radiation
- [ ] Therapeutic Radiation
- [ ] Substance Abuse Treatment (with medication)
- [ ] Sterile Surgical/Invasive Procedures
- [ ] Venipuncture
- [ ] Genetic Testing
- [ ] HIV Testing
- [ ] Tissue Bank/Registry/Database
- [ ] Prospective Collection of Specimens/Data
- [ ] Analysis or Collection of Existing/Retrospective Specimens/Data
- [ ] Planned Emergency Medicine Research
- [ ] Stem Cell Research
- [ ] Procedures/methods that require Institutional Biosafety Committee (IBC) or Environmental Health and Safety (EH&S) (such as recombinant DNA/RNA, viral vectors, infectious agents, biotoxins, CDC select agents, carcinogens, human cell lines, human blood/serum/tissue manipulated in non-clinical areas, etc.)
- [ ] Investigational Procedures (Innovative Practices)

Methods/Procedure

☐ Other Medical Procedures/Considerations

Costs Related to Participation

1.0 *** Select all categories indicating costs which participants or their insurance companies will be responsible for:**

Name
☐ Participants will have no costs associated with this study
☐ Study Related procedures which would be done under standard care
☐ Study related procedures not associated with standard care
☐ Administration of drugs-devices
☐ Study Drugs or Devices
☑ **Other**

2.0 **If study participants or insurance companies will assume costs for this study, describe the procedures, drugs, or devices for which the participants must assume costs:**
Participants will have no costs associated with this study, however, for participants who are age-eligible but are yet to have a screening colonoscopy will be offered other modalities for Colon Cancer Screening. If they oblige, then their insurance company may be responsible for the cost

Risk Assessment-Safeguards

1.0 *** Risk classification for this study (select one).**

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

- ● **Minimal Risk**
- ○ Greater than Minimal Risk

2.0 *** Risks, Discomforts and Potential Harms:** Describe the risks/discomforts associated with each research related intervention as well as risk related to data privacy and confidentiality. Include consideration of physical, psychological, social, and other factors. If data is available, estimate the probability that a given harm may occur and the potential reversibility.
There will be no risk involved.

3.0 *** Describe the safety precautions that will be taken to minimize the above risks/harms:**
This is a qualitative study. No risk is anticipated. PHI will be securely kept as well.

4.0 *** Will a federal Certificate of Confidentiality be obtained for this study?:**
○ Yes ● **No**

If yes, please attach the Certificate of Confidentiality:

5.0 *** Describe any additional safeguards in place to manage illegal, significantly intimate or potentially embarrassing information gathered in this research study.**
PHI will be securely kept

6.0 *** Include steps to handle information that may require mandatory reporting to officials (e.g., child abuse or neglect), reportable health problems (e.g., HIV/AIDS, hepatitis), or information that requires seeking professional assistance (e.g., expression of intent to harm one's self or others).**
We will not be collecting such data

7.0 *** If the research study involves HIV testing, describe the plans for pre/post test counseling, partner notifications, referrals for care and any other related considerations.**
Not applicable

8.0 *** Outline the mechanism for reporting Unanticipated Problems to the IRB, participants or others for this study.**
We will notify the IRB either via email or telephone call.

Risk/Benefit Analysis-Potential Benefits and Alternatives

1.0 *** Describe any potential for direct benefits to participants in this study:**
Potential to identify patients that may be at risk of Colon cancer

2.0 *** Describe any potential benefits to society:**
Identify potential barriers to colon cancer screening and overcome them.

3.0 *** Alternatives to Participation:** If applicable, describe alternatives (research or non-research) that are available to participants if they choose not to participate in this study.
It is voluntary.

4.0 *** Risk/Benefit Analysis:** Justify why individuals should participate in this research study based on the risk/benefit ratio (relative to non-participation and/or alternatives).
Potential to identify patients that may be at risk of colon cancer.

Informed Consent

1.0 *** Indicate the types of consent that will be involved in this study (check any or all that apply):**

Informed Consent Category
☐ Written/signed consent by participant.
☐ Written/signed consent by a Legally Authorized Representative (for adult research participants).
☐ Written permission for a child participant by a parent or legal guardian.
☐ Written/Signed Assent by child.
☑ **Online/Verbal consent or written information sheet (If research is Expedited or needs Full board review, a Waiver of Documentation of Written or Signed Consent is required).**
☐ No Consent (If research is Expedited or needs Full board review, a Waiver of Consent is required).

2.0 **Waivers: If you are applying for any waivers of consent (check any or all that apply):**
(Waivers only apply to no more than minimal risk studies.)

Name
☐ Waiver of Consent
☐ Waiver of Assent
☐ Waiver of Parental Permission
☑ **Waiver of Documentation of Written or Signed Consent (i.e. Information Sheets, online/telephone consent, verbal script)**
☐ No Waiver at all

3.0 *** Do you plan to include non-English speaking participants in this research study?**

Yes ○ No

4.0 **How will you accommodate a potential participant who does not speak English?**

Name

Other

If other, please describe:
A hospital-designated interpreter will be used for the study

Consent Forms & Process of Consent

1.0 **There are several different types of consent form templates provided. Please follow the instructions below to complete the process.**

Instructions:

1.1) Download the applicable consent form template to your machine and modify this where applicable.

- Consent Template for Benign Behavioral Interventions (ONLY for use in Exempt Category #3 research)
- Consent Template: Consent Letter for Expedited Survey Research
- Consent Template: Consent Paragraph for Exempt Survey Research
- Consent Template: More Than Minimal Risk Research
- Consent Template: No More Than Minimal Risk Research
- Genetic Testing Consent Template
- Local Boilerplate Language for NCI-CIRB Approved Consents Only
- Local Boilerplate Language for NCI-CIRB Approved Youth Information Sheets (Assents)
- Local Boilerplate Language for Sponsor's Consent Template (does not apply to NCI-CIRB approved studies)
- Minor Assent Template
- Parent Consent to Use Child's Data for Research Purposes (ONLY for use in Exempt Category #1 research)
- Parent Permission Form Template: No More than Minimal Risk Research

*** 1.2) Upload consent forms, assent forms, or information sheets here:**

Name	Modified	Version
Telpehone consent	10/17/2019 3:53 PM	0.03

1.3) If available, upload sponsor templates:

Name	Modified	Version
There are no items to display		

1.4) Upload Tracked Changes versions of consent forms, assent forms, or information sheets here:

Name	Modified	Version
There are no items to display		

2.0 *** Describe how, when, and where the consent process will be initiated:**
Via telephone, during the weekday business hours, at the Vidant Gastroenterology Clinic in a private conference room.

3.0 *** For those team members obtaining consent, describe how they have been trained to consent potential participants and how they have the appropriate expertise to address concerns/questions of potential participants related to this study:**

Team members include residents and fellows who have experience obtaining informed consent. Team members will meet prior to the beginning of the study to discuss the consent process and each teach member will a have a copy of the protocol.

4.0 *** Describe the process to minimize undue influence and coercion during the consent process:**
We would explain the voluntary nature of participation to the study, explain the study, the participant's ability to withdraw at any time, and the decision made whether to participate or not will hot have an impact on the availability of further care.

5.0 *** Outline procedures for obtaining informed consent from participants with limited or low literacy:**
Use of simple language and using the teach-back method. For example "I want to make sure we have the same understanding of about the study. Can you tell me in your own words what the study is about?" If we are unable to communicate with potential participants, he/she will not be enrolled.

6.0 *** Describe the process for determining cognitive impairment or other conditions that may make a participant more vulnerable:**
Assess capacity by the use the teach-back method as previously mentioned. If adequate decisional capacity is not found, we will either exclude the participant from the study.

7.0 *** Describe the process for identifying the legally authorized representative and the process to debrief and subsequently obtain consent from the study participant, when feasible:**
If we find that the participant does not have adequate decisional capacity, we will exclude the participant from the study.

Non-English Speaking Participants

1.0 *** Describe the process of how you will explain the study and assure that the non-English speaking participants understand the study and their participation in research.**
A hospital designated interpreter, or Martti (an application device that provides readily available access to interpreters; It is provided by the hospital and clinic) will be present at the time of obtaining consent and conducting the study (survey).

2.0 *** If the research will primarily include participants who speak a language other than English, the informed consent documents should be translated into that language. Please indicate the language(s) and method of translation.**
A hospital designated interpreter will be used.

3.0 **Upload translated version of consent document(s) here:**

Name	Modified	Version

There are no items to display

4.0 **Upload Tracked Changes version of translated consent document(s) here:**

Name	Modified	Version

There are no items to display

5.0 **Check this box if the translated ICD will be submitted as an amendment to the study after the English version has been approved:** ☐

Waiver of Documentation of Written or Signed Consent

This may be used when an investigator wishes to provide the participant the same written information that would normally be provided in a consent document, but the signature (or written documentation) by the participant would not be required.

Justify the request to waive this documentation of consent by addressing the following:

1.0 *** To waive the requirement to obtain a signature on the consent document, at least one of the following must be true of your study. Select the option(s) below that describes your study:**

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Data Privacy & Confidentiality

1.0 * Will you view, collect, generate or analyze protected health information (PHI) from any source (not limited to ECU or Vidant data) as part of your research study?

● **Yes** ○ No

1.1

* Choose the option that applies to your research study (check all that apply):

Waiver of HIPAA Authorization requested (upload Waiver request form below)

Upload all applicable HIPAA documents:

	Document	Description
View	HIPAA from updated Colon cancer screening.pdf(0.01)	HIPAA Authorization
View	Waiver of HIPAA authorization(0.03)	HIPAA Authorization

1.2

* Will the records you use or collect in preparation for your study or any time during your study (inclusive of any temporary collection) contain any of the 18 Personal Identifiers as specified by HIPAA Privacy? (Check all the Personal Identifiers contained in the data you plan to use or collect):

Patient Names

Telephone Numbers

Medical record numbers

Date of Birth/Death/treatment/admission/discharge/diagnosis/age (if older than 90) or any other element of date (except year) which is directly related to the individual

Note: If any of the 18 Personal Identifiers are utilized then the research data is considered PHI (Protected Health Information) and subject to HIPAA privacy regulations.

1.3

* Will PHI data be stored electronically, on paper, or both?:

Electronically

1.3.2

* Please provide location(s) and storage devices(s) below:

ECU Departmental Folder in Pirate Drive

REDCap

1.4

*** Please provide the name AND the contact information for the appointed HIPAA Administrator for all electronic PHI for this study.:**

Gbeminiyi Samuel

Email: Samuelgb18 @ecu.edu

2.0 *** Where will you obtain the data for this research study?**

Medical Records

3.0 *** Describe how the identity of individuals research data and/or specimens will be recorded (check all that may apply):**

Coded (Data will be linked to subjects via encrypted codes and code does not include HIPAA identifiers, such as initials, date of birth, etc.)

Identified (Data will be linked directly to individuals via the use of one or more of the 18 HIPAA identifiers including initials, date of birth, etc.--if a master key is being kept, "Identified" should be selected.)

If identity is coded, describe how the code is created (random, sequential, computer generated, etc) and give an example:

sequential: 001, 002 etc.,

4.0 **List all categories of data to be collected for this research study (e.g., Name, Date of Birth, Age, Disease status, etc) or upload your data collection sheet below:**

Name, Date of Birth, MRN, Telephone number and Gender

If applicable, upload data collection sheet:

There are no items to display

5.0 *** Where will the paper and electronic research data be stored? Please specify the physical location (building and room number) and how it will be secured to protect privacy and maintain confidentiality:**

Redcap. Co researchers will have a central storage device where they will save the patient's information. This central storage device - ECU departmental internal medicine folder on Pirate Drive

Note: Data collected and/or generated during the course of the study that includes protected health information (PHI) should have identifiers removed at the earliest opportunity consistent with the conduct of the research and/or clinical needs (if applicable). ***However, regulatory documentation (including signed consent/assent form(s), signed stand-alone HIPAA Authorization(s), documentation of verbal consent/authorization(s), research records documenting that a request for waiver of HIPAA Authorization was approved) must be retained for 6 years following completion of the research.***

6.0 *** How long will data be stored after the study is complete?**

HIPAA waiver will be kept for a minimum of 6 years post study closure as per Privacy Regulations. Other data will be maintained for up to 3 years. Identifiers will be destroyed as soon as possible

7.0 *** Who, other than the specified study team, will have access to the study records or data? Specify their name, role, and affiliation.**

People designated by Vidant Health to monitor research activity.

Data Privacy & Confidentiality

1.0 * Will coded or identified data be released or shared with individuals or entities (outside of the study team)?

○ Yes ● **No**

2.0 *** Describe what will happen to the data or data set when the study is completed. Please indicate your plans for the destruction of identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs, if applicable:**
data will be destroyed by ECU policy

3.0 *** If audio/video recordings or photographs will be used, specify your plans for de-identifying or anonymizing the material. Indicate when and how these will be destroyed.**
not applicable

4.0 *** If the participants' data or samples from this study will be used for other research studies in the future, please describe the type of data that will be used and how their privacy will be protected.**

not applicable

Data Safety Monitoring Plan

1.0 *** Check the one box below that most accurately reflects the plan for data and safety monitoring for this study.**

Name

- (●) **The study will be monitored only by the study investigators and/or sponsor.**
- ( ) The study will be monitored by at least one individual who is not associated with the study, but not by a formally constituted Data and Safety Monitoring Board (DSMB).
- ( ) A formally constituted Data and Safety Monitoring Board (DSMB) will monitor the study.

2.0 **If this study will be monitored by individuals not associated with this study and there is no formal DSMB, provide the names of those individuals.**

3.0 **Describe the clinical criteria for withdrawing any individual participants from the study due to safety or toxicity concerns.**

4.0 **Summarize any pre-specified criteria for stopping or changing the study protocol due to safety concerns.**

5.0 **Are there any plans to perform an interim efficacy analysis?**
( ) Yes ( ) No

6.0 **If you answered Yes, please describe the plans to conduct an interim analysis.**

Institutional Ancillary Approval

Based on your answers to the following questions, you may need to answer additional questions.

1.0 *** Will this study generate or require the use of protected health information (PHI) or medical records by any ECU research team member at the research location?**

● **Yes** ○ No

2.0 *** Will this study require the use of medical records at Vidant Medical Center (or any other Vidant facility)?**

● Yes ○ No

3.0 *** Will this study utilize clinical areas within ECU Physicians, require recruitment of subjects/procedures/tests/medications/surveys or any other study requirements to be performed at ECU/BSOM?**

● Yes ○ No

4.0 *** Will this study involve inpatient or outpatient units/staff at a Vidant Health facility, require recruitment of subjects/procedures/tests/medications/surveys or any other study requirements to be performed at a Vidant Health facility?**

○ Yes ● **No**

5.0 *** Will this study take place at the Leo W. Jenkins Cancer Center (LJCC)?**

○ Yes ● **No**

6.0 *** Will this research study utilize resources within the School of Dental Medicine (SoDM), including Community Service Learning Centers, require the use of any SoDM databases or are any study procedures to be performed at the SoDM?**

○ Yes ● **No**

Use of Medical Records at Vidant

Based on your answers to the following questions, you may need to answer additional questions.

1.0 HIPAA designations chosen for this study:

Name
Waiver of HIPAA Authorization requested (upload Waiver request form below)

HIPAA documents uploaded:

	Document	Description
View	HIPAA from updated Colon cancer screening.pdf(0.01)	HIPAA Authorization
View	Waiver of HIPAA authorization(0.03)	HIPAA Authorization

There are no items to display

Note the following information:

1. Research access to medical records will be "view only".
2. The legal medical record for Vidant is the imaged medical record.
3. A researcher must have and maintain the appropriate UMCIRB and HIPAA approvals prior to requesting or accessing any protected health information from the hospital medical records system.
4. The researchers will follow all established Vidant policies for the conduct of research and use of protected health information.

Questions?
Contact Vidant Health Information Management Services or Vidant Privacy Office/Research Compliance Office of Audit & Compliance

11.3 BSOM/ECU Physicians Clinical Areas

Based on your answers to the following questions, you may need to answer additional questions.

1.0 **Will this study involve ionizing radiation?** ○ **Yes** ● **No**

What are the type and frequency of tests using ionizing radiation, which are a part of the protocol?

List the tests that are using ionizing radiation which are not routine services. Routine services are services that are generally available to Medicare Beneficiaries.

Questions?
Contact Radiation Safety

2.0 **Will the study require Pathology Services?** ○ Yes ○ No

Will hospital pathologists or pathologist assistants be asked to collect or examine tissue specimens as part of this study? ○ Yes ○ No

If pathologist or pathology assistants will be asked to collect or examinee tissue specimens as part of the study, respond to the following questions:

What type of tissue will the pathologist be required to send for further study: select fresh tissue, tissue section, or tissue block?

Will the pathologist be required to provide additional information and/or description of a gross specimen beyond that usually required for diagnosis (see http://www.cap.org/apps/docs/cancer_protocols/protocols_index.html for standard gross information provided)? ○ Yes ○ No

Will the pathologist be required to provide additional information and/or description of microscopic features of the specimen beyond that usually required for diagnosis (see http://www.cap.org/apps/docs/cancer_protocols/protocols_index.html for standard microscopic information provided)? ○ Yes ○ No

Have arrangements been made to reimburse the pathologist for services provided in relation to this clinical trial? ○ Yes ○ No

Note the following information:
1. The Pathology Department is prepared to support clinical trials research by providing professional services that are routinely required for specimen diagnosis.
2. Requests for professional services that are not a part of those routinely required for diagnosis, including selection of tissue, sections, or blocks, and gross and microscopic descriptions of specimens, should be fully described and submitted to BSOM Pathology at (252) 744-3748.
3. BSOM Pathology can provide investigators with appropriate fee schedules to determine pathology costs related to clinical trials.

Questions?
Contact BSOM Pathology

3.0 **Will this study involve investigational or approved medications?** ○ Yes ○ No

Are the drugs investigational? ○ Yes ○ No

Are the drugs FDA approved but involve non-approved uses? ○ Yes ○ No

What is the charge for the medication to the patient?

Where will the study drugs be stored and will the drugs be labeled for each study patient?

Who will be accountable for the dispensing and documentation of study drugs?

Questions?
Contact BSOM Pharmacy

4.0 **Will this study involve the use of ECU Physicians clinical areas?** ○ Yes ○ No

Identify and list applicable clinical areas:

What research related functions will be performed in the clinic (ie questionnaires, administration of medications etc)?

How frequently will patients be seen?

How long will an average visit take?

What types of clinical staff will be involved in the care of the patients? (e.g. R.N.s, L.P.N.s, mid-level providers, physicians, etc.)

Describe the Staff Education plans:

Upload any relevant educational materials to be used with staff:

Name	Version	Document

There are no items to display

Questions?
Contact ECU Physicians Clinical Operations

5.0 **Will any clinical services be performed as part of this study (including those services paid for by the sponsor?)** ○ Yes ○ No

All claims will reflect the typical BSOM charge for service. Confirm that the mechanism for direct billing has been established with the services required for the research study. If there has been no established mechanism contact the following: Pharmacy – (252) 744-1830, Pathology – (252) 744-3748, Other – (252) 744-3108

What is the turnaround time for payment of the claim?

Who is responsible for payment of the claims?

What is the billing address and contact person for claims payment?

Upload Financial Services Review Form:

Note: The **research participant list** (enrollees) needs to be faxed to BSOM Finance at (252) 744-3679.

Questions?
Contact BSOM Finance

Additional Material

Please upload any other items for review and approval if not already uploaded on a previous page of this application.
Additional Items for IRB Review and Approval:

Name	Version	Document

There are no items to display

Final Page

If you have completed your application, click "Finish" to finalize and exit the application. **This action does NOT submit the application for review,** it just means you have finished editing the application at this particular time.

For those studies that are being submitted for review and approval by the UMCIRB:

1. All research personnel/team members must login to ePIRATE and click the "Agree to Participate" button before ePIRATE will allow a study to be submitted.
2. A submission may only be submitted to the UMCIRB by the Principal Investigator. To do this, the Principal Investigator must login and click the "SUBMIT STUDY" button under My Activities for this Study ID:MS1_UMCIRB 19-000848.

For those studies that are being submitted for acknowledgment of the use of an external IRB:

1. Research personnel/team members are not required to "Agree to Participate" before ePIRATE will allow a study to be submitted.
2. A submission may be submitted by any listed team member. To do this, the team member must login and click the "SUBMIT STUDY" button under My Activities for this Study.

You can track the ongoing status of your submission by logging into the study workspace.

Please wait until you receive your final approval/acknowledgement notice prior to beginning your study and feel free to contact the UMCIRB with any questions or concerns.