JEFFERSON—Office of Human Research

SUMMARY OF INTERVENTIONAL HUMAN SUBJECTS RESEARCH

Version Date – FOR OHR USE: 11/11/21

Please address all applicable points to create a complete and succinct synopsis of the protocol. If a point does not apply to your study, please state "NA." Use language, insofar as is possible, that can be understood by a layperson, and provide meanings for all acronyms used. Please maintain all questions in the body of the text. For non-interventional research (questionnaires, surveys, and all sociobehavioral research), use form OHR-2B. **Form must be typewritten.**

PART A - SUMMARY OF STUDY

1. Brief Summary
   a. Provide a brief (2-3 sentences) lay language synopsis of the study. Include an explanatory sentence about the study article *(e.g., product X is a compound that increases excretion of salt and therefore may be of use in the treatment of high blood pressure)*
      - Gastric point of care ultrasound (G-POCUS) can show if a postoperative patient's stomach is empty or full, and a full stomach has been correlated with delayed return of bowel function after surgery, longer time to GI-3 recovery (defined as the ability to tolerate a regular diet and have either flatus or bowel movement), and increased length of stay. In the study group, patients will have a gastric POCUS exam at 0600 on post-operative day 1 and daily thereafter until they have return of bowel function whereas in the control group, patients will receive standard postoperative care without the addition of any G-POCUS exams. In the study group, the results of the G-POCUS exams will be employed in a care algorithm designed to help clinicians decide how to advance patients' diets and when to place and remove nasogastric tubes (NGT).

2. Objectives and Significance
   a. State the primary objective(s) of the study.
      - Determine if using G-POCUS as a clinical decision-making tool reduces rates of aspiration pneumonia/pneumonitis, length of hospital stay, need for additional/unplanned procedures in the patient population.

   b. State the secondary objectives(s) of the study.
      - Secondary: Determine if G-POCUS can be used to develop clinical practice guidelines for when to advance/de-escalate diets postoperatively and when to insert/remove NGTs in patients who are recovering from abdominal/colorectal surgery.

   c. What benefit or knowledge will be gained?
      - This study builds on the findings of our preliminary studies, which showed that a full stomach on handheld G-POCUS exam on postoperative day one was correlated with longer length of stay, increased incidence of delayed bowel function (DBF), emesis, and nasogastric tube placement. It will help determine if G-POCUS can be

used as an objective clinical decision-making tool for postoperative patients. Ultimately, we hope that integrating G-POCUS exams into the clinical workflow will help reduce rates of DBF, ileus, and aspiration pneumonia.

d. State hypothesis you are testing.

- We hypothesize that G-POCUS can be used as an objective measure to diagnose delayed bowel function after surgery, and consequently reduce the serious complication associated with impaired return of bowel function.

3. Briefly describe the background and rationale for the research in lay language. Please limit response to one paragraph. State the perceived problem and why it is being investigated. *(Do not include references and please do not cut and paste grant application or review articles. "See investigator brochure" is not an acceptable response.)*

Delayed bowel function (DBF) and postoperative ileus (POI), or disruption of the normal forward peristaltic bowel activity after abdominal surgery are common complications in general surgery patients that can lead to nausea, emesis, bowel perforation, or aspiration pneumonitis. DBF and POI increase length of stay, morbidity, and mortality in general surgery patients. It is extremely difficult to predict who will develop DBF and POI. Further, diagnosing patients with postoperative DBF or POI is almost entirely based upon clinical acumen, history, and physical exam. To date no imaging or laboratory studies are specifically recommended to diagnose these complications.
Gastric Point of Care Ultrasound (G-POCUS) is a simple and reliable imaging modality that can be performed at the bedside and does not involve ionizing radiation. In our pilot study, we hypothesized that G-POCUS volume (ie: whether a patient's stomach appears full or empty) would correlate with measures of delayed bowel functioning based on identification of full versus empty stomach postoperatively following colorectal surgery. To test this hypothesis, we performed a small pilot study and found that patients with full stomachs had a higher incidence of DBF, length of stay, emesis, and need for NGT placement.

4. Briefly describe the research design. ***(Use charts and flow diagrams if applicable**. "See protocol" is not an acceptable response.)*

a. Subjects: State inclusion and exclusion criteria.

- Inclusion criteria:
  - Completed signed and dated informed consent form
  - Willing to comply with all study procedures
  - Male or female, 18 years of age or older
  - Presenting for a schedule elective colorectal/abdominal surgery, either open or laparoscopic
- Exclusion criteria:
  - History of gastroparesis or known gastric/intestinal motility disorder
  - History of gastric/bariatric surgery
  - Intubated/sedated postoperatively
  - Presence of open abdominal wounds (including abdominal wound vac)
  - Patients who received a complex abdominal wall reconstruction
  - Class III/IV Wound (Contaminated/Infected/Dirty)

- Surgery was emergent/urgent/unscheduled
- NGT placed or present at time of operation
- Presence of ileostomy/colostomy
- J-pouch reconstruction patients
- Currently pregnant patients
- Patients aged <18 years old

b. Procedures: Provide study visit details.

- This will be a randomized single-blinded study of handheld G-POCUS in which our study population will be inpatients hospitalized after abdominal/colorectal surgery at TJUH, Methodist Hospital, or Abington Hospital. Patients will be randomized to an unblinded intervention arm or an unblinded standard of care arm. On POD1, patients will be asked if they are having any GI symptoms. These are defined as presence of nausea, emesis, belching, and/or hiccups. In the intervention arm, clinicians will use the results of G-POCUS and presence/absence of GI symptoms to inform decision making according to one of two standardized algorithms (see Appendix). In the control arm, presence of GI symptoms will be assessed, and once of two standardized algorithms which are representative of the current standard of care for postoperative diet management. Data from both groups will be used to determine if the G-POCUS studies' results can predict the incidence of primary or secondary outcomes (control) or if intervening on results of G-POCUS can decrease the incidence of undesirable outcomes. This will be a multicenter study enrolling patients at TJUH, Methodist Hospital, and Abington Hospital.

c. Data analysis: (*Provide statistical design **for primary endpoint only.** Please indicate **how the study is powered** and what statistical tool(s) will be applied. Please do not cut and paste entire statistical section from the sponsor protocol. Pilot studies **do not require** a statistical plan but need to outline how the results will be used to power future studies.)*

- Sample size = 128 participants
  80% power using 2-sided t test – would require 64 patients per group (128 total) to show a 25% decrease in time to GI3 recovery in G-POCUS group vs standard care group.

  Sample size calculation was performed using a continuous variable as the primary endpoint (number of days to GI-3 recovery), and assuming an alpha of 0.05 and a power of 80%. Results from the pilot study were used to inform sample size calculation. All patients in the pilot study took on average 1.5 days (SD 1-3 days) to reach GI-3 recovery, while patients in the pilot study with empty stomachs on G-POCUS on POD1, took 1 day on average (SD 1-2) to reach GI-3 recovery.

d. If the protocol involves sending tissue to a commercial entity, please certify that the following criteria are met (see TJU policy #110.17, "Collection, storage, use and distribution of tissue for research purposes"). Also, please provide a copy of the sponsor contract/agreement or an e-mail from ORA certifying same. The PI certifies that he or she (check applicable statements):

☐ Will have significant input into the study design and/or conduct of the study.
☐ Will receive experimental data and participate in data analysis.
☐ Has established the right to be a co-author on any publications related to this protocol.
☐ Certifies that Jefferson ORA is negotiating a sponsored research agreement, to be signed prior to work commencing.

5. Delineate procedures that are standard of care from those that are being performed specifically for the research. *Delete examples and add additional rows to table as appropriate. Provide the information to the best of your ability.*

Procedure	Research	Standard of Care
G-POCUS on POD1	X	
G-POCUS on POD 2-5, if criteria met	X	

6. Describe the Data and Safety Monitoring Plan (DSMP) for this protocol. See OHR Policy G 616 for guidance.

_X_ Study is minimal risk and does not require a DSMP. Accuracy of data will be confirmed by PI before study is locked.

- For Investigator Initiated Treatment Trials:
  Will the study be overseen by the KCC Data Safety Monitoring Committee?
  __X__ YES _____ NO

  If NO, please provide information regarding a DSMP or independent study monitor
  Who is the monitor or describe the expertise of the DSM Committee:
  What will be monitored:
  Stopping rules:
  Frequency of monitoring reports:

- For commercially sponsored research:
  Is there a DSMP or DSMC? _____ YES ____NO

  If NO, please provide sponsor rationale and indicate how the site will receive information about study-wide adverse events or unanticipated problems involving risk to subjects or others?

- For NIH-sponsored studies:
  Is this a National Clinical Trial Network (NCTN) study? _____ YES _____ NO

  If NO, please provide information regarding a DSMP or independent study monitor
  Who is the monitor or describe the expertise of the DSM Committee:
  What will be monitored:
  Stopping rules:
  Frequency of monitoring reports:

If Jefferson is a subcontracted site of a multi-center NIH-sponsored trial, how often and by what mechanism will safety or other reports be received from the coordinating center?

7. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data.
   - All patient-related data will be obtained from Epic via chart review by investigators, as well as via patient interview at their preoperative clinic visit. Results of G-POCUS exams, patient demographics, patient medical history, data from the intraoperative record, data from the medication administration record, data from notes, and radiographic data obtained postoperatively will be reviewed in Epic by investigators and stored in Redcap. Name, Length of Stay, Dates (treatment), MRN#, ultrasound images, ultrasound measurements, diet at times of evaluation, patient reported symptoms of DBF and POI, and need for NGT placement will be collected.

8. The following steps must be taken to ensure that identifiable data remains confidential and secure. Please check each box to confirm your understanding. There are fields below to provide explanations and to describe deviations as well as additional measures.

   a. ☒ A separate research chart must be maintained apart from the medical record/chart of the subject.
   b. ☒ There are 18 identifiers described in 45 CFR 164.514 that make data identifiable. To be considered de-identified, data must not contain any of the identifiers (also see OHR-5 for list of identifiers).
   c. ☒ When not in use, identifiable data should be stored in a locked cabinet or desk in a locked room.
   d. ☒ Access to the data should be limited. Only the individuals who need the data should have access.
   e. ☒ If hardcopies of identifiable data must be taken to another building, a locked container such as a banker bag should be used. The container should be marked with instructions for returning the container if misplaced.
   f. ☒ If hardcopies of identifiable data must be mailed, there must be a contract in place which specifies the method of doing this. The data should be placed in one envelope inside of another envelope. Both envelopes should have tamper-evident seals and should be addressed to the specific recipient. Signatures should be required for receipt, or lockable mailboxes should be used.
   g. ☒ If research data is stored on your work computer, encryption software must be installed on the computer. Contact IS&T if you are not sure if the encryption software is installed.
   h. ☒ PHI may be emailed between Jefferson email addresses. Jefferson email must not be sent from or forwarded to a non-Jefferson email address such as your personal email.
   i. ☒ Research data and PHI should not be stored on portable devices including laptops. If research data must be stored on a portable device, contact IS&T.
   j. ☒ External monitors will only be given access to subjects' medical records as specified in the signed consent form.
   k. ☒ Research data and PHI must be maintained per Jefferson policies.

If you have any explanations for, or deviations to the items listed above, **please describe them:**
If applicable, **please describe any additional measures that will be taken:**

9. Will the subjects bear any costs that are not part of routine clinical care? ____Yes _X_No

10. How will the cost of reasonably foreseeable medical care in the event of a research-related injury be covered? This information can be found in, and must be consistent with, the contract. Contact your contracts specialist with any questions.
    ____Covered by the Commercial Sponsor
    __X__Covered by the Subject
    ____Covered by Jefferson, Government, Philanthropy or other grant (Please identify):_____

PART B- SUBJECTS AND FACILITIES

1. What is the expected number of subjects to be enrolled?

No. subjects per year	Total No. subjects	No. Subjects Nationally or Internationally (if applicable)	No. subjects at collaborating Institutions (if applicable)
Up to: 128	Up to: 128	N/A	N/A

2. Identify where the research will be conducted and describe the adequacy of facilities.
   - Research will be performed at Thomas Jefferson University Hospital (TJUH), Methodist Hospital, Abington Hospital and their outpatient clinics in the department of surgery. Patients will be enrolled and consented, preoperatively in the surgical clinic on the 5th floor of the medical office building (MOB) or in the Wolf building if enrolled at Methodist. They will undergo surgery in TJUH or MHD operating rooms and have a corresponding inpatient hospital stay at TJUH or MHD. Postoperative follow up also occurs at 5MOB or 1300 Wolf St. These facilities are well equipped to manage these subjects. We additionally anticipate enrolling patients at Jefferson Abington. Their outpatient clinics, operating room, and inpatient facilities are well-equipped to manage these subjects.

3. Please identify any facilities to be used for research other than those assigned to Department or division.
   - We anticipate enrolling patients at Jefferson Abington

4. Describe provisions to protect the privacy of participants during the course of the study. (Privacy can be defined as the participant's desire to control the ways in which s/he is approached and/or the ways in which his/her private information is shared with others.)
   - Patients will be offered participation in this study as part of our standard pre-operative visit in the surgical clinic. The treating physicians as well as the study coordinator will inform them of the details of the study. Their personal health information will be protected according to HIPAA standards. They will be advised of their right to discontinue participation at any time.

5. How has the research staff been trained regarding study protocol and their duties related to the protocol (in-service, investigator meeting, etc.)?

- Participating surgeons have all been notified that the study will be performed. Participating physicians and physician extenders in the 5MOB and 1300 Wolf surgical clinic are competent in explaining the study to subjects. The PI in proper collection of data has trained research staff. Additional training will be performed by the PI and research team prior to the study opening at the weekly Department of Surgery GI conference to familiarize all involved in the study with the details of the conduct of the study such as enrollment, randomization, data collection, HIPAA standards, etc. Surgical residents will be trained in the use of handheld ultrasounds for G-POCUS prior to study initiation, and will be able to contact research staff for assistance with obtaining exams or using the handheld ultrasounds. Training logs and delegation logs will be maintained in the regulatory binder to document training and responsibilities for each study personnel.

6. Within the study population, are the following groups eligible to be subjects in this study?

	Yes	**No**
*Women of reproductive potential	X	
Pregnant women/fetuses/neonates (*if yes, and study is interventional or targets pregnant women, include OHR-27 as an addendum to the OHR-2*)		X
Men of reproductive potential	X	
Vulnerable Populations (Please see list below)		
Individuals with impaired decision-making capacity (check yes *only if research targets and could benefit this population)* Note: If yes, please also review and complete the information in this form for decisionally – impaired subjects.		X
*Minorities	X	
Prisoners (*if yes, notify the IRB in advance of the meeting*)		X
*Economically or educationally disadvantaged persons	X	
Students/employees		X

7. If applicable, what additional protective mechanisms are in place to protect the rights and welfare of vulnerable populations?
   Participation will be offered to all eligible patients in our practice who can freely provide consent without coercion and do not meet defined exclusion criteria.

8. If one of the populations with an (*) in the table above are excluded, provide the reason. N/A

Note: NIH policy requires that minorities and women be adequately represented as research subjects. If this is an NIH-funded study and you will be excluding either of these populations, you must provide a scientific reason for such exclusion.

PART C- DRUGS AND DEVICES

I. General Information

1. Identify all investigational drugs and/or devices to be used in this study and provide related information: *(please note that an approved drug is investigational if it is a test article/comparator in a research study)*

☒ NA – No Investigational Drugs or Devices Used in this Study

Drug or Device	IND# / IDE# / HDE#	Organization / Person Holding IND / IDE / HDE	FDA Approved	Not Being Used for Intended Indication
☐ Drug – Specify:	IND #:	☐ Jeff - Specify: ☐ Other - Specify:	☐	☐
☐ Device – Specify:	☐ IDE ☐ HDE #:	☐ Jeff - Specify: ☐ Other - Specify:	☐	☐
☐ Drug – Specify:	IND #:	☐ Jeff - Specify: ☐ Other - Specify:	☐	☐
☐ Device – Specify:	☐ IDE ☐ HDE #:	☐ Jeff - Specify: ☐ Other - Specify:	☐	☐

If research involves an investigational drug or device, the Principal Investigator (PI) will confirm that the IND/IDE/HDE numbers are valid by providing the IRB with one of the following:

- The sponsor protocol imprinted with the IND/IDE/HDE number
- A written communication from the sponsor documenting the IND/IDE/HDE number
- A written communication from the FDA documenting the IND/IDE/HDE number (required if an investigator listed on the protocol holds the IND/IDE/HDE)

2. When the investigator or Jefferson holds the IND/IDE/HDE, the Investigator/Jefferson becomes the "sponsor" of the research and assumes responsibility to ensure that all FDA regulatory criteria for sponsors are met. Please provide your plan for meeting FDA regulatory criteria for sponsors.

   For example:
   - Investigator who holds an IND/IDE/HDE will assign some or all responsibilities to meet FDA sponsor requirements to a contract research organization (CRO).
   - Investigator will undergo an audit by a CRO to ensure that procedures are in place so that all FDA regulatory requirements of sponsors will be met.
   - Investigator will assign responsibility of compliance with some FDA regulatory requirements to a CRO and investigator will obtain an audit from a CRO to ensure that procedures are in place so that all other FDA regulatory requirements of sponsors will be met.

   NOTE: If you intend to use someone who is in-house and who has expertise on sponsor requirements, please justify that that person has equivalent expertise to a CRO.

3. Identify all non-investigational medications and/or devices specified in the protocol that the subject will receive while on this study. *This refers to drugs or devices that the subject will receive but are not being tested as part of this study.*
    - Gastric POCUS studies will be obtained using Kosmos, a handheld portable ultrasound that is FDA approved for clinical use. This product has already been validated for use, and this is not a novel application of the technology.

II. Drugs

Does study involve drugs? YES _____ NO __X__

III. Devices

1. **Does study involve a device?** YES ___ NO __X__ If no, delete the REST of this Device section.
    If YES, please submit OHR-25 Investigational Device Worksheet.

2. Does the study involve an in vitro diagnostic device? YES _____ NO __X___
    If YES, please submit OHR-28 In Vitro Diagnostic Device Worksheet.

PART D - RISKS, BENEFITS, AND ALTERNATIVES

1. What are the risks of the research?
    - There are minimal risks involved in participation. The main risk is mild physical discomfort during the ultrasound exam.

2. Discuss how the study design minimizes risks and maximizes benefits associated with this study.
    - This study poses minimal risk to enrolled participants above what is standard of care at Jefferson. If a patient at any point in time feels uncomfortable with the ultrasound, they may request that the care team stops and they will be removed from the study immediately.

3. What are the potential benefits of participation?
    - Benefits of participation include possible reduced risk of delayed bowel function and postoperative ileus. Additionally, the information we learn during this study may help patients in the future.

4. Explain how the risks of the research are justified by potential benefit to the subject or society.
    - By implementing ultrasound into the patients' evaluation, there is minimal risk than standard of care. However, with this additional clinical information, a more informed decision can be made regarding their bowel function and diet status, potentially leading to increased clinical accuracy, and better patient outcomes.

5. How would you treat this patient in a non-investigational setting? Please describe the treatment that is considered standard of care, as well as any alternative procedures or drugs or other courses of therapy that might be used, if such alternatives exist (include palliative care).

- The current standard of care for assessing the risk for both of these complications heavily relies on interview and physical exam, both of which can be skewed by subjective differences amongst patients.

6. How do the risks and side effects of the standard therapies compare to those associated with the study therapy?
   - The side-effect of gastric ultrasound is mild discomfort during the examination. If a patient experiences this, and wishes to terminate the exam, they will not receive additional gastric ultrasounds and will be removed from the study.

7. If this is a placebo-controlled trial, please provide rationale for use of placebo.
   - NA

8. If subjects will not receive standard of care, provide rationale for this and address risks of not receiving standard of care.
   - As stated in question 4, we are adding minimally-invasive diagnostic data into these patients' care and, therefore, minimal risk is assumed by the patient. This will potentially lead to more informed clinical decisions. This is a low-risk method by which we hope to refine and redefine what the standard of care will be.

9. Please address any risks associated with a "washout" period if applicable.
   N/A

PART E - CHILDREN

1. Will this study involve children (age 17 or under)?

___ **YES –** Complete form OHR-26, "Research Involving Children" and submit as an addendum to the OHR-2.
_X_ **NO –** Delete the REST of this Children section and skip to Part F.

PART F – RECRUITMENT, EQUITABLE SELECTION, AND CONSENT PROCESS

1. Discuss the recruitment plan and describe recruitment methods and materials (e.g., physician referral, newspaper ad, radio, TV spot, e-mail, etc.).
   - Patients will be recruited from our current clinical practice. No additional recruiting efforts are planned.

2. Will all qualified subject populations have adequate access to recruitment materials? Please explain.
   - All individuals referred to our practice will be offered participation provided they meet eligibility requirements and are capable of providing informed consent.

3. Is the location and cultural setting of the research equally accessible to all qualified subject populations? If not, what can be done to make the location and setting more accessible?
   - Our location is currently accessible to all persons referred to Thomas Jefferson University Hospital for care.

4. Are non-English speaking participants anticipated?
   - No – non-English speaking subjects are not anticipated. If a non-English speaking subject who is eligible for the study wants to participate, the subject will be consented following TJU's OHR policy IC705

(Please note that in general, non-English speaking subjects should not be excluded from studies with possible therapeutic benefit unless there is a valid scientific, ethical, or logistical reason.)

Please do one of the following:

a. Provide the rationale for excluding non-English speaking participants.

-OR-

b. ☒ The following steps will be taken if non-English speaking subjects are anticipated:
   - A translated full consent form, in the subject's language, will be IRB approved prior study initiation.
   - All translated documents must be included with the IRB submission, along with proof of translation (certification from agency or name and qualifications of individual). Please note that this includes consent forms, recruitment materials, and all relevant patient-facing documents.
   - At the time of the consent discussion, a translator will need to be present (in-person or via telephone interpreter service). The translator must be an adult who is fluent in both languages.
   - All parties will sign the translated consent form.

-OR-

c. If the above process will not be used, please describe the process that will be used if non-English speaking subjects are anticipated:

Note: For additional information, including information about unexpected non-English speaking subjects, please see OHR Policy IC 705.

5. If you are requesting a waiver of written consent, describe the information that will be provided to participants.
   - N/A – we will obtain written consent for all participants

6. Who will conduct the consent interview?
   - Either the treating surgeons who are the PI and co-investigators for this study or the study coordinator will conduct consent interview.

7. Who will provide consent or permission (e.g., subject, legally authorized representative, parent, caregiver, etc.)?
   - Patients will provide their own consents. Surrogate consent will not be obtained.

8. Where will the consent interview take place?
   - 1100 Walnut St, 5th floor, Department of Surgery Clinic or 1300 Wolf St, Department of Surgery Clinic at Methodist Division

9. Provide a step-by-step description of the consent process.
   - Patients are seen in our office and evaluated for surgery.
   - Patients felt to be candidates for the trial and who meet the inclusion criteria for the study, are then informed of the risks and benefits of participating in the study by the treating surgeon who is a co-investigator on the trial.
   - Their questions are answered until they are able to reach a decision about participating in the trial.
   - After the initial discussion of the study, additional questions are typically answered by the study coordinator who guides that patient through the remainder of the consent process and completion of the consent form.
   - Patients unable or unwilling to reach a decision at that time are given the opportunity to return at a later date for further discussion.

10. Describe your plan to assess a person's capacity to consent.
    - Our plan to assess capacity to consent to research is the same as our current approach to assessing patient's ability to consent to surgery. This is done as part of our standard pre-operative evaluation in the clinic. Any patients / potential subjects thought to be potentially decisionally impaired will be referred to mental health specialists as part of our standard practice prior to obtaining informed consent.

11. Will you seek assent from decisionally-impaired individuals? If so, describe your plan for obtaining assent. Note: If decisionally-impaired subjects will be included and are not capable of consenting themselves, the OHR-8 consent template must be submitted along with a simplified consent form (e.g., OHR-8C) and/or the surrogate consent form (OHR-8B).
    - No

12. Will the potential subject be informed of the research or be provided a copy of the consent to review prior to the actual time of consent? If so, how much time in advance? How much time will be available for the consent process?
    - Patients will be provided a copy of the consent at the initial office visit. Typically, patients are seen in the office 2 to 3 weeks prior to their scheduled operation. Patients will be afforded time during the initial office visit to review the consent form and ask questions. Patients will be informed that they can provide consent at that point or at any point up until two weeks before their operation. They will be informed that if they are undecided, need additional time to review the consent, need additional time to reach a decision, or would like to further discuss the study with one of the investigators or the study coordinator, then appropriate arrangements will be made.

13. What provisions will be made if the potential subject does not wish to proceed with the consent interview at the first encounter?

- Patients will not be approached additional times after the first encounter. They will be informed that they may contact the PI or co-investigators and further discuss participation at any time after the initial interview if they so wish. Patients will receive the same standard of care despite their decision to participate or not.

14. Is surrogate consent involved? YES _____ NO __X__

15. Will subjects be paid or receive any other inducements for participating? If yes, please explain. *Please note that payment of subjects must be on a pro-rated basis unless there are compelling reasons not to prorate. There cannot be a requirement to finish all visits in order for subjects to be paid, as this is considered coercive.*
    - No

16. Describe any steps taken to minimize the possibility of coercion or undue influence.
    - Voluntary participation will be stressed. The ability of patients to have colorectal surgery at Jefferson without participating in any research protocols and still be treated at the same high level as all of our patients will be emphasized. Patients will also be aware that they can stop study participation at any time they wish.

17. The following list of procedures (referred to as MCARE procedures) is used to determine which investigator signature line option should be used in the consent form.

☒ None - The study does not involve any of these procedures -OR- Check All that Apply:

1. ☐ Administration of anesthesia (local, general, conscious sedation, etc.)
2. ☐ Performance of surgical procedures
3. ☐ Administration of chemotherapy and therapeutic radiation
4. ☐ Administration of blood and/or human source products
5. ☐ Refusal to allow transfusion of blood and/or human source products
6. ☐ Insertion of a surgical device or appliance
7. ☐ Performance of abortion
8. ☐ Performance of sterilization
9. ☐ Performance of any HIV-related testing (See Policy #113.58, HIV Testing, for specific documentation requirements)
10. ☐ Performance of ECT
11. ☐ Administration of an experimental medication, use of an experimental device, use of an approved medication or device in an experimental manner or the removal of bone, fluids or tissue for use in research or in the manufacture of a product. Experimental procedures and consent forms must be approved by the Institutional Review Board ("IRB").
12. ☐ Invasive procedures, such as halo placement, central venous catheterization, pulmonary artery catheterization
13. ☐ Performance of vaginal delivery/cesarean section

18. Based on the answer above, select the appropriate option for the investigator signature line. The option you choose must match the option in the consent form.

☐ Include for studies involving MCARE procedures.

By signing below, you the physician investigator, certify that you and/or a qualified practitioner who is also a co-investigator or key personnel, reviewed the purpose, procedures, risks, benefits, and alternatives to participation with the study participant. The other elements of consent may be provided by properly trained and qualified key personnel.

☒ Include for all other studies.

By signing below, you the investigator, certify that you, a co-investigator, or other properly trained and qualified key personnel, reviewed the elements of consent with the study participant.

19. If your study involves MCARE procedures, but you do not intend to have a physician investigator or a qualified practitioner who is also a co-investigator or key personnel review the purpose, procedures, risks, benefits, and alternatives to participation with the study participant, please provide the rationale.

20. A copy of the signed and dated consent form must be given to the subject and this must be documented. How will it be documented that subjects are given a copy of the signed and dated consent form? Check All that Apply:

☒ Checkbox on the consent form
☐ Consent Checklist
☐ Progress Note
☐ EPIC
☐ Screening and enrollment log
☐ A log indicating that each subject received or declined the consent form
Other (Indicate Method):

PART G - STANDARD / EXPERIMENTAL RADIATION USE

1. Does this study involve the use of radioactive material or radiation source?
YES __X__ NO ____ If no, skip to Part H.

2. a.) Will the subject receive radiation greater than normally received in the course of standard therapy or diagnostic procedures? ____ Yes _X_No

If YES, complete the OHR-32 and submit as indicated in the form.

b.) If yes, indicate what type of radiation the patient will be receiving:
__X__ Diagnostic _____ Therapeutic _____ Both. If both please explain.

3. Is any radiation modality experimental? ____ Yes __X_No

If yes, what are the risks associated with the experimental modality?

Please provide a copy of the approval letter from the Radiation Safety Committee when received.

PART H - LOCATION/COLLABORATION

1. This study involves research to be performed at/in/with *(check ALL appropriate entries)*:
   - ☒ Abington-Jefferson Health
   - ☐ East Falls (Philadelphia University)
   - ☐ Jefferson-Northeast
   - ☐ Jefferson Health-New Jersey
   - ☒ Jefferson-Center City
   - ☐ Jefferson as part of a multi-center, commercially sponsored study
   - ☐ Jefferson as part of an NCTN study
   - ☐ JKCCN sites (specify sites):
   - ☐ Rothman Institute (specify sites):
   - ☒ Methodist
   - ☐ Jefferson and Other Institution(s) *Please name institutions only for investigator-initiated and federally funded studies where data will be shared between institutions. Please provide copy of collaborating institution IRB approval letter if applicable. The OHR will effect IRB Authorization Agreements with collaborating institutions as required. Please name institutions:*
   - ☐ Collaboration with City Services *(City of Philadelphia IRB must approve study. For more information, go to http://www.phila.gov/health/irb/.) Please list collaborating city services:*
   - ☐ Unaffiliated Investigators. *Each will need to complete an unaffiliated investigator agreement available on the OHR website.* Please specify by name and role in study:

2. This question is not applicable if research is a commercially sponsored multi-center trial.

   Will research be conducted in states other than Pennsylvania? ☐ YES ☒ NO

   If YES, does research involve subjects age 17 or younger? ☐ YES ☒ NO

   If YES to either or both, in what state(s) will research be conducted? _____

   Below please (a) verify the age at which participants in such state(s) have the ability to consent to participation in research, including any medical treatments or procedures, if applicable and/or (b) verify the requirements for determining who may serve as a Legally Authorized Representative, including a guardian for a child to participate in research. You must also provide information on any state specific regulations on privacy requirements and genetic research if applicable. Please contact the Privacy Office for information, as needed.

   Age at which participants have the ability to consent to participate in research: _____

   State specific requirements: _____

3. If the investigator is the lead investigator or Jefferson is the lead site in a multi-site study, please address the following: N/A

   a. Where is the repository for adverse events and unanticipated problems and how will information be disseminated to other sites?

b. Who will tabulate and disseminate interim results?

c. Who will provide information to other sites concerning protocol modifications?

d. Describe how information that is relevant to participant safety will be managed (i.e., notifying site investigators of SAEs and Unanticipated Problems Involving Risks to Subjects or Others, communicating DSMB or Interim Reports, etc.)

e. Is this study part of a cooperative single IRB submission? ☐ YES ☒ NO
   a. If yes, please attach documentation of approval by the Federal department or agency supporting or conducting the research or lead institution as part of your submission. IRB approval will NOT be issued until documentation has been received.
   b. List all institutions submitted as part of the cooperative single IRB submission:

Collaborative Studies: For investigator-initiated studies that are collaborative or multi-center, or for federally funded studies where Jefferson is the lead site, please provide documentation of approval by the Federal department or agency supporting or conducting the research or lead institution. If the collaborating institution does not have its own IRB, then the institution must first obtain a Federal-Wide Assurance (FWA) from the Office of Human Research Protection (OHRP). This registers the institution with the federal government for conducting human subjects research.
Unaffiliated investigators involved with this study should fill out an Unaffiliated Investigator Agreement, also available at the above Website address.

PART I - CERTIFICATION

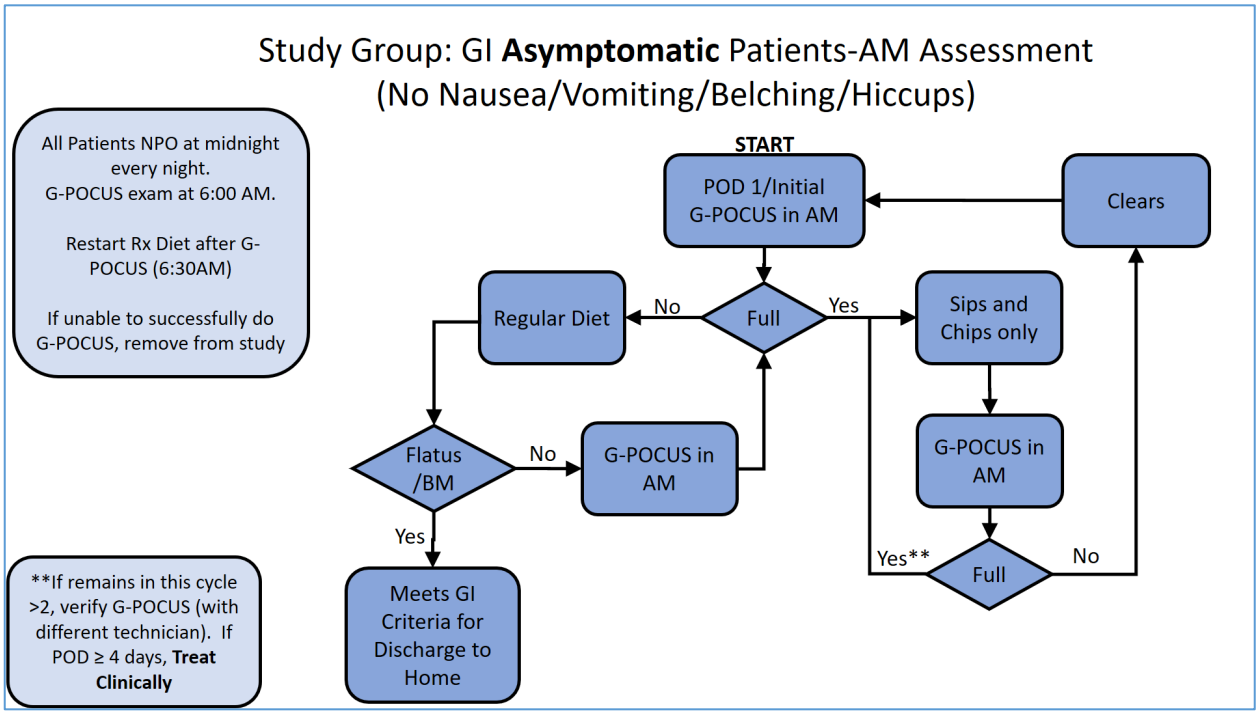
Federal Regulations require the following responsibilities of the Principal Investigator. Please check those items to which you have conformed, and sign.

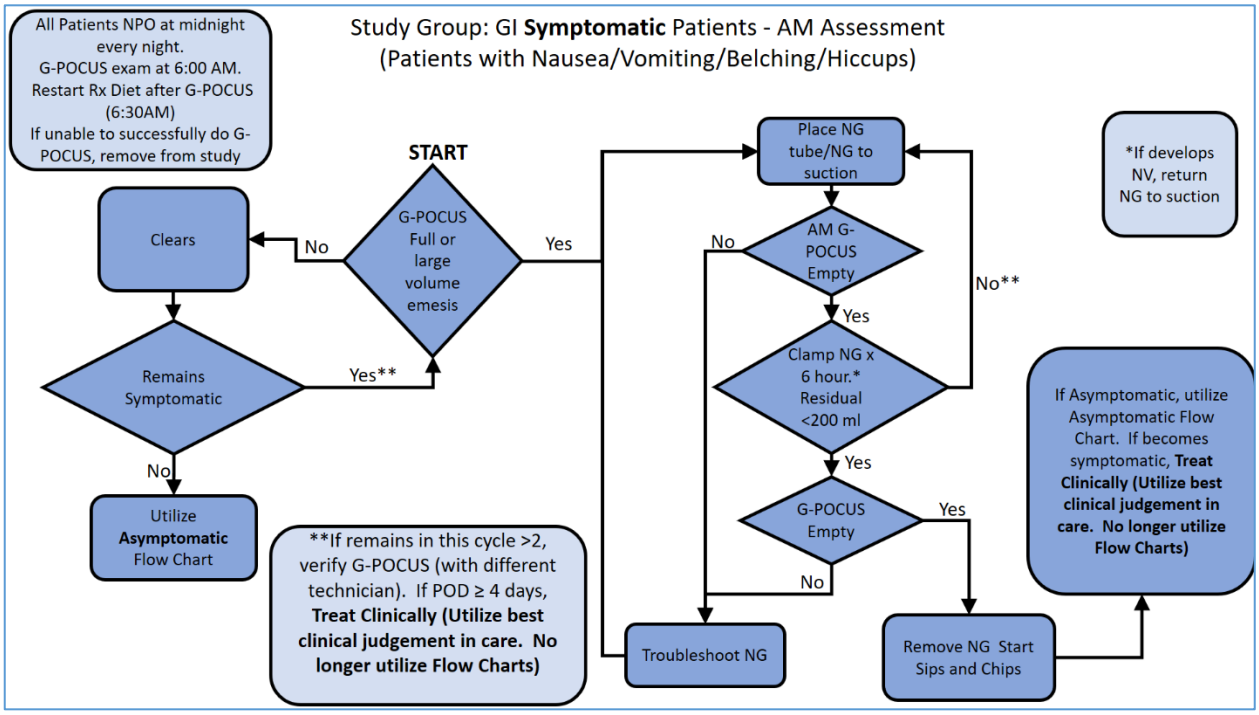
As Principal Investigator, I certify that: *(check appropriate boxes)*

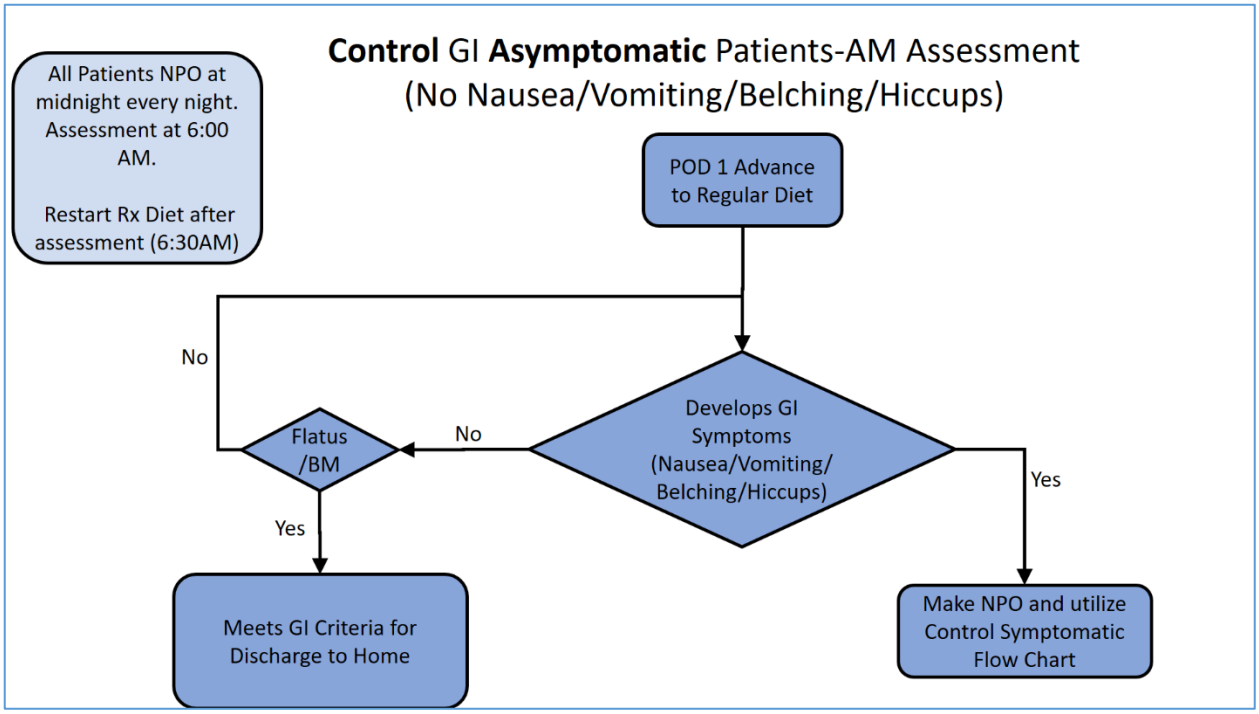
☒ I understand the federally-mandated responsibilities of a research investigator in conducting a clinical protocol.
☒ I will conduct this clinical protocol in accordance with these responsibilities.
☒ I will consent all subjects with an IRB-approved consent form, if applicable to the project, and store the consent forms in a safe repository.
☒ I will provide all subjects with a copy of their signed and dated consent form.
☒ All personnel have been appropriately trained for their assigned roles in this research.
☒ If this study utilizes an investigational agent(s), the dose(s) of the agent(s) cited in the IRB internal forms and the consent form agrees with the dose(s) cited in the protocol.

_____ _____
Signature of Principal Investigator **Date**

APPENDIX: Clinical treatment algorithms







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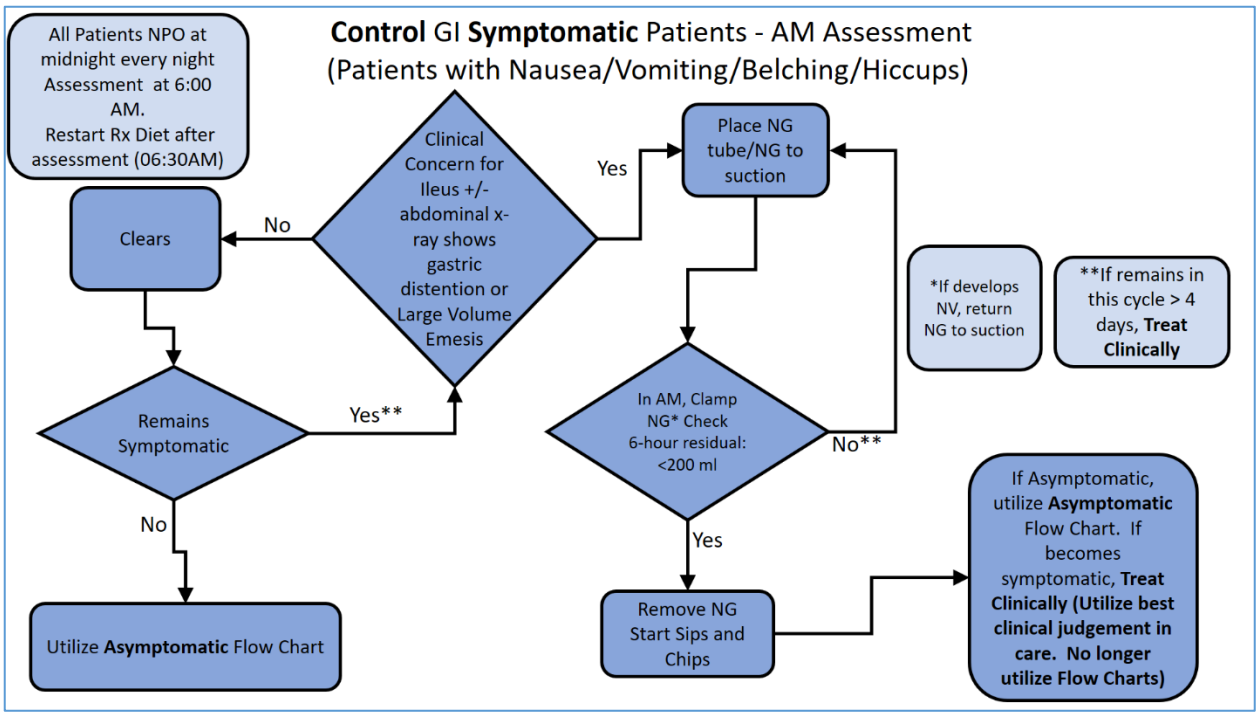

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