UNIVERSITY OF MINNESOTA

HEALTH & BIOLOGICAL/MEDICAL APPLICATION FORM

Version 6.2

Updated January 2015, check http://www.irb.umn.edu for the latest version

Route this form to: See instructions below.	U Wide Form: UM 1571 Jan. 2015

Submit this application, along with all required appendices and supplemental documents to the University of Minnesota IRB	IRB Use Only IRB Study # Click here to enter text.

Electronic Submission (preferred):
Submit to: irb@umn.edu
PI must submit request using University of Minnesota e-mail Account. **Academic advisor and/or Co-investigators must be cc'ed on the emailed submission.**

U.S. Mail Address:
Human Research Protection Program
MMC 820
420 Delaware St. SE
Minneapolis, MN 55455-0392

For more information please visit our website
http://www.research.umn.edu/irb/index.html
Contact our office
Phone: 612-626-5654
Email: irb@umn.edu
Fax: 612-626-6061

Project Title

If the project is funded, the Sponsored Project Administration (SPA) project title must match the IRB project title. If the project is funded by multiple grants, provide all grant titles below:

Transversus Abdominis Plane (TAP) Infiltration vs. Surgical Infiltration of Local Anesthetic in Laparoscopic and Robotic assisted Hysterectomy

Section 1 Principal Investigator

Name	**Highest Earned Degree**:
Geller, Melissa A	MD

Preferred contact information: gelle005@umn.edu

Preferred email or phone number at which the PI may be contacted by IRB staff or reviewers to resolve questions or concerns.

Affiliation and contact information

☒ University of Minnesota (complete contact info section 1 only)

☐ Fairview (complete contact info section 2 only)

☐ Gillette (complete contact info section 2 only)

Required Contact information **Section 1 - U of M only**	**U of M Internet ID (x.500):**	gelle005
	U of M Employee/student ID Number:	
	University Department:	Department of Obstetrics, Gynecology and Women's Health, Division of Gynecologic Oncology

Required contact information **Section 2 Non-U of M only**	**Address:**	**Phone number:** ☐ Mobile ☐ Pager ☐ Office **Email address:**

Occupational Position:

☒Faculty ☐Physician ☐Staff ☐Student - Students must complete the faculty academic advisor section below and submit Appendix J

☐Other:

Conflict of Interest:

Does the PI have a reportable conflict as defined in Section 11 of the application?

☐Yes ☒ No

Required CITI Human Subjects Training	**HIPAA TRAINING**
Date (Month/Year) CITI completed (either initial or refresher course): Note: The IRB requires researchers to complete refreshers courses every three years after completion of initial course. For more information on training requirements see IRB Training	Check box below if HIPAA training is required. ☒ HIPAA Required – Data contains PHI HIPAA Training completed through: ☒ UMN ☐ Other:

For information regarding human subjects and HIPAA training requirements please go to http://www.irb.umn.edu/training.html,

As Principal Investigator of this study, I assure the IRB that the following statements are true:

- The information provided in this form is correct.
- I have evaluated this protocol and determined that I have the resources necessary to protect participants, such as adequate funding, appropriately trained staff, and necessary facilities and equipment.
- I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc.
- I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study.
- I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation.
- I will not begin my research until I have received written notification of final IRB approval.
- I will comply with all IRB requests to report on the status of the study.
- I will maintain records of this research according to IRB guidelines.
- The grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application.
- If these conditions are not met, I understand that approval of this research could be suspended or terminated.

	MD	Today's date.
Signature/Digital signature/x.500 of PI	Title of PI	Date

Faculty Academic Advisor - Student Research

If the PI of this research is a student, include Appendix J filled out by the advisor with this application form.

Student research requires the approval of a faculty academic advisor. As academic advisor to the student investigator, the advisor assumes responsibility for ensuring that the student complies with University policies and federal regulations regarding the use of human subjects in research.

Faculty Academic Advisor Name (Last name, First name MI):	**University Department:**

U of M Employee ID:	U of M x.500 ID (ex. smith001):
Conflict of Interest: Does this person have a reportable conflict as defined in Section 11 of the application? ☐ Yes ☐ No	
Human Subjects Training: CITI – Date completed (either initial or refresher course): Note: The IRB requires researchers to complete refreshers courses every three years after completion of initial course. For more information on training requirements see IRB Training	**HIPAA TRAINING** Check box below if HIPAA training is required. ☐ HIPAA Required – Data contains PHI HIPAA Training completed through: ☐ UMN ☐ Other:
	Today's date.
Signature/Digital signature/x.500 of Advisor Advisor must be cc'ed on emailed submission to the IRB	Date

Person preparing this document

☒ PI prepared this application – section 1 complete

☐ The person named below prepared this application

Name:	Preferred contact info:

Role on study: ☐ Co-Investigator ☐ Study Coordinator (Research Staff)

The person preparing the document must be listed on the application as a co-investigator or in a role that allows him/her to receive correspondence related to the application. See section 13 of the application for more information

Additional study personnel? Complete section 13 of this application.

Section 2 Summary of Activities

The following questions must be answered in lay language or language understood by a person unfamiliar with your area of research. **A research plan or protocol is required with this submission.** In the responses below, area-specific jargon should be avoided or explicitly explained. Do not say "see protocol" or "protocol attached".

Protocol templates are available on the IRB forms page.

2.1 What is your research question?

State hypothesis or primary objective, and provide a brief background on subject population, treatment procedures, and the rationale for conducting the study.

This study aims to test whether there is a difference in the analgesic effect between TAP blocks and surgical infiltration during the first 72 hours following laparoscopic and robotic total hysterectomies.

Laparoscopic and Robotic assisted hysterectomy is a surgical procedure that is a minimally invasive way in which to remove the uterus, which has less scarring and fewer complications. However, this procedure, much like its open-surgical counterpart, is often associated with significant post-operative pain. To augment this pain there are many

different analgesic techniques available to offset pain. Ultrasound-guided transversus abdominis plane (TAP) block is one such procedure involving the injection of a local anesthetic into the plane of the transversus abdominal muscle where the terminal branches of nerves lie. A similar, yet different analgesic approach is that of direct injection of local anesthetic into the incision by the surgeon during or just after surgical procedures. These two approaches have both been proven to decrease post-operative pain in patients for many procedures, but never compared to one another.

Background and Significance

Even with the advancement of using laparoscopic and robotic technologies in total hysterectomies, patients still suffer from pain. This study hopes to use a randomized controlled double-blinded approach to investigate the different analgesic outcomes from surgical infiltration of analgesics to that of ultrasound-guided transversus abdominis plane (TAP) blocks in this procedure.

Other studies have looked at the enhanced analgesic efficacy of both TAP blocks in laparoscopic and robotic procedures, as well as that of direct infiltration of anesthetics into the incisions following surgery.1 Up to this point, however, these two practices have not been undertaken in a single double-blind study in which to compare the analgesic efficacies.

2.2 Who developed the research plan/protocol?

☒ Principal Investigator ☐ Business and Industry Sponsor ☐ Other:

2.3 Explain how the study design and methods will answer the research question.

This is a double blinded randomized study. All patients will receive one form of local anesthetic pain relief either from TAP or infiltration. Patients will be randomized to one of two study arms in a double-blinded, placebo controlled study. All patients will receive a TAP infiltration and all patients will receive infiltration into the incision. In one arm the TAP infiltration will contain 10 mL of 0.25 % bupivacaine with epinephrine injected followed by 20 mL of a 50:50 mixture of liposomal bupivacaine and normal saline. This will then be repeated on the contralateral side. In the same arm the surgeon infiltration into the incision will consist of 10 ml of normal saline per port site, 5 ml prior to incision and 5 ml prior to closure at each port site.

In the second arm the bilateral TAP infiltration will consist of 30 mL of normal saline per side. In the same arm the surgeon infiltration will consist of 10 mL of 0.25% bupivacaine per port site. The surgeon infiltration will consist of 5 ml of 0.25% bupivacaine prior to incision and 5 ml of 0.25% bupivacaine prior to closure at each port site.

A TAP infiltration is an injection of local anesthetic under the covering of the transversus abdominis muscle layer which provides effective post operative analgesia.2-5 This layer is found using an ultrasound, which is a beam of high frequency sound that allows one to visualize images in the body. Then using this ultrasound we can see our needle as it pierces the covering of the transversus abdominis muscle layer and watch as the local anesthetic is infiltrated into this plane. This is done on both sides of the abdomen to provide analgesia to the skin, muscle, and facial layers of the abdomen. This is currently standard of care at our institution and will be performed within one hour of surgical incision. The injection will consist of 10 mL of 0.25% bupivacaine with epinephrine followed by 20 mL of liposomal bupivacaine saline mixture or 10 ml of saline followed by 20 ml of saline and then repeated on the contralateral side.

Surgical Infiltration of the study solution will be performed both prior to incision and at the end of surgery just prior to closure of incisions. At each time, the surgeon will inject 5 mL of 0.25% bupivacaine into each of the port site

incisions.

Investigational Drug Service (IDS) pharmacy will be charged with the blinding of medications vs. saline for these procedures.

2.4 What will the subjects be asked to do solely for the purpose of this research?

Subjects will be asked to be randomly assigned to receive either a TAP with liposomal bupivacaine or infiltration with bupivacaine. They will also be asked to answer questions at various time points related to their pain, answer a survery on their quality of recovery. They will also be asked to allow the research staff to access their medical chart to obtain information about their pain medication use, complications, demographics, and time of discharge.

2.5 Does the study involve treatment?

☐ No.

☒ **Yes. List any procedure that would be performed if research was not conducted (i.e. procedures performed for diagnostic or treatment purposes).**

all procedures would be performed if research was not conducted as both the TAP and infiltration are standard of care.

2.6 Indicate whether your research includes any of the following to determine which supplemental forms must be submitted with your application:

If the research includes	Appendices and supplemental materials required
☐ Administration of approved or unapproved drugs, chemical or biological agents	Appendix E required with the application
☐ Administration of approved or unapproved devices	Appendix F required with the application
☐ Genetic testing (whether or not results are returned to subjects)	Appendix G required with the application
☐ Use of (collecting or having access to) Protected Health Information (PHI)	Appendix H required with the application
☐ Field Work	Appendix L required with the application
☐ Use of a deceptive technique	Appendix N required with the application A debriefing script is also required.
☐ Community based participatory research	Appendix Q required with the application
☐ Collection or storage of biological samples	Appendix T required with the application

	(including blood draws, marrow biopsy sampling, biopsy of other tissues)	
☐	Use of Magnetic Resonance devices housed at the Center for Magnetic Resonance Research (CMRR)	Documentation of CMRR Safety Committee approval required. CMRR users must submit the completed CMRR Device and Safety Review form to the CMRR prior to submission of their IRB application. A draft copy of the IRB application must be included for CMRR Safety Committee review. Documentation of approval by the CMRR Safety Committee will be provided to the researcher to include with the IRB application.
☐	Potential biohazards including recombinant and synthetic nucleic acid, human gene transfer, biologically-derived toxins or infectious agents	Institutional Biosafety Committee approval required prior to final approval. If an IBC application has been submitted for this research, provide the study number.
☐	Biologically-derived toxins (including truncated or mutated toxins)	Institutional Biosafety Committee approval required prior to final approval. If an IBC application has been submitted for this research, provide the study number.
☐	Infectious agents (bacteria, viruses, protozoans, fungi)	Institutional Biosafety Committee approval required prior to final approval. If an IBC application has been submitted for this research, provide the study number.
☐	Use of radiation (x-ray imaging, radiopharmaceuticals, external beam or brachytherapy)	All University Radiation Protection Committee (AURPAC) approval required prior to final IRB approval.

Section 3 Risks and Benefits

3.1 Please indicate if the proposed research will include any of the following (check all that apply). The list below is not exhaustive but represents common elements or procedures in research with associated risks that are frequently overlooked or not clearly articulated.

☐	Administration of physical stimuli
☐	Probing for personal or sensitive information in surveys or interviews
☐	Collection of data with identifiers

☒	Possible invasion of privacy of the subject or the subject's family
☐	Modification or extension of a surgical process to achieve research related objectives.
☐	Major changes in diet, exercise, or sleep
☐	Manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stresses
☒	Placebo Use
☐	Treatment will be withheld or subjects will discontinue current treatment (a wash out period is included)
☐	None of the above

3.2 Describe in detail the nature and degree of the risk associated with participation. The risks must be disclosed in the consent form. Include in the response all potential risks, not just those indicated in the checklist above.

There is the potential of loss of privacy as the medical chart is accessed by the research staff. In addition there is a placebo used however no patient will be without pain medication. The TAP will either consist of local anesthetic or saline. When the TAP consists of saline the infiltration will consist of local anesthetic and when the TAP consists of local anesthetic the infiltration will consist of saline.

With injection of local anesthetic there is risk of the block or infiltration not working. There is risk of it being injected in the wrong area and there is risk of local anesthetic toxicity albeit the dosages used are well below those which would place the patient at risk of local anesthetic toxicity.

3.3 Describe the precautions that will be taken to minimize each of the risks identified in questions 3.1 and 3.2.

All patient charts will be accessed by a trained research personnel. They will not record any identifiers. Patient's will be asked if they are willing to answer questions prior to each round of questions regarding pain scores and surveys.

All TAP and infiltration are standard of care. Either or would be used if we were not doing the research. The TAP infiltration is performed by trained anesthesiologists and are under ultrasound real time guidance. The infiltration is performed by trained surgeons.

3.4 List any anticipated direct and societal benefits to participation in this research project. If none, state that in the space provided below and in the consent form. The benefit of receiving treatment is not necessarily a benefit to participation in the research project. ***Compensation paid to subjects is not considered a benefit.***

none

3.5 Justify the risk in terms of the potential scientific yield and in relation to the anticipated benefits to the subjects.

The benefits of this study would be to find the most effective method of pain control which would not only decrease patient's pain but decrease their use of opioids. As opioids are a significant burden on society in terms of misuse, addiction, and even death. It is important we find ways to minimize postoperative pain and postoperative

opioid use.

Section 4 Subject Profile

4.1 How many people will need to go through the consent process (but not necessarily enroll) to get the data sets necessary? Subjects who go through the consent process are counted toward the total number of subjects approved by the IRB even if they have no further participation in the study (i.e. Drop out, are screened out, etc.)

Note that this is the number of subjects for which IRB approval will be granted.

Total: 80	Of the total requested indicate	Percent Male 0%	Percent Female 100%

4.1.1 Provide justification if all or more of one gender is targeted for participation

Hysterectomy

4.2. How many subjects are needed to enroll to get the data sets required to answer the research question? For multi-center trials provide the number enrolled locally.

Total: 60

4.3 if this is a multi-center study, provide the total number of subjects to be enrolled from all centers:

Total: n/a

4.4 Which of the following describe the subjects (check all that apply)

☒ Inpatients ☒ Outpatients ☐ Healthy volunteers ☐ Condition-matched controls

4.5 What is the age range of the subjects?

Exact Age Range: 18 to 99	See information below for required supplemental materials.

If age range includes	Required Supplemental Materials
0-7 years	Parental consent form and Appendix Y required
8-17 years	Child's assent, parental consent form and Appendix Y required

4.6 List the criteria for subject INCLUSION in this study:

- ASA physical status I-III
- Females >/=18-years of age
- Scheduled for laparoscopic/robot-assisted hysterectomy.

4.7 List the criteria for subject EXCLUSION from this study:

- Contraindication to surgical infiltration or regional blockade
- History of long term opioid intake (greater than 3 weeks prior to surgery) or chronic pain disorder
- Inability to understand the informed consent and demands of the study
- Surgery scheduled to start after 1700

4.8 Are children included or excluded from this study?

☐ **Included** – Appendix Y required – go to question 4.8

☒ **Excluded.** Provide Justification below

☒ No direct benefit to participation (exclusion of children permissible)

☐ Potential for direct benefit exists for adults only (i.e. disease/condition does not occur in children)

☐ Potential for direct benefit exists for children. Provide justification for exclusion of children:

Note Regarding Exclusion of Children

NIH guidelines advise that the exclusion be justified, so that potential for benefit is not unduly denied. Indicate whether there is potential for direct benefit to subjects in this study and if so, provide justification for excluding children.

Note: If inclusion of children is justified, but children are not seen in the PI's practice, the sponsor must address plans to include children in the future or at other institutions.

4.9 Indicate if the research includes or specifically targets the populations listed below for participation.

Inclusion of the populations below, either incidentally or by design, requires the investigator to provide additional information to the IRB. In some cases, such as the inclusion of prisoners, certification by the Office of Human Research Protection is required by federal regulations**. If, after final approval, the subject population pool changes to include any listed below, complete a Change in Protocol Form and complete any relevant appendices.**

Population group/description	Resources and Required supplemental materials
☐ Children	Appendix Y required. Review the University of Minnesota policy regarding Safety of Minors
☐ Pregnant women/fetuses/neonates	Appendix B required. See guidance at 45CFR46 subpart B and http://www.research.umn.edu/irb/guidance/women.html.
☐ Prisoners	Appendix C required. See guidance at 45 CFR 46 subpart C.

☐	Minority groups	Appendix I "Populations with Special Considerations" required.
☐	Groups with socioeconomic or educational disadvantage	Appendix I "Populations with Special Considerations" required.
☐	Non-English speakers targeted	Appendix I "Populations with Special Considerations" and consent forms in the language spoken by participants and an English translation.
☐	Non-English speakers included (i.e., non-English speakers will not be turned away)	See guidance regarding the short form consent process. Consent short forms in Arabic, Croatian, French, Hmong, Khmer, Lao, Oromo, Russian, Somali, Spanish and Vietnamese are available for download.
☐	Adults lacking capacity to consent and/or adults with diminished capacity to consent including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders and behavioral disorders.	Appendix I "Populations with Special Considerations" required.

Section 5 Study Location(s)

Indicate in the table below all of the locations where the research will take place.

	LOCATION	Required Supplemental Materials
☒	**Hospital/Clinic (specify below)**	
	☒ University of Minnesota Medical Center (UMMC) – Fairview, Amplatz ☐ Fairview Health Services (Southdale, Ridges, Lakes, Northland ☐ Gillette Children's Specialty Healthcare ☐ Clinical and Translational Science Institute (CTSI) ☐ University of Minnesota Physicians (UMP) Clinics (Oncology Clinic, Phalen, Family Medicine, etc.) ☐ Fairview Clinics (Maple Grove, Oxboro, Eden Center, etc.) ☐ TRIA Orthopedic Center ☐ Other, Specify:	
☐	**University Campus (Non-clinical location)**	
	☐ Minneapolis/St Paul ☐ Rochester ☐ Duluth ☐ Crookston ☐ Morris ☐ Other, specify:	
☐	**Veteran's Administration Medical Center**	Veteran Administration IRB approval

☐ **Center for Magnetic Resonance Research (CMRR)**	Submit Documentation of CMRR Safety Committee approval. CMRR users must submit the completed CMRR Device and Safety Review form to the CMRR prior to submission of their IRB application. A draft copy of the IRB application must be included for CMRR Safety Committee review. Documentation of approval by the CMRR Safety Committee will be provided to the researcher to include with the IRB application.
☐ **Elementary school/secondary school**	Submit Appendix M "Research in Schools" and appropriate documentation of approval from school district
☐ **University of Minnesota Child Care Center**	
☐ **Prison/Halfway House**	Submit Appendix C "Prisoners as Subjects"
☐ ☐ Federal Prison ☐ State Prison ☐ Halfway house, specify:	
☐ **International Location**	Submit Appendix K "International Research"
☐ **Sovereign Nation within United States borders**	Submit documentation of approval from sovereign nation
☐ **Military base or facility owned by any component of the Department of Defense**	Submit Appendix D "Department of Defense"
☐ **Nursing home, specify:**	Documentation of approval from site administrators
☐ **Community center, specify:**	Documentation of approval from site administrators
☐ **Research will be conducted online**	
☐ **Other, specify:**	

Section 6 Recruitment & Compensation

University of Minnesota policy prohibits researchers from accepting gifts for research activities. Research staff must decline any incentive (i.e. finders fees, recruitment bonus, etc.) offered by the study sponsor connected with subject enrollment or completion of the research study. For more information, please see Code of Conduct

http://www1.umn.edu/regents/policies/academic/Code_of_Conduct.pdf

6.1 Which of the statements below describes the recruitment strategy? If both apply, select both.

☐ Statement A. Potential subjects will self-identify based on response to an advertisement, flyer, presentation or respondent driven sampling. **If ONLY statement A selected, go to question 6.2**

☒ Statement B. Potential subjects will be recruited based on information contained in private/protected records (medical records, student records). This also includes subjects who will be recruited from the PI or Co-I's

patient population.

If statement B is selected, answer the questions 6.1.1. – 6.1.3 below

6.1.1 Explain how the researcher has legitimate access to these records.

The PI is a surgeon at the University of Minnesota

6.1.2 Identify who will make initial contact with potential subjects.

THe PI or Co-Investigators

6.1.3 Will the records include MEDICAL records?

☐ No, go to question 6.2

☒ Yes. Indicate the mechanism the PI will use to confirm that the patient has agreed to release their PHI contained in their medical record for research purposes; for example, the patient has documented consent to research on their treatment, intake or hospital admitting form. (MN Statue 144.334 Subd. 3; Access to Medical Records for Research)

☐ Academic Health Center Information Exchange (AHC-IE)

☒ Other. Describe: EPIC

6.2 Check the box(es) that describe the recruitment strategy. Any required documents as detailed below should be submitted with this application.

	Method	Required Supplemental Materials
☐	Flyers	Submit Flyer with application
☐	Newspaper ads	Submit draft of ad with application
☐	Radio or television ads	Submit script with application
☐	Social networking sites	Text, page mock up or description of posting including any images or videos Indicate site(s):
☐	Letters or emails	Submit letter or email with application
☐	Phone call	Submit phone script with application
☐	Group presentations	Submit outline of presentation and any materials provided to participants with application
☐	University of Minnesota research recruitment tool (e.g. REP, SONA or Carlson School Recruitment)	

☐ Non-University of Minnesota research recruitment tool (e.g. MTURK, Research Match)	
☒ Other method not described above	Specify: Patients will be identified in clinic. There they will be presented with the consent form and then on day of surgery they will sign final consent after speaking with the anesthesiologist.

6.3 Provide a brief narrative to describe the recruitment process. Include in the description how potential subjects will be informed of the research.

Patients will be identified in clinic. There they will be presented with the consent form and then on day of surgery they will sign final consent after speaking with the anesthesiologist.They will be able to ask quesitons in surgery clinic as well as on the day of surgery. A phone number will be made available so they can ask questions regarding the study prior to day of surgery as well.

6.4 Will gifts, payments, compensation, reimbursement, services without charge or extra credit be provided to the subject for participation in research?

☒ No If no, go to Section 7 Confidentiality and Privacy

☐ Yes Complete 6.4.1 – 6.4.4

6.4.1 Indicate the type of compensation and the maximum value a subject may receive during the course of his/her participation.

6.4.2 When will compensation be provided? Include in the response if payment for multiple visits is prorated and the compensation schedule

6.4.3 Who will receive the compensation?

☐ Subject

☐ Other, specify:

6.4.4 Will Research Experience Points (REP) be awarded?

☐ Yes

☐ No

Section 7 Confidentiality and Privacy

Confidentiality refers to how the subject's identifiable data will be handled, managed, stored, and, if applicable, disseminated.

Privacy refers to having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally or intellectually) with others

7.1. Will researchers maintain any identifiers (e.g. names, addresses, telephone numbers, etc.)?

☒ No. Go to question 7.13

☐ Yes.

7.2 Indicate which of the direct identifiers below will be maintained?

	☐ Full names	☐ Initials	☐ Photographs of participant
	☐ Telephone numbers	☐ Email address	☐ Videos of participant
	☐ Birth date	☐ Postal Address	☐ Other:

7.3 Why it is necessary to maintain direct identifiers?

7.4 Describe the coding system that will be used to protect against disclosure of these identifiers.

7.5 How long will the link between identifiers and code be maintained?

7.6 Could any disclosure of the participant's responses place the participant at risk of criminal or civil liability or could the disclosure be damaging to the participant's financial standing, employability, or reputation?

☒ No

☐ Yes Explain how the researcher will mitigate these risks (e.g. limiting access to identifiers, obtaining a Certificate of Confidentiality, etc.)?

7.7 Will the researcher obtain a Certificate of Confidentiality for this project?

☒ No

☐ Yes Documentation of Certificate of Confidentiality must be provided to the IRB when obtained.

7.8 How long will the identifiable data be maintained?

n/a

7.9 What format will be used to maintain the data (paper, digital, electronic media, video, audio or photographic)?

n/a

7.10 Where will data be stored?

All data will be stored on a password protected encrypted jump drive in a locked drawer in locked office.

7.11 What security provisions will be taken to protect the data (password protection, encryption, etc.)? See the University of Minnesota's Safe Computing recommendations

password protection and encryption

7.12 Will a copy of the consent form or other research study information be placed in the subjects' non-research records such as medical, employment or educational records?

☒ No

☐ Yes This information must be included the confidentiality section of the consent form**.**

7.13 Even if direct identifiers are not recorded or maintained, are there potential ethical or legal circumstances when it would be necessary to break confidentiality (e.g. requirements for mandated reporting)?

☒ No

☐ Yes This information must be included in the consent form. **Explain below the circumstances when breaking confidentiality is required.**

7.14 Describe the conditions under which interaction with subjects will occur (e.g., consent discussion occurs in a private room). Explain how these conditions adequately protect the PRIVACY interests of subjects.

consent discussion will occur in a private room as well as signing of the consent. All staff will undergo research training to ensure they protect privacy of the patients.

Section 8 Expedited Review Eligibility

Federal criteria for risk assessment make some studies eligible for Expedited Review (see 45 CFR46.110 and 21 CFR 56.110). Expedited review categories are below and may also be found at http://www.irb.umn.edu/expedited.html

Studies eligible for Expedited Review must meet the federal definition of minimal risk which is:

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.

8.1 What is the level of risk to subjects in this research study?

☒ **Greater** than minimal risk (full committee review required) – go to Section 9 Informed Consent Process

☐ **Not greater** than minimal risk.

Review the table in question 8.2 below and check the box next to the expedited review category the investigator asserts applies to this research.

Note: Final expedited review eligibility decisions are made by the IRB after initial review of the application. Studies involving drugs/biologics or devices are rarely eligible for expedited review.

8.2 Check the box next to the Expedited Review Categories (2-7) that apply to the proposed project. Per UMN IRB policy, clinical studies involving drugs or devices are not eligible for expedited review category 1.

Not available per UMN IRB policy	**1. Clinical studies of drugs and medical devices only when condition (1) or (2) is met.** 1. 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.) 2. 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.
☐ **Cat. 2**	**Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:** 1. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or 2. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
☐ **Cat. 3**	**Prospective collection of biological specimens for research purposes by noninvasive means.** Examples: 1. hair and nail clippings in a nondisfiguring manner; 2. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; 3. permanent teeth if routine patient care indicates a need for extraction; 4. excreta and external secretions (including sweat); 5. 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; 6. placenta removed at delivery; 7. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; 8. 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; 9. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; 10. sputum collected after saline mist nebulization.
☐ **Cat. 4**	**Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.** Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review,

	including studies of cleared medical devices for new indications.) Examples: 1. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; 2. weighing or testing sensory acuity; 3. magnetic resonance imaging; 4. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; 5. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
☐ **Cat. 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.)
☐ **Cat. 6**	**Collection of data from voice, video, digital, or image recordings made for research purposes.**
☐ **Cat. 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.)

Section 9 Informed Consent Process

Document the Elements of the Informed Consent Process

It is the responsibility of the investigator to assess comprehension of the risks and benefits of participation in the research and only enroll subjects who can demonstrate understanding of the research study (45 CFR 46.116). The federal regulations require that consent be in language understandable to the subject. If subjects do not comprehend English, translated consent forms are required, or the use of short forms with an oral explanation can be accepted.

Consent forms must be submitted for IRB review. It is highly recommended that researchers use the sample consent for template available on the IRB Forms page. Do not submit sponsor prepared forms without editing the form to include University of Minnesota IRB standard language and all essential elements of informed consent.

Resources for preparing consent forms are available at:
Informed Consent Online Tutorial – http://www.research.umn.edu/consent/

If the researcher is requesting a waiver of consent, complete questions 9.9 and 9.10 only. Be advised that waiver of consent is rarely granted.

9.1 Document the informed consent process timeline. Detail when consent will be discussed and documented in relation to research data collection, if there will be any waiting period or if process will occur over multiple contacts or clinical visits.

The consent will be discussed in the ciinic visit with the surgeon. They will be given a copy of the consent and a phone number to call if they have questions. Then on the day of surgery after they have had adequate time to

review the consent they will sign consent after discussion with the anesthesiologist (co-PI).

9.2 Will anyone not listed on this application obtain consent? Except in rare circumstances, all individuals who will obtain consent must be listed as research personnel on the IRB application so that basic human subjects' research training is documented. If in-person consent will not be obtained, select the option below and provide rationale.

☒ No If no, go to question 9.3

☐ Yes Explain who, other than those listed as personnel on this application, will obtain consent

☐ N/A In-person consent will not be obtained. Explain below:

9.3 Provide a brief description of the plan to train those individuals who will be obtaining consent from subjects to participate in this project.

all staff will complete CITI training.

Note: Everyone obtaining consent must complete CITI training.

9.4 Will all subjects consent for themselves?

☒ Yes If yes, adults lacking capacity to consent must be listed in the exclusion criteria (question 4.7).

☐ No If no, indicate below who, when appropriate, will provide consent

- ☐ Parent/guardian
- ☐ Legally authorized representative – **Appendix I required**

9.5 What questions will be asked to assess the subjects' understanding? Questions should be open-ended and go beyond requiring a yes/no response.

What are the benefits and risks of the tap or infiltration?

What are the benefits and risks of either local anesthetic medication?

How will your pain be managed post-operatively in both options of the study?

What are the alternative treatment options to control your pain post-operatively?

What will be done if you have an allergic reaction or reaction to the pain medication in this study?

9.6 Participation in research must be voluntary. Describe the steps taken to minimize the possibility of undue influence on potential subjects.

As the intervention we are providing two options which is the current standard of care, it is considered safe and efficacious. We will discuss the options, as well as the risks and benefits with the patient. No additional benefit is gained by the anesthesiologist if this technique is used and this will be discussed with the patient.

Care of Subjects in Case of Accident

If this research involves a potential for injury, injury compensation language must be included in the consent form (see 21 CFR 50.25). If a contract to pay for research-related injuries exists, the language in the consent form should not contradict the language in the contract.

9.7 Is there a potential for research related injury?

☐ No If no, go to question 9.8

☒ Yes If yes, indicate which of the following statements is included in the consent form

☒ **Non-Sponsor Funded Compensation**

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

☐ **Sponsor Funded Compensation**

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. The sponsor of the study has some funds available to pay for care for injuries resulting directly from being in this study. If you think that you have suffered a research related injury and that you may be eligible for reimbursement of some medical care costs, let the study physicians know right away.

☐ **If the preferred injury compensation language is unacceptable to the study sponsor, the following alternative language may be used:**

Under some circumstances the sponsor of the study will pay for care for injuries resulting directly from being in the study. If you want information about those circumstances or if you think you have suffered a research related injury let the study physicians know right away.

Waiving Documentation of Consent

Waiving written documentation assumes that there will be an informed consent process but signatures will not be collected on the consent form. The IRB may waive the requirement for written documentation under specific conditions.

9.8 Does the researcher wish to waive documentation of consent?

☒ No If no, go to question 9.9

☐ Yes If yes, check the statement below that applies to justify waiving documentation of consent. If neither statement applies, researcher may not request waiver of documentation

- ☐ The only record linking the subject and the research would be the consent form and the principal risk of the research would be the potential harm from a breach of confidentiality (the IRB may allow an option to sign or decline)
- ☐ The research presents no more than minimal risk and includes no procedures for which written consent is normally required outside the research context.

NOTE: Researchers requesting a waiver of documentation must submit a consent form without signature lines with the IRB application.

Waiving Consent

The IRB may, in some **rare and specific** circumstances, waive the requirement for consent in accordance with 45 CFR 46.116(d). Answer the questions below to determine if waiver of consent may be considered.

9.9 Does the researcher wish to waive consent?

☒ No If no, go to section 10 - Funding
☐ Yes Indicate if the following statements apply

The research involves no more than minimal risk to subjects.
☐ Yes
☐ No – **waiver may not be requested**

Granting a waiver will not adversely affect the rights and welfare of the subjects.
☐ Yes
☐ No – **waiver may not be requested**

The research could not practically be carried out without a waiver or alteration.
☐ Yes
☐ No – **waiver may not be requested**

If consent is waived, whenever appropriate the subjects will be provided with additional pertinent information after participation. **Describe below the process for providing subjects with this information.**

Section 10 Funding

10.1 Has funding for this project been applied for, requested or received or do you intend to request/apply for funding?

☐ **No** **Explain how the research will be conducted without funding:**

☒ **YES** Indicate in the table below who will provide/manage funds.

Funds provided/managed by	Required Supplemental Materials
☒ Internal University of Minnesota (departmental funds, internal grant program, etc.) Describe: Anesthesiology funds	none
☐ University of Minnesota Sponsored Project Funding	Appendix A required
☐ Non-University of Minnesota source or management	Appendix A required

Section 11 Conflict of Interest

Federal Guidelines emphasize the importance of assuring there are no conflicts of interest in research projects that could affect the welfare of human subjects. Reporting of financial interests is required from all individuals responsible for the design, conduct or reporting of the research. If this study involves or presents a potential conflict of interest, additional information will need to be provided to the IRB.

Examples of conflicts of interest may include, but are not limited to:

- A researcher participating in research on a technology, process or product owned by a business in which the researcher or family member holds a significant financial interest or a business interest.

- A researcher participating in research on a technology, process or product developed by that researcher or family member.
- A researcher or family member assuming an executive position in a business engaged in commercial or research activities related to the researcher's University responsibilities.
- A researcher or family member serving on the Board of Directors of a business from which that member receives University supervised Sponsored Research Support.
- A researcher receiving consulting income from a business that funds his or her research.
- A researcher receiving consulting income from a business that could benefit from the results of research sponsored by a federal agency (i.e. NIH).

11.1 Do any of the Investigators or personnel listed on this research project have a business interest or a financial interest of $10,000 or more ($5,000 or more if research is funded by a Public Health Service (PHS) agency or researcher is involved in clinical health care) associated with this study when aggregated for themselves and their family members?

☐ No

☒ Yes List the investigator(s) with conflicts:

Jacob Hutchins is on speakers bureau, consultant and has received research funds

11.2. Do any of the investigators or personnel (when aggregated for themselves and their family members) listed on this research have*:*

11.2.1 Ownership interests more than $10,000 ($5,000 if research is funded by PHS or researcher is involved in clinical health care) when the value of interest could be affected by the outcome of the research?

☒ No

☐ Yes List the investigator(s) with conflicts:

11.2.2 Ownership interests exceeding 5% interest in any one single entity (or any equity interest in a non-publicly traded entity if research is funded by PHS or researcher is involved in clinical health care)?

☒ No

☐ Yes List the investigator(s) with conflicts:

11.2.3 Compensation greater than $10,000 ($5,000 if research is funded by PHS or researcher is involved in clinical health care) when the value of the compensation could be affected by the outcome of the research?

☒ No

☐ Yes List the investigator(s) with conflicts:

11.3 Have all business or financial interests indicated above been reported?

☐ No

☒ Yes

☐ N/A There are no conflicts of interest on this study

- University of Minnesota researchers need to report business or financial interest online via the Report of External Professional Activities (REPA)
- Fairview Health System researchers need to complete the Fairview Health Services Conflict of Interest Disclosure forms and submit the completed forms to the Fairview Office of Research.
- Gillette Children's Specialty Healthcare researchers must contact the Director of Research Administration, at 651-229-1745.

The IRB will verify that a management plan is in place with the Conflict of Interest (COI) Program. If the COI Program does not have an approved management plan in place for this research, they will contact the individual(s) for additional information.

Final IRB approval cannot be granted until the IRB has reviewed the management plan and all potential conflict matters are settled. The IRB receives a recommendation from the Conflict of Interest Review Committee regarding disclosure to subjects and management of any identified conflict. The convened IRB determines what disclosure language should be in the consent form.

Section 12 Research Services, Assessment and Oversight

Section 12.1 RESEARCH COLLABORATIONS

12. 1 Does this research project involve collaborations with any sites or personnel outside of the University of Minnesota, its coordinate campuses, the Fairview Health Systems or Gillette Children's Specialty Healthcare?

☒ No Go to question section 12.2

☐ Yes **Briefly describe the collaboration (with whom and for what purpose):**

Additional requirements for ensuring appropriate IRB oversight may apply. These requirements are often dependent on whether or not the site/personnel is considered "engaged" in human subjects research according to federal definitions. Contact the UMN IRB office (irb@umn.edu) to determine how IRB oversight of the research activity with the external site/personnel should be address.

Section 12.2 AFFILIATED ENTITIES WITH OVERSIGHT RESPONSIBILITIES

12.2.1 Will this research use services, resources, or funding from the Clinical and Translational Science Institute? Examples include pilot funding, career development awards, biostatistics support, facilities, staffing, project management, regulatory assistance, or informatics consultation and support

☒ No **Go to question 12.2.2**

☐ Yes **Provide CTR Portal ID#**:

12.2.2 Does this research require Masonic Cancer Center Protocol Review Committee (CPRC) review?

The CPRC is required to evaluate, approve or reject, monitor, and re-review on an annual basis all University of Minnesota clinical cancer research protocols including those with non-therapeutic intent.

☒ No **Go to question 12.2.3**

☐ Yes Documentation of approval must be provided to receive final IRB approval.

12.2.3 Will this research utilize Gillette Children's Specialty Healthcare resources or medical records?

☒ No **Go to section 12.3**

☐ Yes If using Gillette resources, please contact:

Joyce Trost, PT
Research Administration Manager

Gillette Children's Specialty Healthcare
651-325-2339/651-312-3182/jtrost@gillettechildrens.com

12.2.4 Will this research use Magnetic Resonance (MR) Devices housed at the Center for Magnetic Resonance Research (CMRR) facilities?

☒ No **Go to section 12.3**

☐ Yes **Review and approval by the CMRR Safety Committee is required prior to IRB submission.**

CMRR users must submit the completed CMRR Device and Safety Review form to the CMRR prior to submission of their IRB application. A draft copy of the IRB application must be included along with the CMRR Device and Safety Review form for CMRR Safety Committee review. Documentation of approval by the CMRR Safety Committee will be provided to the researcher to include with the IRB application submission.

Section 12.3 PAYMENT FOR RESEARCH RELATED SERVICES

12.3. 1 Does the protocol require the use of tests, procedures, clinic space, clinic visits, professional fees, lab services, pharmacy services, or hospital services in order to answer the research question?

☐ No **Go to section 12.4**

☒ Yes

12.3.2 Will subjects or a third party be charged for research related procedures?

☐ No

☒ Yes **Explain:** These are standard of care and as such are charged to the patient as per routine

Provide written documentation from the FDA to charge for investigational products.

12.3.3 Will Services be provided by Fairview Health Service or U of M Physicians?

☐ No

☒ Yes Provide TASCS Number:

Provide a copy of the TASCS billing grid noting whether the study does or does not meet Medicare criteria for a Qualifying Clinical Trial.

Applications will not be assigned for review until the TASCS information is submitted.

CLINICALTRIALS.GOV REGISTRATION

Important Information about clinicaltrials.gov registration
Resources available, penalties for failure to register and publication requirements

Potential risks associated with failure to register with clinicaltrials.gov:

- Loss of funding (National Institute of Health)
- Financial penalty levied against the PI
- Denial of publication (ICMJE)
- Denial of payment to healthcare providers.

Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) establishes penalties for Responsible Parties who fail to comply with registration or results submission requirements. Penalties include civil monetary penalties and, for federally funded studies, the withholding of grant funds.

The International Committee of Medical Journal Editors (ICMJE) defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like.

Research projects that meet the ICMJE definition may not be accepted for publication if they are not registered in a registry that is electronically searchable and accessible to the public at no charge. For more information on this requirement see http://www.icmje.org Note that retrospective registration of projects is not allowed.

Additionally, healthcare providers are required to include the clinicaltrials.gov number on all claims during the time period the patient participates in the study.

The Clinical and Translational Science Institute (CTSI) will assist University of Minnesota investigators to comply with the registration requirement. Complete the section below to document status or determine if registration is required. Applications submitted without a Clinicaltrials.gov registration number (either received or pending) will be forwarded to the CTSI for review.

Section 12.4 CLINICALTRIALS.GOV REGISTRATION DETERMINATION

12.4.1 Is this project registered with clinicaltrials.gov?

☐ No **Go to 12.4.2**

☒ Yes	**Clinicaltrials.gov registration number:**pending If registration is pending enter "pending" in the space provided. **Section complete. Go to Section 12.5**

Does this project meet the Food and Drug Administration Amendments Act (FDAAA) definition of "applicable clinical trial"? Applicable clinical trials generally include controlled, clinical investigations of drugs and biologics; and controlled trials of devices that include health outcomes, including pediatric postmarket surveillance.

12.4.2 Is registration with clinicaltrials.gov required?

☐ No	**The PI understands the registration requirements and the consequences, as described above, of failure to register if applicable.** CTSI will review this application for concurrence with the PIs decision. CTSI will contact the PI and the IRB to confirm registration requirement. If registration is required, the PI may request assistance with this process from CTSI. **Go to Section 12.5**	
☐ Unsure	**CTSI will contact the PI and the IRB with a determination regarding the registration requirement. If registration is required, the PI may request assistance with this process from CTSI. Go to Section 12.5**	
☒ Yes	**Answer the questions below to determine who (either the PI or other entity) is responsible for registration with clinicaltrials.gov**	
	Is this study initiated by a University of Minnesota investigator?	☐ No ☒ Yes – registration by PI required.
	Is this study federally sponsored and the University of Minnesota is the only study site OR the study's coordinating center?	☐ No ☒ Yes – registration by PI required.
	Is a University of Minnesota investigator the holder of an Investigational New Drug (IND) application for the test article OR it has been determined the proposed use of the test article is IND exempt?	☒ No ☐ Yes – registration by PI required.
	Is a University of Minnesota investigator the holder of an Investigational Device Exemption (IDE) for the device being studied OR a non-significant risk (NSR) determination has been made for the device being studied?	☒ No ☐ Yes – registration by PI required.
	If registration is required, the registration number must be provided before final IRB approval is granted. Email ctsi@umn.edu for additional information and registration assistance. CTSI will evaluate all applications not registered with clinicaltrials.gov.	

Section 12.5 SCIENTIFIC ASSESSMENT

Research involving human subjects must be reviewed for sound scientific design prior to review by the IRB committee. Documentation of scientific assessment including the content of the review must be provided before the project will be reviewed by the IRB. Scientific assessment is not required for new studies that meet the federal criteria for expedited review. If a study is submitted for expedited review but is determined by the IRB to NOT meet the criteria for expedited review, then scientific peer review will be required before IRB review.

12.5.1 Has the IRB scientific assessment requirement been met?

☐ **N/A**	**Project qualifies for expedited review. Sections 12.5, 12.6 and 12.7 are not required if expedited review eligible. GO TO Section 13 Additional Staff.**

☒ **Yes**	Indicate below how the requirement has been met		Required supplemental materials
	☐ Option1	Reviewed by a **federal funding agency** (National Institutes of Health, National Science Foundation, etc.) employing peer review mechanisms for awarding of funding.	
	☐ Option 2	Reviewed by a **nationally based non-federal funding agency** (March of Dimes, American Academy of Pediatrics, etc.) employing peer review mechanisms for awarding of funding	*Note: industry-sponsored clinical trials designed by the sponsor with or without external consultants do not satisfy this criterion for independent peer-review.*
	☐ Option 3	Reviewed by **locally constituted mechanisms using peer review** for awarding of funding, or for permission to use resources: Cancer Protocol Review Committee (CPRC); CTSI funded pilot awards; Vikings; departmental peer review etc.	Attach the review and the signed form documenting that departmental or collegiate peer review of the research protocol has been performed.
	☒ Option 4	Reviewed by HRPP facilitated Scientific Assessment committee	Submit approval notification with application.

Section 12.6 DATA AND SAFETY MONITORING PLAN

A data and safety monitoring plan (DSMP) is meant to assure that each clinical investigation has a system for oversight and monitoring of the conduct of the clinical investigation. This oversight is intended to ensure the safety of the participants and the validity and integrity of the data. A DSMP should be commensurate with the risks.

A DSMP can be as simple as the investigator reporting adverse event information to the IRB. A DSMP can be as complex as having a Data and Safety Monitoring Board.

A DSMP can include clinical trial monitoring. Clinical trial monitoring refers to the methods used to oversee the conduct of, and reporting of data from, clinical investigations including appropriate clinical investigator supervision of study site staff. Monitoring activities include communication with the investigator and the study site staff; review of the study site's processes, procedures, and records; and verification of the accuracy of the data.

12.6.1 In addition to the Principal Investigator, are there other DATA monitoring entities responsible for this function? Select all that apply.

☒ **No, the PI is the only entity monitoring DATA.**
☐ **Yes** ☐ **A review entity will provide ongoing DATA monitoring**

- ☐ **Clinical and Translational Science Institute (CTSI)**
- ☐ **Data coordinating center or project principal investigator (multi-center studies)**
- ☐ **Commercial sponsor, contract research organization (CRO)**

☐ **Other:**

12.6.2 In addition to the Principal Investigator, are there other SAFETY monitoring entities responsible for this function? Select all that apply.

☒ **No, the PI is the only entity monitoring SAFETY.**

☐ **Yes** **Select all below that apply**

☐ **A Data Safety Monitoring Board (DSMB) will be appointed.**

When established, the list of the DSMB members including their affiliation and credentials and the DSMB charter must be submitted to the IRB. A description of the DSMB must be provided with the application.

A Data and Safety Monitoring Board (DSMB) is an independent group of experts that advises the study investigators. Primary responsibilities of a DSMB are to 1) periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy, and 2) make recommendations concerning the continuation, modification, or termination of the trial. The DSMB considers study-specific data as well as relevant background knowledge about the disease, test agent, or patient population under study.

The DSMB reports should be provided to the IRB as they are received.

☐ **Medical Monitor**

☐ **Cancer Center Data Safety Monitoring Council**

☐ **Other, describe:**

Section 12. 7 DATA AND SAFETY MONITORING RESPONSIBILITIES

Data to be monitored	PI	Review entity	DSMB/other	Unassigned
Study Safety (e.g., collection, reporting, and management of AEs, SAEs, and other study risks).	☒	☐	☐	☐
Data Accuracy & Quality Assurance (e.g., data collection, entry, transmission and analysis).	☒	☐	☐	☐
Trial Management (e.g., site coordination, enrollment and population distribution).	☒	☐	☐	☐
Regulatory Issues (e.g., SAE reporting, IRB Actions, disclosures of conflict of interest).	☒	☐	☐	☐
Interim Analysis.	☒	☐	☐	☐

It is the investigator's opinion that this protocol does not require a data safety monitoring plan. Provide justification:

Section 13 Additional Research Staff

Co-Investigators

Co-Investigators, responsible for knowing and following the protocol, should be listed below. Include any individual who will have responsibility for the consent process, direct data collection from subjects, or follow-up.

Note: If emailing this application to the IRB, all co-investigators must be cc'ed on the submission email.

Co-Investigator Name (Last name, First name MI):	Highest Earned Degree:
Argenta, Peter,	MD

Affiliation and contact information

☒ University of Minnesota (complete contact info section 1 only)
☐ Gillette (complete contact info section 2 only)
☐ Fairview (complete contact info section 2 only)
☐ Other (complete contact info section 2 only)

Required Contact information **Section 1 - U of M only**	**U of M Internet ID (x.500):**	argenta
	U of M Employee/student ID Number:	
	University Department:	Department of Obstetrics, Gynecology and Women's Health, Division of Gynecologic Oncology

Required contact information **Section 2 Non-U of M only**	**Address:**	**Phone number:** ☐ Mobile ☐ Pager ☐ Office **Email address:**

Occupational Position:

☒ Faculty ☐ Physician ☐ Staff ☐ Student ☐ Other:

Project responsibilities:

☒ Obtain consent from subjects ☒ Provide access to patient population ☐ Other:

Conflict of Interest:

Does this person have a reportable conflict as defined in Section 11 of the application?

☐ Yes ☒ No

Required CITI Human Subjects Training	**HIPAA TRAINING**
Date CITI completed (either initial or refresher course): Note: The IRB requires researchers to complete refreshers courses every three years after completion of initial course. For more information on training requirements see IRB Training	Check box below if HIPAA training is required. ☒ HIPAA Required – Data contains PHI HIPAA Training completed through: ☒ UMN ☐ Other:

Signature/Digital signature/x.500 of Co-PI	Title of Co-PI

Co-Investigator Name (Last name, First name MI):	Highest Earned Degree:
Hutchins, Jacob	MD

Affiliation and contact information

☒ University of Minnesota (complete contact info section 1 only)
☐ Gillette (complete contact info section 2 only)
☐ Fairview (complete contact info section 2 only)
☐ Other (complete contact info section 2 only)

Required Contact information **Section 1 - U of M only**	**U of M Internet ID (x.500):**	hutc0079
	U of M Employee/student ID Number:	2182198
	University Department:	Anesthesiology

Required contact information **Section 2 Non-U of M only**	**Address:**	**Phone number:** ☐Mobile ☐ Pager ☐Office **Email address:**

Occupational Position:

☒ Faculty ☐ Physician ☐ Staff ☐ Student ☐ Other:

Project responsibilities:

☒ Obtain consent from subjects ☒ Provide access to patient population ☐ Other:

Conflict of Interest:

Does this person have a reportable conflict as defined in Section 11 of the application?

☒ Yes ☐ No

Required CITI Human Subjects Training Date (Month/Year) CITI completed (either initial or refresher course): 4/14 Note: The IRB requires researchers to complete refreshers courses every three years after completion of initial course. For more information on training requirements see IRB Training	**HIPAA TRAINING** Check box below if HIPAA training is required. ☒ HIPAA Required – Data contains PHI HIPAA Training completed through: ☒ UMN ☐ Other:

hutc0079	MD
Signature/Digital signature/x.500 of Co-PI	Title of Co-PI

Research Staff

Research staff, including study coordinators, responsible for knowing and following the protocol, should be listed below. Include any individual who will have responsibility for the consent process, direct data collection from subjects, or follow-up.

Study Staff Name (Last name, First name MI): **Cohen, Melissa**	**Highest Earned Degree:**

Affiliation and contact information

☒ University of Minnesota (complete contact info section 1 only)

☐ Gillette (complete contact info section 2 only)

☐ Fairview (complete contact info section 2 only)

☐ Other (complete contact info section 2 only)

Required Contact information	**U of M Internet ID (x.500):**	cohen045

Section 1 - U of M only	**U of M Employee/student ID Number:**	
	University Department:	Anesthesiology

Required contact information **Section 2 Non-U of M only**	**Address:**	**Phone number:** ☐Mobile ☐ Pager ☐Office **Email address:**

Occupational Position:

☐ Faculty ☐ Physician ☒ Research Coordinator ☐ Staff ☐ Student ☐ Other:

Project responsibilities:

☒ Obtain consent from subjects ☐ Other:

Conflict of Interest: Does this person have a reportable conflict as defined in Section 11 of the application?

☐ Yes ☒ No

Should This Person Be Copied on All Correspondence? ☒ Yes ☐ No

Required CITI Human Subjects Training Date (Month/Year) CITI completed (either initial or refresher course): Note: The IRB requires researchers to complete refreshers courses every three years after completion of initial course. For more information on training requirements see IRB Training	**HIPAA TRAINING** Check box below if HIPAA training is required. ☒ HIPAA Required – Data contains PHI HIPAA Training completed through: ☒ UMN ☐ Other:

Study Staff Name (Last name, First name MI): **Bryant-Huppert, Joe**	**Highest Earned Degree:** **MS**

Affiliation and contact information

☒ University of Minnesota (complete contact info section 1 only)

☐ Gillette (complete contact info section 2 only)

☐ Fairview (complete contact info section 2 only)

☐ Other (complete contact info section 2 only)

Required Contact information	**U of M Internet ID (x.500):**	hupp0037
Section 1 - U of M only	**U of M Employee/student ID Number:**	2973892
	University Department:	Anesthesiology, Medical student at Medical school

Required contact information **Section 2 Non-U of M only**	**Address:**	**Phone number:** ☐Mobile ☐ Pager ☐Office **Email address:**

Occupational Position:

☐ Faculty ☐ Physician ☐ Research Coordinator ☐ Staff ☒ Student ☐ Other:

Project responsibilities:

☐ Obtain consent from subjects ☒ Other: asssist with data collection

Conflict of Interest: Does this person have a reportable conflict as defined in Section 11 of the application?

☐ Yes ☒ No

Should This Person Be Copied on All Correspondence? ☒ Yes ☐ No

Required CITI Human Subjects Training

Date (Month/Year) CITI completed (either initial or refresher course):

07/15

Note: The IRB requires researchers to complete refreshers courses every three years after completion of initial course. For more information on training requirements see IRB Training

HIPAA TRAINING

Check box below if HIPAA training is required.

☒ HIPAA Required – Data contains PHI

HIPAA Training completed through:

☒ UMN

☐ Other: