Date: Saturday, December 04, 2021 2:45:07 PM
View: 01-00 Study Information

Print Close

## 1.0 Study Information:

**1.1** * **Short Title:** ICE T for post GYN surgery pain

*The Short Title Should be the sponsor protocol number. If there is no sponsor protocol, then enter 3-5 words or numbers that capture the important study characteristics and help identify the study.*

**1.2** * **Full Title of Research Project:**
"ICE-T" Postoperative Multimodal Pain Regimen Compared to the Standard Regimen in Laparoscopic Gynecologic Surgery: a Randomized Controlled Trial

Enter the Full Title of the study.

**1.3** **Principal Investigator:** Robert Pollard

**HSR Certification Status:** Certified **HSR Certification Expiration Date:** 1/13/2023 ;

**COI Expire Date:** 7/16/2022 ; **COI Yes or No:** No ; **COI Management Plan:** ; **PI Non-Compliance:** Yes

The PI must be a MetroHealth Staff person or have privileges to practice at MHS. The PI must assume full responsibility for the conduct of the study.

**1.4** **Key Personnel:**

| | Name | CREC Status | CREC Expiration | COI | COI Expire | Management Plan? | Study Roles | Employer Name | Non-Compliance |
|---|---|---|---|---|---|---|---|---|---|
| View | Sarah Sears | Certified | 6/17/2022 | no | 11/4/2022 | | Co-investigator | The MetroHealth System | |
| View | Rozina Aamir | Certified | 12/10/2024 | no | 5/4/2022 | | Research Support Staff Interviewer (Survey, Focus Group) | The MetroHealth System | |

Add additional Staff as needed.

Update to add Study Roles

If using Epic, add role of DRA to one person

| | Name | CREC Status | CREC Expiration | COI | COI Expire | Management Plan? | Study Roles | Employer Name | Non-Compliance |
|---|---|---|---|---|---|---|---|---|---|
| View | Ryan Darvish | Certified | 6/28/2023 | no | 7/10/2021 | | eIRB Notification Recipient<br>Study Coordinator<br>Co-investigator<br>Interviewer (Survey, Focus Group)<br>eIRB Notification Recipient<br>Obtaining Informed Consent<br>Co-investigator<br>DRA (only one) | The MetroHealth System | |
| View | Linda-Dalal Shiber | Certified | 6/21/2022 | no | 7/7/2022 | | Interviewer (Survey, Focus Group)<br>eIRB Notification Recipient<br>Obtaining Informed Consent<br>Co-investigator | The MetroHealth System | yes |
| View | Nicole Findlay | Certified | 1/30/2024 | no | 7/2/2022 | | Co-investigator | The MetroHealth System | |

**1.5 Type of Research:**
Clinical Drug Trial

**1.6 If "Other" Type of Research Please Explain:**

View: 01-01 Study Information

**1.1 Study Information:**

**1.7 * Department-What Department approvals are required?**
Name
Obstetrics/Gynecology

**1.9 Definitions to keep in mind when selecting the degree of risk:**

**Minimal Risk is defined in 45CFR46 and in FDA regulations 21CFR50.3 as:**
*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

*** Degree of Risk: (This is the investigator's assessment of the risks involved in the research which will informed the IRB Decision but which will not automatically be accepted. The Board is the final arbiter of risk. The risk level will be set by the IRB staff at the time of approval.)**

Select most appropriate one.

Name

- (●) Risk
- ( ) Not Greater Than Minimal Risk

**1.10 * Type of IRB Review Requested:**
Full Board

*Select one. If you select Exempt or Expedited you will be taken to that section when you hit continue.*

View: 01-02 Study Information

**1.2 Study Information:**

**1.11** **Will you require access to Epic to conduct this study?** ◉ **Yes** ○ No

If you answer this question yes you will need to identify a Designated Records Administrator one person only.

***The DRA's employee number must be listed on their registration form.***

**Please add the role of "DRA" to one study staff member on page 1 of the application.**

**1.12** **Is the Principal Investigator a resident or trainee?**

Please check yes or no.

○ Yes ◉ **No**

*NOTE: Residents, Fellows, and non-MHS Personnel cannot be listed as the Principal Investigator*

View: 01-03 Study Information

**1.3 Study Information:**

**1.13** * **Will CRU Be Used:**

*Will the CRU be used?*

No *If you answer yes to this question this application will be sent to the CRU for review after departmental review and before it is submitted to the IRB.*

**1.14** * **Has this research protocol ever been submitted to another CASE affiliated IRB (i.e. UH, CCF, VA or CASE)?**

If this study has been reviewed at another CASE affiliated IRB

| | | |
|---|---|---|
| | No | you should answer yes. |
| **1.15** | **If yes, was it:** | Select one from drop down menu. |
| **1.16** | **Please supply the following information: At which institution was it approved? If it was disapproved, why was it disapproved?**<br><br>**Please attach the Approval letter/letters from other IRBs (i.e. UH, CCF, VA or CASE):**<br>Name Description<br>There are no items to display | *What institutions have approved this study. If it has been disapproved, please give a brief explanation of why study was disapproved.*<br><br>*Please attach approval letter/letters.* |
| **1.17** | | |

View: 01-04 Study Information

**1.4 Study Information**

**These Questions are specifically about the adequacy of resources, are there the necessary resources to complete this study? There are two questions which focus on nursing resources. If this research will require the use of nursing resources then the Nursing Resources Form found on the IRB Home Page under forms and templates will need to be completed and attached to this research application.**

| | | |
|---|---|---|
| **1.18** | **Can you assure the IRB that there are adequate numbers of qualified staff to conduct this research?**<br>◉ **Yes** ○ No | Please answer yes or no. This is an assurance to the IRB. |
| **1.19** | **How will the investigator ensure that persons assisting with the research were adequately informed about the protocol and their research-related duties and functions and requirements for maintaining the confidentiality of all data?**<br>**All co-investigators will be informed about their roles in the study prior to its commencement. All data that is included in this study will be de-identified and stored in a Redcap that will be accessible in the MetroHealth Urogynecology office.** | i.e. investigator meeting, formal protocol review with PI, monitor, sponsor. |
| **1.20** | **Will the PI and study staff have sufficient time to conduct and complete the research?** | Please answer yes or no. This is an assurance to the IRB. |

◉ **Yes** ○ No

**1.21 What facilities are available to conduct the research? Are they adequate? Please describe.**

The facilities include the the clinic and/or preoperative area where patient consents will be obtained, the post operative area, electronic medical records, post surgical floors where visual analog scores will be obtained. Patients will then receive post operative phone calls. The facilities are adequate.

Please describe the facilities, i.e. lab, procedure room, chemo treatment room.

**Nursing Resources:**

**1.22 Is this study using MetroHealth staff nurse time or labor ? (i.e. giving medcations, teaching, or additional documentation)**

This is in addition to the time of the study/research nurse.

○ Yes ◉ **No**

**1.23 Attach Nursing Resources Form here:**

*Click here for Nursing Resources form*

*Open the form, Complete the form and save it to your files then attach it to the study by hitting the browse file and selecting the file and hitting OK.*

*Click here for the MHS Policy*

View: 04-00 Scientific Review

**4.0 Scientific Review:**

***All Studies need a Science Review. Has your study been reviewed by any of the following?***

**4.1 Please Check all that Appy to this study so that the IRB may make a determination if there needs to be further scientific review:**

Select all that apply. Note FDA Approval does not equal science review.

Review Type

- [ ] Initiated and sponsored by industry under an IND, IDE, HDE, or 510K exemption issued by the FDA for which no scientific integrity concerns were identified during the FDA review process
- [ ] Trial initiated and sponsored by industry that has undergone a scientific merit review by the sponsoring agency, but is not being conducted under an IND, IDE, HDE, or 510K exemption
- [ ] Sponsored by a Cooperative Group
- [ ] Proposed research has been awarded funding by a federal agency
- [ ] Peer reviewed by a federal funding agency and received a favorable funding score
- [ ] Peer reviewed by a federal funding agency with the acknowledgment of scientific merits, but not likely to be funded for reasons unrelated to scientific merit
- [ ] Sponsored by a foundation or a private agency that requires a separate scientific merit review process at the sponsoring agency
- [ ] No Science Review

**4.2 Do any of the following apply to your study? Please check all that apply:**

Check all that apply your answers will assist the IRB in deciding if further science review is necessary.

Additional Reasons Why Science Review May Be Required

Investigator-initiated study

**4.3 Does this study require review by the Biosafety Committee?**

All studies involving vaccines, potentially hazardous materials or genetic research must go to the biosafety committee at CASE.

No

**4.4 Does this study require review by the Radiation safety committee?** No

If a study involves more than routine exposure to radiation on the part of subjects the study must go to the radiation safety committee.

**4.5 Does this study require Review by the Nursing Committee?**
No

The nursing committee must review all studies where the PI is a nurse, and all studies which have as the primary objective to contribute to nursing knowledgebase, and/or have implications for nursing practice.

View: 05-00 Funding Information I

**5.0 Funding Information I:**

**All Research Projects must have an identified funding source!**

**5.1 Is this research externally funded?** No

*Check one*

*Research can be both externally and internally funded so you can answer yes to both 5.1 and 5.6.*

**5.2 Types Of External Funding:**
Name
There are no items to display

Check all that apply.

**5.3 If other, external funding please explain:**

If other please describe.

**5.4 Sponsor Information:**
Name Sponsor/Agency Address Telephone FAX Contact Person
There are no items to display

Please supply this information as your application can not be processed without it.

**5.5 Have you received and/or submitted a Notice of Award or Contract?**

*Select one from drop down menu.*

*Attach notice of award.*

**If yes, attach your Notice of Award letter here (not your grant):**
Name Version
There are no items to display

View: 05-01 Funding Information II

**5.1 Funding Information II**

**5.6** ***Is Research Internally Funded (internal funding is any MetroHealth System or MetroHealth Foundation funds):***

*Check one, research can be both externally and internally funded so you can answer yes to both 5.1 and 5.6.*

◉ ***Yes*** ○ *No*

**5.7** **Internal Funding Sources List:**
Internal Funding Source
Department Operating Budget

Check all the apply.

**5.8** **If a MetroHealth Foundation funds or any MetroHealth System funds are being used, has department approval been received?**
◉ **Yes** ○ No

Check yes or no.

**5.9** **If a MetroHealth Foundation funds or any MetroHealth System funds are being used indicate the Account Number:**

Please enter the account number if this applies.

**5.10** *** Are there current Conflict of Interest Forms for all Key Personnel? [It is the responsibility of the Principal Investigator to ascertain this information and check this box.]**
◉ **Yes** ○ No

*This question is not asking if there are COI forms for all Key Personnel it is asking if all Key Personnel have current COI forms so that any SFI is reported and can be dealt with if a management plan is need or reporting to NIH is required.*

*In order to submit a new protocol all COI Forms for key personnel and investigators must be current = provide up to date information.*

**5.11** **Please check below any Conflicts of Interest (Financial) you as Principal Investigator or your study staff [Co-Investigator, Coordinators, Other Study Staff] may have on this Study:**
Potential Conflict of Interest
None of the above options apply and there are no other financial conflicts of interest in the conduct of this research.

*This question pertains to this study and is not a general question. Check all that apply.*

*You and/or your study staff will need to file a Conflict of Interest Disclosure Form annually.*

*If anyone working on this study has a Conflict of Interest or a perceived conflict. This information will need to be included in the consent form i.e. company is paying MHS to do this study.*

**5.12** **Please attach a copy of your grant application here:**
Name Description
There are no items to display

*You must attach a copy of your grant application here (i.e. NIH Grant Application).*

*You have the option to attach a copy of the budget, clinical trial account authorization form, contract and Approval letter(s) now or you can email them to your grants management specialist in the RABO office.*

*Copies of all RABO forms are available at:*

*http://www.metrohealthresearch.org/raboforms.html*

View: 06-00 Performance Site Information

**6.0 Performance Site Information:**

**6.1 At what sites will the study team be performing this research, (please enter information about all non-MHS sites in 5.2):**

Name

The MetroHealth System

Select all that apply. If you select other please enter information about that site in question 6.2.

**If this study is being done at MetroHealth where is it being done give the physical location (i.e. 8B, ED, Broadway, Old Brooklyn, PICU, Cath Lab):**

MetroHeath Main Campus Pre-OP OR, PACU, Postoperative Units, i.e. 8B, 8C.

*Where is the research going to be done? What physical location on the Main campus or the community health centers?*

**6.2 Please provide information about other external sites here:**

Name of Site | Address | Telephone Number

There are no items to display

Please enter contact information. Please include name of facility, address and department.

**6.3 If you are doing this research at an external site does this site have an IRB?**

○ Yes ◉ **No**

Select yes or no.

**6.4 If the External Site has an IRB will that IRB defer review to the MHS IRB?**

○ Yes ◉ **No**

This only applies if there is no IRB or if there is a legal agreement between

institutions permitting a reciprocal review, i.e. CASE.

**6.5 Attach letter from external site agreeing to permit the MHS to review this protocol:**

Attach letter.

Name Description

There are no items to display

**6.6 Has the external site granted permission for the research to be conducted?**

○ Yes ◉ **No**

This applies to sites where there is no IRB and the investigator must get a letter from the site that gives permission to conduct the research at the site.

**6.7 Attach letter from external site granting permission for the research to be conducted:**

Attach letter of support.

Name Description

There are no items to display

View: 06-01 Performance Site Information

**6.1 Performance Site Information**

**6.8 Is MHS the lead institution of a multi-site study?** ○ Yes ◉ **No**

Please answer yes or no.

**6.9 If yes, is there a plan to communicate information obtained through research that might be relevant to the protection of human subjects, including a plan to provide the IRB with information on unanticipated events, interim results, and protocol modifications.**

Please answer yes or no.

○ **Yes** ○ **No**

**6.10 Please give a detailed explanation of the above plan:**

This plan must give the IRB enough information to decide if

the plan is appropriate and adequate.

**6.11 Will the Principal Investigator conduct this study at any location outside the United States of America?**

○ Yes ◉ **No**

Answer these questions only if there are research sites outside the USA.

**6.12 Country, City, and address:**

Country | Address of Research Facility

There are no items to display

Give country and location.

View: 07-00 Research Objectives and Background

**7.0 Research Objectives and Background:**

**7.1 * ABSTRACT: Please give the IRB a 500 word Abstract that contains the specific objectives of the study.**

The purpose of this randomized controlled trial is to determine whether, "ICE-T," a multimodal postoperative pain regimen composed of around the clock ice packs, toradol, and tylenol, has improved pain control compared to the standard narcotic based postoperative pain regimen in patients undergoing total laparoscopic gyn surgery.

This is your abstract also known as a synopsis from an industry sponsored study. Please limit to 500 words.

**7.2 * What are the specific aims of this study i.e. what are the question(s) this research intends to answer? Provide at a maximum 3 primary and 3 secondary aims.**

**HYPOTHESIS: "ICE-T" (around the clock Ice packs, toradol, tylenol) postoperative pain management protocol leads to improved patient perception of pain compared to the standard post operative pain regimen (primary outcome).**

**PRIMARY OUTCOMES: Visual Analog Scores (VAS) Scores in the morning of post op day 1.**

**SECONDARY OUTCOMES:**
**-VAS Scores at 4 hours post surgery**
**-VAS Scores Post Op day 1**
**-Quality of Recovery scores on post op day 1**

This is your Hypothesis also know as your aims (NIH) or safety and efficacy aims (industry). Please list no more than 3 primary and 3 secondary clearly label these aims primary and secondary.

**-Satisfaction scores in the morning after surgery (~7AM)**
**-Satisfaction scores 4 days after surgery**
**-Length of stay**
**-Hemoglobin difference preop/postop**
**-Total dose of opioids administered during hospitalization in morphine equivalents upon hospital discharge.**
**-Postoperative nausea and vomiting post op day 1 of surgery, dizziness, headache, blurry vision, pruritus, drowsiness within the first day after surgery**
**-Time to first void**
**-Incidence of urinary retention (discharge home with foley)**
**-Time to first bowel movement (patients will ask to record this and there will be follow up via phone call if patient is not hospitalized on post op day 1 and post op day 4 after surgery.**
**Statistical analysis will be performed using statistical software.**

**7.3 Please provide a summary of the present knowledge relevant to the research and make citation to any applicable scientific literature:**

*This is your literature search and bibliography. Also known as Background and significance (NIH) or Introductory Section from industry sponsored trial.*

In a recent study performed here at Metrohealth (IRB16-00498) that evaluated postoperative pain control after vaginal reconstructive surgery, ICE-T a novel post op pain regiment was compared to the mainstay of therapy which was opioid driven and was shown to decrease perception of post OP pain. Generally, postoperative pain control in gynecologic surgery has been opioid driven, frequently involving multiple narcotics for analgesia, resulting opioid related complications, including nausea, vomiting, constipation, urinary retention, and central nervous system side effects. In an effort to combat opioid use in gynecologic surgery, multimodal therapy has been gaining momentum with goals of improved pain control and decreased opioid requirements . Ice packs, toradol, and acetaminophen have been used in various trials to decrease postoperative opioid requirements in various surgeries.
Ice packs have been shown to be effective in the treatment of postoperative pain after abdominal midline incisions . A Cochrane Review of patients subject to post vaginal delivery perineal cooling included 10 randomized controlled trials with 1825 patients with some evidence that local cooling in the form of ice packs, cold gel packs, cold/ice backs may be effective in pain relief . Toradol has been extensively studied in a multitude of surgeries including spinal, obstetric, orthopedic, urologic, and gynecologic. It has been administered preemptively, intraoperatively, and postoperatively for pain control with evidence that toradol decreases postoperative subjective pain scores and decreased narcotic use. Acetaminophen is mainstay for postoperative pain control as part of multimodal pain regimens to complement other, opioid sparing medications in a multitude of

surgeries including abdominal hysterectomy . Therefore, the purpose of this randomized controlled study is to determine whether, “ICE-T” a multimodal postoperative pain regimen composed of around the clock ice packs, toradol, and tylenol, has improved pain control and decrease opioid intake compared to the standard postoperative pain regimen in patients undergoing laparoscopic gyn surgery.

**7.4 Option to Upload Documents related to question 7.3:**

If it is easier to attach your response to question 7.3 please do so here. *Please limit to three pages.*

Name | Description

Citations | History

View: 08-00 Methods and Procedures I

**8.0 Methods and Procedures I:**

**8.1 Will this research involve the following Social-Behavioral Procedures:**

Check all that apply.

Name

Surveys/Questionnaires

**8.2 Will this research involved any of the following Medical Procedures/Considerations:**

Check all that apply.

Name

Investigation/Approved drugs

Clinical Assessments (EEG, EKG, SCID, etc.)

**8.3 Identify Data Collection types for this study:**

*Check all that apply.*

*Note if you are doing, recordings, Video-Recording/Photographs then subjects will need to sign the MetroHealth Audio-Video Consent form. See the IRB Forms and Templates.*

Name

Chart Review - Prospective

Interviews, questionnaires or psychological tests

View: 08-01 Methods and Procedures II

**8.1 Methods and Procedures II:**

**8.4 * Please specify in detail the methods and procedures that are involved in this research:**

If this field is not completed your protocol will not be reviewed. Do not enter N/A. Please describe what

EXPERIMENTAL DESIGN AND METHODS:

IRB approval will be obtained at MetroHealth Medical Center. This will be a

randomized controlled trial that will be conducted at MetroHealth Medical Center. Preoperative written consents explicitly explaining the risks and benefits of the study will be obtained from the patients. Once patients are selected and consents are obtained, they are randomized into the active and control group using computer generated randomization with sequentially numbered opaque sealed envelopes. Intraoperatively, duration of anesthesia, duration of surgery, estimated blood loss, intraoperative medications are recorded for each type of surgery.
Depending on what postoperative regimen patients will be randomized to they will be given one of the following after surgery:

Regimen #1 “ICE-T” Opioid Sparing Regimen
At the end of surgery patients will receive 30mg of intravenous (IV) toradol.
Once out of the post anesthesia care unit (PACU) patients will receive
1. ICE PACKS applied to the surgical sites every hour for 20 minutes Around the clock (ATC) until discharge.
2. 6 hours from the time of first dose of surgery patients will receive 30mg of IV toradol ATC until discharge.
3. Once out of the PACU will receive 1 gram of Tylenol per os (PO) every 6 hours for a total of 4 grams daily ATC until discharge
4. Patients will receive dilaudid 0.2mg IV every 3 hours as needed (PRN) for breakthrough pain.
5. Patients will be discharged home with (PO) Tylenol and PO toradol as needed (PRN).

Regimen #2 STANDARD Postoperative Regimen
1. Once out of the PACU patients will receive “Standard” postoperative regimen
2. Motrin 600mg PO every 4 hours PRN pain scale 1-3 pain
3. Percocet 1 tab PO every 4-6 hours PRN pain scale 4-6 pain
4. Percocet 2 tabs PO every 7-10 hours PRN pain scale 7-10 pain
5. Patients will receive dilaudid 0.2mg IV every 3 hours PRN for breakthrough pain.
6. Patients will be discharged home with Motrin and Percocet for pain PRN.

-Specific gyn procedures that patients will undergo, but are not limited to:

• Laparoscopic hysterectomy, for uterus 250 g or less
• Laparoscopic hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
• Laparoscopic hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele
• Laparoscopic hysterectomy, for uterus 250 g or less; with repair of enterocele

methods and procedures will be involved in this research.

• Laparoscopic hysterectomy, for uterus greater than 250 g
• Laparoscopic hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
• Laparoscopic hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele
• Laparoscopic hysterectomy, for uterus greater than 250 g; with repair of enterocele

**8.5 Does this study only involve the use of existing/retrospective data/specimens?**
**No**

Check yes or no.

**8.6 Describe in <u>detail</u> the study design also known as the experimental flow. Include all study procedures a subject will go through, in order of sequence and timing, including frequency of visits, duration of visits, length of subject participation etc. *Please Note this needs to be written for an educated person who is not an expert in the field, do not exceed 300 words*:**

Once patients are selected and consents are obtained, they are randomized into the active and control group using sequentially numbered opaque sealed enveloped that are developed by statisticians at Case Western University.

Once randomized, patients they will be given one of two postoperative pain regimens as described above. 4 hours after surgery the visual analog scale (VAS) score will be obtained by the study investigators. This should take a minute. The morning of postoperative day 1 approximately 24 hours after surgery a VAS will be obtained and they will be asked questions by the study coordinators via questionnaire about the quality of recovery, this should take approximately 10 minutes to complete. They will be called on post op day 4 from surgery and a survey will be administered via telephone call. This survey should also take 10 minutes to complete.

**This is also known as NIH Experimental Procedure section or Clinical Trial Procedure/Experimental Flow section. Do not just attach documents in response to this question you must do a study design summary for IRB Review.**

**8.7 Please attach study design/subject visit schedule here:**

| Name | Description |
|---|---|
| There are no items to display | |

If you have an electronic schedule of study visits and/or procedures please attach here.

View: 09-00 Inclusion/Exclusion Criteria

**9.0 Inclusion/Exclusion Criteria:**

**9.1 What are the inclusion criteria? Put this information in bullet form:**

The inclusion criteria are the following:
-Consenting, English speaking women between ages 18 and 80 who will under go laparoscopic gyn surgery at MetroHealth Medical Center

Please list inclusion criteria.

-Ability to read VAS Scores
-Specific procedures include, but are not limited to:

• Laparoscopic hysterectomy, for uterus 250 g or less
• Laparoscopic hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
• Laparoscopic hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele
• Laparoscopic hysterectomy, for uterus 250 g or less; with repair of enterocele
• Laparoscopic hysterectomy, for uterus greater than 250 g
• Laparoscopic hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
• Laparoscopic hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele
• Laparoscopic hysterectomy, for uterus greater than 250 g; with repair of enterocele

**9.2 What are exclusion criteria? Put this information in bullet form:** Please list exclusion criteria.

**History of chronic pelvic pain**
**-Abdominal surgery**
**-Uncontrolled psychiatric disease in the opinion of the investigator**
**-Currently taking analgesic medications**
**-Currently taking sedatives**
**-Liver disease**
**-Renal disease with CrCl < 60cc/min.**
**-History of burns from application of ice.**
**-Women who did not consent for the study.**
**-Intraoperative concern for increased blood loss**
**-Unable to speak English**
**-Unable to understand VAS Scores**
**-Undergoing concomitant abdominal procedures.**
**-Allergy to motrin, toradol, Percocet, Tylenol**
**-Active or history of peptic ulcer disease**
**-History of GI bleeding or perforation**
**-Hemorrhagic diathesis**
**-Severe uncontrolled heart failure**
**-Inflammatory bowel disease**

**9.3 How will subject eligibility be determined and by whom?** Please describe in detail.

Eligibility will be determined during the consent process by the study investigators during patient questioning and chart review.

**9.4 Will you exclude women and minorities, or persons under 21 from enrollment?** Check yes or no.
No

**9.5 If yes, which groups are you excluding? Provide justification for your decision.** *List groups to be excluded then provide justification.*

**9.6 Attach Documents:** *If you are unable to fit your answers in the text boxes provided please attach as a word document.*

| Name | Description |
|---|---|
| There are no items to display | |

View: 10-00 Risk/Benefits

**10.0 Assessment of Risk I:**

**10.1 Identify and distinguish between those procedures that are standard versus those that are experimental. Include the frequency and duration of each activity and the total length of subject participation:** Please distinguish between those procedures that are standard versus those that are experimental. Describe in detail all experimental procedures.

The experimental procedure is the randomization of the two different postoperative pain regimens to the standard regimen vs. the ICE-T. There are no investigational new drugs used. Subjects will participate for 4 days from time of surgery. The post op questionnaires are experimental but with minimal risk.

**10.2 Describe any therapeutic alternatives to the research that may exist. How are they different from those procedures that subjects would normally undergo? Alternatives that patients may choose are to receive standard surgery medications prior to and after surgery.** Describe any therapeutic alternatives. Can subjects receive this drug or device outside of a research study?

**10.3 What are the outcome variables and how will they be analyzed? What are the statistical and analytical methods that will be used? *Note this section can be copied from the NIH Grant Application or from the Statistical and Analytical Methods section of the industry trial protocol.*** Define outcomes and describe data analysis, please include a power calculation.

PRIMARY OUTCOMES: Visual Analog Scores (VAS) Scores in the morning of post op day 1.

SECONDARY OUTCOMES:
-VAS Scores at 4 hours post surgery
-VAS Scores Post Operative (post op) day
-Quality of Recovery scores on post op day 1
-Satisfaction scores in the morning after surgery (~7AM)
-Satisfaction scores 4 days after surgery

-Length of stay
-Hemoglobin difference preop/postop
-Total dose of opioids administered during hospitalization in morphine equivalents upon hospital discharge.
-Postoperative nausea and vomiting post op day 1 of surgery, dizziness, headache, blurry vision, pruritus, drowsiness within the first day after surgery
-Time to first void
-Incidence of urinary retention (discharge home with foley)
-Time to first bowel movement (patients will ask to record this and there will be follow up via phone call if patient is not hospitalized on post op day 1 and post op day 4 after surgery.

Statistical analysis will be performed using statistical software.

27 patients in each arm would be needed to achieve 90% power to detect a mean difference of ~25 mm on a 100mm VAS scale for a significance level of 0.05. We will add 20% to account for loss to follow up and we will need 66 patients, 33 in each arm. This difference was selected based on multiple previous articles stating that a pain score difference between 20 and 30 is significant for most patients that perceived this as a moderate improvement in their pain after various types of surgery including head and neck, thoracic, abdominal orthopedic, and spinal. This sample size is in concordance with the sample size of 27 patients in each arm used by Crisp, a urogynecologist, evaluating patient controlled analgesia (PCA) vs. nurse administered analgesia after vaginal reconstructive surgery patients to determine a significant difference in VAS scores.

SPSS and R software will be used for data analysis.

**10.4 If the above requested information does not fit in the text box please attach a word document here:**

*If the requested information does not fit in the text box please attach a word document.*

Name Description

There are no items to display

View: 10-01 Risk/Benefits

**10.1 Assessment of Risk II:**

**10.5 List and quantitate the risks involved for each experimental procedure in bullet form. Identify risks as common (greater than 10%) uncommon (greater than 1% up to and including 10 %) rare (1% or less). This must match the**

Select all that apply.

**risks listed in the Consent Form:**
**Overall, risk of dissemination of PHI is rare (1% or less).**
**Rare risk of feeling uncomfortable answering some questions.**

**Tylenol Risks:**
**Rare cause of liver toxicity (1% or less)**
**Rare cause of serious kidney disease (1% or less)**
**Rare risk of allergic reaction (1% or less)**
**Rare risk of overdose (1% or less)**

**ICE**
**Uncommon risk of hypothermia (>1% to 10%)**
**Uncommon risk of shivering (>1% to 10%)**
**Rare risk of wound infections/complications (<1%)**

**TORADOL**
**Rare risk of gastrointestinal complications, i.e. bleeding (<1%).**
**Rare risk of cardiovascular disease (<1%) and contraindicated in setting of coronary artery bypass graft (CABG).**
**Rare risk of renal disease (<1%) and contraindicated in patients with renal failure**
**Rare risk of bleeding (<1%) and contraindicated in patients with suspected or confirmed bleeding.**
**Rare risk of allergic reaction (<1%) and contraindicated in patients with previous reaction to NSAIDs**
**Neither of these medications are experimental in a postoperative setting as they are frequently used. The key here is their combination to limit postoperative opioid use.**

**10.6** **Are there defined stopping rules?** ◉ **Yes** ○ No

Describe in enough detail for the IRB to assess safety.

**What are the stopping rules for the study? What are the conditions under which a subject will be withdrawn from the study for safety reasons, i.e. disease progression?**
If the investigators notice an in increase complications, >10% that are associated with the ICE-T postoperative pain regimen, the study will be terminated prematurely. This may include any of the complications listed in the previous section.
The study may be terminated by the clinical investigator for any reason. In the event of a serious adverse event (one that is fatal, life threatening, requiring

inpatient hospitalization or prolongation of existing hospitalization, results in persistent
or significant disability/incapacity, is medically significant or requires intervention to prevent one or other of the outcomes listed above). Study will be stopped if there is a significant increase in pain scores and significantly higher rescue dilaudid use.

**What findings, events, or conditions would require a research subject to be removed from the study? (i.e. disease progression)**
Patients will be removed from the study at their request. Patients will be removed from the study if they experience any serious adverse events listed above. The event does not necessarily have to have a causal relation with the procedure.

**10.7** **What Category of risk will study participants be exposed too?**
Name
Physical
Privacy

Should be consistent with risks listed in the Consent Form.

**10.8** **If Other listed above please specify:**

*A text box is provided for further explanation.*

**Describe the availability of medical or psychological services that participants might require as a consequence of participation in this the research:**

*A text box is provided for further explanation.*

**10.9**
Medical care (including hospitalization) is available if participants are injured or become ill because of research procedures.
Standard of care will be provided. Adverse events related to the administration of the ICE-T post-operative pain regimen or the control will undergo triage for treatment as appropriately deemed by the medical staff team including routine post-operative care,
referrals for outpatient treatment, and referrals to emergency room care. All of these services are on site at our recruiting institution should a patient require expedited care.

**10.10** **Describe in detail any measures in place to minimize or protect against the exposure of study subjects to these risks:**
Patients past medical history and any inclusion/exclusion criteria will be screened prior to participation in the study to limit adverse events

Discuss any provisions for intervention in the event of an Adverse Event i.e. stopping rules.

**10.11** **Please add any documents related to the above questions:**
Name Description

If your answers to the above questions are too long for the

There are no items to display

space provided please attach them here.

View: 10-02 Risk/Benefits

**10.2 Benefits:**

**10.12 Describe the potential benefits to the subject as a result of participating in this research. If there is no direct benefit to subjects please state that as well:**
***Note: payment or compensation to subjects for participation is not to be considered a potential benefit.***
The direct benefit to the patient may be decreased postoperative pain and decreased opioid requirement, decreased nausea and vomiting as well as earlier bowel movement.

Describe potential benefits to the study subjects.

**10.13 Describe the potential benefits to society as result of this research:**
**As mentioned in the background, we may decrease opioid intake in laparoscopic gynecologic surgery which may result in decreased rates of postoperative complications and decrease length of hospitalization in patients with these surgeries.**

Describe potential benefits to society.

**10.14 What is the risk/benefit ratio of the research?**
The risks, although present, are minimal compared to the potential postoperative benefits to the patient as discussed.

Discuss why the risks are reasonable in relation to the anticipated benefits.

**10.15 Attach Documents:**

Attach documents here.

Name Description
There are no items to display

View: 11-00 Study Participant Information I

**11.0 Study Participant Information I:**

**11.1 How will the Principal Investigator assure he/she has access to a population that would allow recruitment of the required number of study participants (i.e. prep for research):**
Our OBGYN department performs approximately 250 laparoscopic hysterectomies per year, which will provide a very sufficient population for recruitment.

*How does the PI know he/she has the required number of subjects?*

*Please give the total #of subjects to be enrolled at all sites and anticipated subjects to be enrolled at MHS.*

**Anticipated number of subjects (all sites): [enter a number]**
66

**11.2**

**Anticipated number of subjects to be enrolled at MHS: [enter a number]**
66

**Anticipated number of potential subjects to be approached: [enter a number]**
100

**11.3 If this is a multi-site study, how many sites will there be? [enter a number]** How many total sites?
**1**

**11.4 Subject Characteristics:** Check all that apply
Subject Population Categories
Outpatients
Patients with the "disease in question"

**11.5 Subject Source:** Check all that apply
Subject Source Characteristics
Subjects from the Practice of the Principal Investigator
Subjects referred or recruited from other physicians practices

**11.6 If "other" list above in either 11.4 or 11.5 please describe:** *If applicable please describe.*

View: 12-00 Study Participant Information II

**12.0 Study Participant Information II:**

**12.1 Select age range of study participants:** Check all that apply.
Subject Age Range
18 - 64
65 - 89

**12.2** * Will the study enroll vulnerable subject groups? Check yes or no.
**Yes**

* Will you be enrolling Children?
○ **Yes** ◉ **No**

* Will you be enrolling Pregnant Women and/or Fetuses?
○ **Yes** ◉ **No**

* Will you be enrolling decisionally impaired subjects?
○ **Yes** ◉ **No**

* Will you be enrolling Prisoners? ○ **Yes** ◉ **No**

**12.3** **Please identify any vulnerable populations participating in the study:** Check all that apply.
Vulnerable Populations
Poor / Uninsured
Elderly
Employees
Students
Minorities

**12.4** **If you selected "other" above please describe:** *Please describe other.*

**If you are going to enroll <u>any</u> vulnerable populations please describe the safeguards you will put in place to protect these vulnerable Populations.** *Please enter a detailed plan.*
**12.5** Data security measures are in place to protect these vulnerable subjects.

View: 13-00 Recruitment I

**13.0 Recruitment I:**

***All external advertisements (for radio, print media or TV) must be approved by MHS Communications Department prior to submission to the IRB so the IRB can see the final advertisement or script. All Advertisements on the MIV or On Hold messaging must be approved by the IRB before they are placed. You may not advertise a study which is not approved by the IRB. Please note that all studies which have a contract which an external sponsor must have that contract signed before any advertising can be done.***

**13.1** **Recruitment Methods/Sources:** *Check all that apply.*
Name
Other

**13.2 If "Other" checked in 13.1 please explain:**
**Prior to surgery, patients will be asked to participate in the study in their private patient rooms or in clinic. No other form of advertisement.**

Please explain what other means.

**13.3 Describe in detail all recruitment strategies for each subject group (as listed in Section 11.0) selected for this research:**
Prior to surgery, patients will be asked to participate in the study in their private patient rooms or in clinic. No other form of advertisement.

Please describe recruitment strategies in detail.

**13.4 What measures will be taken during the recruitment process to safeguard against the potential coercion or appearance of coercion of human subjects, particularly vulnerable subject groups?**
Patients will be approached in clinic or in pre op up to two hours prior to surgery and will be given as much
time as they require to determine if they would like to participate in the study or not. Standard of care will be given to the patient should they decide not to participate. Eligible subjects will be told that participation is voluntary and has no bearing on the care they receive at MetroHealth. They will also be told that their identifying data will be kept confidential and will not be shared with anyone outside of the study team and that they can stop their participation at any time.

Please give an explanation of safeguards to be used.

**13.5 Incentives to Subjects: Will subjects receive any incentives (payments, free service, gifts, etc.) for participation in the research?**
No

*This information must mirror the consent form language.*

**13.6 If yes, please describe these incentives and how they will be disbursed: *Note: payment or compensation to subjects for participation is not to be considered a potential benefit.***

*Describe incentives, if they are to be pro-rated based on visits completed please give that information. This information must mirror consent form language.*

**13.7 Please attach copies of all recruitment/advertising materials and verbal scripts:**

Attach copies of all recruitment and advertising materials.

| Name | Version |
|---|---|
| There are no items to display | |

View: 13-01 Recruitment II

**13.1 Recruitment II:**

**13.8** **Expense to Subjects: Will subjects incur any expenses as a result of participation in the study or will they be billed for any study-related procedures?**
No

Check yes or no, make sure this information is in the consent.

**13.9** **If yes, please describe the expenses or charges that subjects will be assessed:**

Please provide information regarding expenses to subjects and add information to consent.

**13.10** **Compensation For Injury: If applicable, will funding be available to compensate subjects for injuries sustained as a result of participation in this research?**
No

Check yes or no, make sure this information is in the consent.

**13.11** **Who will cover the costs related to any injuries sustained due to participation in the study?**
If a patient is injured or becomes sick during the study period, the MetroHealth System will provide them with the appropriate care, but their insurance company is responsible for the costs.

Please describe in detail. Examples subjects or their insurance company, study sponsor.

View: 14-00 Data Collection

**14.0 Data Collection:**

**14.1** **A. What type of data will you be collecting as part of this research?**

*Existing data must be in place or on the shelf prior to the submission of the research protocol to the IRB.*

*Prospective data is collected in real time.*

**Will you collect existing data?**

**or**

**Will you collect prospective data?**
○ Yes ○ No

**or**

**Will you collect both existing and prospective data?** ◉ **Yes** ○ No

***Definitions:*** ***Data are considered to be existing data only if they were in place or "on the shelf" prior to the submission of the research protocol to the IRB. Data***

*Tell the IRB why you are collecting this data i.e. to verify inclusion criteria.*

***are considered prospective if they are created and collected as part of the research i.e. from surveys, questionnaires.***

**B. Why are you collecting this data?**

**What will be the purpose of collecting and/or reviewing the data (new data or existing data).**
Patients characteristics and medical history need to be described for the study in addition to verify patients for inclusion and exclusion for the study.

**14.2 If you are collecting existing data:**

*Specify the types of existing data you will use in this study.*

**Specify the type(s) of existing data sources you will use (medical records, school records, publicly available records, existing database). If you are collecting data from an exisitng database and that database contains PHI, you must provide the IRB Approval letter (attach to Section 27.00 Additional Documents).**
**We will be reviewing existing electronic medical records from the inpatient and ambulatory setting.**

*Time frame i.e. last 10 years or from 1990-2000.*

**What is the timeframe of the existing data you wish to review? (i.e. 2000-2006)**
**2000-present**

**14.3 If you are collecting prospective data:**

**Where or how will the data be obtained? (i.e. surveys, questionnaires, psychological tests)**
Data will be obtained from surveys and EMR

*Where will data be obtained? i.e. survey.*

**14.4 How will the data you collect be identified?**

**Types of Data Identification:**
Name
Deidentified/Confidential- Data will be linked to subject(s) via a code or indirect identifier (i.e. study IDs or numbers)

*Please select how your subject data will be identified.*

**14.5 Will the information collected from these records be linked to any research subjects by identifiers? (i.e. name, MRN#, DOB)**
◉ **Yes** ○ No

*Will your data be linked to subjects?*

***Please answer questions about the security of the data in section 15.00***

**14.6 If subject data will be deindentified using a code will there be a link or a key? Please describe. Who will have the key and where will the key be kept?**

Data will be stored in the redcap software. The key will be electronic, created in RedCap. Only study staff will have access to the key.

*Explain how Data will be linked.*

Under the HIPAA Regulations, deidentified key codes must be stores separately from data & must not be kept on paper, but electronically. The MetroHealth Research Informatics Support should be contacted at REDcap@metrohealth.org for assistance. They will assist personnel in developing a key in MetroHealth REDcap database. They can also assist with training & development for your study. REDcap is a free database provided in part by the Case CTSA.

**14.7 Data Collection Form(s):**

*Add data collection forms and CRFs.*

| Name | Version |
|---|---|
| ICE T Data collection \| History | 0.01 |

View: 15-00 Data Security I

**15.0 Data Security I:**

**It is imperative that the IRB is proactive and consistent in protecting all research data containing Protected Health Information(PHI).**

**15.1 * Are the records for this study (some or all) electronic?** ◉ **Yes** ○ **No**

**What is Protected Health Information? The Privacy Rule protects certain information that covered entities use and disclose. This information is called protected health information (PHI), which is generally individually identifiable health information that is transmitted by, or maintained in, electronic media or any other form or medium. This information must relate to 1) the past, present, or future physical or mental health, or condition of an individual; 2) provision of health care to an individual; or 3) payment for the provision of health care to an individual. If the information identifies or provides a reasonable basis to believe it can be used to identify an individual, it is considered individually identifiable health information.**

**The following questions must be answered when submitting a new protocol.**

**15.2 * Are you collecting PHI?** ◉ **Yes** ○ No

**15.3 Is any PHI going to be stored as paper files?** ◉ **Yes** ○ No

**15.4 Is any PHI going to be stored in an electronic file format? (i.e. access, excel)** ◉ **Yes** ○ **No**

**15.5 Is your data being stored on a laptop computer?** ○ Yes ◉ **No**

**15.6 Will you be using RedCap to store your data?** ◉ **Yes** ○ **No**

**Which RedCap Database will you be using?**

Name
MetroHealth

**15.7 Are you planning to store your data using a portable storage device?(i.e. jump drive, external hard drive, cd)**
○ Yes ◉ **No**

***Per current MetroHealth Policy PHI may not be stored on portable electronic devices.***

**15.8 Are there any circumstances under which you would want to remove data from MHS? (i.e. take data home to work on it) Give details below. Please note identified data can't be removed from MHS unless there is permission granted in the HIPAA Authorization. If you are unsure about what is identified data please consult the IRB staff. If you feel you will need access to your data when you are off campus you should ask the MHS IT Department located in Rammelkamp room R 134 about VPN access.**
○ Yes ◉ **No**

**If you answered yes to question 15.8, please explain?**

| | | |
|---|---|---|
| **15.9** | **Where will the records pertaining to this research be stored? (give the actual physical location of the paper records i.e building name and room number); and/or the secure network drive where the data is being stored.** Paper records will be kept in a locked room that's located on the 4th floor, central towers, S468 (Study Coordinator's Office). Electronic Information will be stored in REDCAP. | State the exact physical location of paper files and the network drive for electronic files. |
| **15.10** | **How will these records be secured (we are refering to both paper records and electronic records)? Examples for electronic records (i.e. secure drive, password protected documents, encrypted jump drive). Examples for paper records, must be double locked (i.e. locked office and locked file cabinet or a locked file box inside a locked cabinet).** **The paper data forms as well as Informed consent files will be stored in a locked file cabinet in the locked research office (S468, central towers).** | i.e. locked cabinet, locked room. |

**15.11** **Who will have access to the data?**
The study staff delegated to perform the study.

Please Note: All study documents must be retained for a minimum of four years after study completion (even when no subjects have been enrolled), twenty-two years if study involves children or pregnant women. Records for device studies must not be assigned a destruction date until the FDA approval status is determined, at which point records will be retained according to the scheme above (minimum of four or twenty-two years as appropriate). Under HIPAA regulations you must keep a record of all medical records where you looked at or recorded PHI (without a HIPAA Authorization) for 6 years (i.e. prep for research).

MHS Record Retention Policy VII-4

Give name and title exclude study staff who are MHS employees.

**15.12** **How long will you keep the records pertaining to this research? Where will these records be stored after the study has been completed?**
4 years. Will be stored in RedCap. Paper data will be in the same office as described above.

*Check the MHS Record retention policy for guidance.*

*You must have a plan for data destruction.*

**15.13** **Where, when, and how will the information be destroyed?**
4 years after conclusion of the study the data will be erased from the computer using the trash operation. Paper files will be shredded in the recycle bin in department offices.

*Please Note: There are EPA regulations surrounding the destruction of CDs, DVDs, Floppy discs and other portable storage media. If you want to destroy these types of media please contact Ron Wallace in Environmental Services at 778-4776.

View: 15-01 Data Security II

**15.1 Data Security II:**

**15.14** **Who (non-study staff) will have access to the records? Give name and title of individuals. Where an individual's name is not known give title i.e. monitor**

*List all those not study staff who will see and have access*

**from CRO.**
Individuals that are not part of the study will not have access to the records.

*to data.*

**15.15 Will data be transmitted to the sponsor?** ○ Yes ◉ **No**

*Are you sending CRFs to sponsor?*

**15.16 If yes, describe what data will be sent to the sponsor and the provisions that have been made for preservation of confidentiality in the transmission of data to the sponsor:**

*Please describe i.e. will you be using encryption software?*

**15.17 Will the data from this research project be transmitted to anyone other than the sponsor?** ○ Yes ◉ **No**

*Check yes or no.*

**15.18 If yes, to whom will this data be transmitted?**

*Please describe organization or individual.*

**15.19 Describe the data that will be sent to entities other than the sponsor and what provisions have been made for the preservation of confidentiality:**

Please describe data, and confidentiality provisions.

View: 16-00 Request for a Partial Waiver of HIPAA Authorization

## 16.00 Request For a Partial Wavier of HIPAA Authorization

An IRB, under certain circumstances, may allow researchers to forgo obtaining an authorization; this is called a waiver of authorization. A waiver of authorization may be full or partial:

- full waiver: an IRB waives the requirement for authorization for all uses of PHI for a particular research protocol (see Section 16.01 Request for a Waiver of HIPAA Authorization);
- partial waiver: an IRB waives the requirement for an authorization only for some uses of PHI for a particular research protocol. Researchers are required to obtain subjects' Research Authorizations after recruiting and enrolling subjects via a partial waiver and prior to creating or using PHI during research procedures.

**Partial Waiver for Preparatory for Research Activities:**
**According to HHS guidance on the Privacy Rule the preparatory to research provision permits covered entities to use or disclose protected health information for purposes preparatory to research, such as to aid study recruitment. However, the provision at 45 CFR 164.512(i)(1)(ii) does not permit the researcher to remove protected health information from the covered entity's site. *As such, a researcher who is an employee or a member of the covered entity's workforce could use protected health information to contact prospective research subjects*. The preparatory research provision would allow such a researcher to identify prospective research participants for purposes of seeking their Authorization to use or disclose protected health information for a research study.**

**Under the preparatory to research provision, a covered entity may permit a researcher who works for that covered entity to use PHI for purposes preparatory to research. A covered entity may also permit, as a disclosure of PHI, a researcher who is not a workforce member of that covered entity to review PHI (within that covered entity) for purposes preparatory to research.**

**16.1** Are you requesting a Partial Waiver of HIPAA Authorization? ◉ **Yes** ○ No

Check yes or no.

**Why are you requesting a Partial Waviver?**

**16.2** Is the purpose of the Partial Waiver Recruitment (including screening of Medical Records)?

◉ **Yes** ○ No

Check yes or no.

Is the purpose of the Partial Waiver to request access to PHI for Non-MetroHealth personnel?

○ Yes ◉ **No**

**16.3** Will the use of Protected Health Information (PHI) involve more than minimal risk to the privacy of the patients?

○ Yes ◉ **No**

Check yes or no.

**16.4** The IRB as part of it's review of this request must have certain reassurances that Patient Privacy will be protected, please respond to the following questions true or false.

*Check true or false.*

1.) The PHI will be used solely to facilitate the research protocol as an aid to study recruitment or to expand the research study. The waiver would allow identification of prospective research participants for the purpose of seeking authorization to use or disclose PHI for a research study. Essentially, PHI will be used to identify and contact potential research participants. Only contact and screening information (race, age, medications, diagnosis, and primary physician) will be recorded, and no information will leave the premises of MetroHealth Medical Center. The information will not be disclosed outside the research group for this study. ◉ **True** ○ False

2.) Information about potential subjects who are not interested in participating will be destroyed after the patient declines enrollment. The information of patients choosing to participate will be further used to schedule an appointment. As soon as the research staff sees the participant, a full authorization will be obtained to collect, use and disclose PHI for the remainder of the study. ◉ **True** ○ False

3.) The PHI will not be reused or disclosed. Because the PHI belongs to individuals who are not yet in the study, oversight provisions do not apply. After subjects are formally enrolled, an authorization will be in effect and the waiver will no longer apply. ◉ **True** ○ False

**16.5** If you did not answer true to all three parts of question 16.4 please explain:

Please explain your response to any statement where you have entered false.

**16.6** Please give a detailed explanation as to why this research activity cannot be practicably conducted without a Partial Waiver or without access to PHI:
Review of the EMR is necessary to help determine subject eligibility. It is also required to establish demographic baseline information necessary in the final analysis of the study.

Example: our study population has xxx disease and we rely on the EMR information to identify and contact potential subjects.

**16.7** Who will have access to PHI? Please list below:

Add the names of persons who will have access to PHI.

| Name | Employer | Department | Employer Name |
|---|---|---|---|
| Graham Chapman | University Hospitals and MetroHealth | OBGYN | The MetroHealth System |
| Ryan Darvish | MetroHealth | OB/GYN | The MetroHealth System |
| Robert Pollard | MetroHealth Medical Center | ob/gyn | The MetroHealth System |
| David Sheyn | UH department of urology | ob/gyn (rotating fellow) | The MetroHealth System |
| Linda-Dalal Shiber | Metrohealth | Ob/gyn | The MetroHealth System |
| Emily Slopnick | UH | Urology | University Hospitals Cleveland Medical Center |

**16.8** Are you or anyone who assists you Non-MetroHealth Personnel? ○ Yes ◉ **No**

*Check yes or no.*

**Note all Non-MetroHealth Personnel have to go through employee orientation, have a security clearance and Epic training before they can access the MetroHealth EMR. Also all all Non-MetroHealth Personnel must work under the control of a member of the MetroHealth Staff.*

*If you filed a Prep for research form with IT and RABO please attach it here.*

If you have previously completed an MHS **Prep for Research form** add that form here:

| Name | Version |
|---|---|
| There are no items to display | |

*Partial Wavier Memos completed prior to 11/26/2010 will populate here.*

**Old Memos Requesting Partial Waivers (prior to 11/26/2010):**

There are no items to display

View: 16-01 Request for a HIPAA Waiver of Authorization

**16.1 Request For a HIPAA Waiver of Authorization:**

| | | |
|---|---|---|
| **16.9** | **Are you requesting a Waiver of HIPAA Authorization?**<br>No<br><br>Check one, if you check no then hit continue and go to the next page.<br><br>**<u>If you are requesting a Waiver In order for the IRB to Grant a Waiver you must answer questions 16.10-16.16</u>** | Check yes or no. |
| **16.10** | **Disclosure of Protected Health Information (PHI) will not involve more than minimal risk to the privacy of the patients/subjects:** | Check true or false. |
| **16.11** | **What is the plan to protect patient/subject identifiers from improper use and disclosure?** | i.e. This unique identifier will be used on the data collection form. Only the PI will have access to the key linking the unique identifier to patient/subject names. |
| **16.12** | **What is the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research?** | i.e. The unique identifier key will be retained in Red Cap and will be destroyed two years after the study ends. |
| **16.13** | **Will PHI be reused or disclosed to others:** | Check yes or no. |
| **16.14** | **Please complete the following: Data will only be used to analyze...** | i.e. Data will only be used to analyze... |
| **16.15** | **Describe why this research can not be conducted without a waiver:** | i.e because many of the subjects who participate in this treatment are dead or have transferred to other treatment modalities, or are transient. To obtain HIPAA Authorization from these individuals would be a greater risk to their loss of privacy. |

**16.16 Describe why this research could not be conducted without access to and use of PHI:**

i.e. It would not be possible to determine linkages between .....and clinical outcomes without the use of PHI.

View: 16-02 HIPAA II

**16.2 HIPAA II:**

**16.11**

*Check all that apply, your answers will help the IRB to determine if your data is a limited data set.*

**Which of the following identifiers about subjects will be collected for this study?**

Name
2. Telephone Numbers
8. Names or Initials
16. Medical record or prescription numbers
21. Dates (except year) related to an individual (birth date, admission date, discharge date, date of death)

*These Questions deal with the collection of data and data use agreements. If you are **not** receiving data or sending data out to another entity this does not apply to you. If you have a signed contract with a sponsor or are in a cooperative group that has a signed agreement with MHS this does not apply to you. Data use agreements specify the conditions under which data can be shared between MHS and other organizations or individuals.*

**16.12 If you have selected only numbers 4, 5, 6, or 22 in question number 16.11 your research is considered to use a limited data set. If either of the following conditions apply, you will need to obtain a Data Use Agreement and complete a waiver of authorization or obtain a HIPAA authorization from the subjects. (check one):**

**Check one, please read carefully if you are not receiving data or sending data out to another entity this does not apply to you, move on to 16.14. If you have a contract with a sponsor or you are in a cooperative group that has a signed agreement with MHS this does not apply to you. In all other cases please contact the MHS Legal**

Name
There are no items to display

| | | |
|---|---|---|
| | | **Department with questions about data use agreements.** |
| **16.13** | **Attach a copy of the Data Use Agreement:**<br>Name Description<br>There are no items to display | Attach Data Use Agreement. |

View: 16-03 HIPAA III

**16.3 HIPAA III:**

| | | |
|---|---|---|
| **16.14** | **If any other unique identifying number, characteristic or code is selected, please specify:** | Please specify this question refers back to the list of 22 identifiers. |
| **16.15** | **If a link to an identifier will be used (i.e. code numbers) is selected, please describe the coding mechanism that will be used:**<br>**Data will be coded by Redcap.** | Describe the coding mechanism. |
| **16.16** | **Will a certificate of Confidentiality be obtained for this study?** No | Check yes or no. |
| **16.17** | **If yes, please attach a copy the Certificate of Confidentiality:**<br>Name Version<br>There are no items to display | Attach a copy of the Certificate of Confidentiality. |
| **16.18** | **Describe how you will protect the privacy of participants. Describe specifically how you will gather information from or about them. *Please note while confidentiality concerns data, privacy concerns people. Example People may be uncomfortable answering questions about their employer in an open cubicle, so investigators may arrange for a more private location.***<br>All information from subjects will be collected either over the phone or in a private patient room. | *Please note while confidentiality concerns data, privacy concerns people.* |

View: 17-00 Waiver of Informed Consent

**17.0 Request for a Waiver or Alteration of Informed Consent:**

| | | |
|---|---|---|
| **17.1** | **Are you requesting a Waiver of Consent [45 CFR 46.116(d)] OR a Waiver of Documentation of Consent [45 CFR 46.117 (c)].**<br>No | Answer yes or no. |

If no hit continue button and you will go to the next page.

If yes please Note:

**Note: Waivers of consent are not applicable if the research is subject to FDA regulations, except the following.**

**FDA Exception from general requirements:**

1. Emergency Ues: Waivers of Informed Consent in FDA-regulated studies are permissible in case of life-threatening situations, inability to communicate, not sufficient time and no alternative method, even if research presents more than minimal risk [21CFR50.23];
2. Planned Emergency Research: If the study satisfies the requirements under 21CFR50.24 “Exception from Informed Consent Requirements for Emergency Research.”

**17.2 Waiver of Consent: If you are requesting a waiver of consent, please provide the justification and address each of the following points for the IRB's consideration:**

*Check true or false.*

*Note: practicably does not mean it would be inconvenient.*

**This research study involves no more than minimal risk:**

**The waiver will not adversely affect the rights and welfare of the subjects:**

**This research could not practicably be carried out without a waiver:**

**Whenever appropriate, the subjects will be provided with additional pertinent information after participation:**

○ **Yes** ○ **No**

**17.3 Please explain your answers to the above questions (You must provide the IRB with enough information to make a decision):**

Please explain in detail.

An IRB may **waive the requirement to obtain a *signed* consent form** for some or all subjects if it finds either of the conditions below. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

**17.4** **(1) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; OR**

*Check true or false.*

*Check yes or no.*

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

○ Yes ○ No

**17.6** **If you are requesting any Alteration to the standard consent form/process (written long form consent is the standard) please provide a detailed explanation or plan.**

*Example of an alteration: verbal consent.*

View: 17-01 Informed Consent Process I

**17.1 Informed Consent Process I:**

**17.7** **Who will be approached to obtain consent/assent:**

Check all that apply.

Consent Method

Subjects will be asked to sign a study consent form after receiving a complete explanation of the study.

**Idendtify all Staff obtaining consent on page 1 question 1.4 by selecting the corresponding role.**

**17.8** **Subject Comprehension: What measures will be taken to ensure that subjects fully understand the nature of their involvement in the research?**

Please give brief explaination.

***Note to Investigator:***

***To address issues of comprehension on the part of the participant or representative, and who is involved in obtaining consent, the answers to following questions should be addressed:***

***1.) Once a potential participant is identified, what process is followed to inform the subject of the study prior to obtaining a signature on the informed consent form?***

***a. Who introduces the study to the potential subject?***

***b. Who reviews the informed consent document in depth?***

***c. Do you require the potential participant to have another person present during the presentation of the study?***

***2.) Who answers the questions presented by the potential participant and/or family?***

***3.) What method is used to determine if the potential participant fully understands the study, what is required from them, risk and benefits, and their rights as a participant?***

***4.) Is the principal investigator usually present during the presentation of the informed consent?***

When a potential participant is identified, the study will be introduced to them. If they express interest, the ICF will be reviewed in detail with them, using the "teach back" technique to ensure they understand the details of the study prior to them signing ICF.

The study will be introduced by study investigators or by the physician performing their surgery.

The ICF will be reviewed in depth by study investigators.

We do not require another person present during presentation of study.

Potential questions will be answered by study investigators.

To ensure participants fully understand study, the "teach back" technique will be employed by investigators when describing study and reviewing ICF.

The principal investigator will be present during presentation of ICF when they are his own patients, which will likely be about 50% of patients.

**17.9** **Capacity to Consent: How will capacity to consent be assessed?** ***This question is to be addressed for all subjects not just those with limited decision making capacity. Identify who will make this assessment? Suggested language....all subjects will be awake, alert and oriented, be able to read etc. It is important to address issues like ability to read and understand information in the consent.*** Awake, alert, oriented patients who are able to read and understand and have the capacity to make their own medical decisions will be approached about recruitment into the study.

How will you determine capacity to consent?

**17.10** **Attach a description of the Consent Process: Explain the process of obtaining consent from subjects. Under what settings and conditions will consent be obtained? What will be the timing/waiting period? What measures will be taken to ensure that subjects will make decisions independently?** *Note to Investigator: The "informed consent process" should include sufficient time for the participant to review and consider participating with the assistance of family*

Attach a plan for consenting subjects. This must give detail about the consent process.

*members, research partners or representative if necessary. Other items to consider regarding time / waiting periods are: Is the potential participant given a copy of the consent form to read prior to the discussion of the study? Is it presented in person or mailed (where they can review it in the privacy of their own home)? How much time elapses between the presentation of the study and informed consent form and the actual signing of the form? The answers to these questions will ensure the PI has considered this component of the process and will reassure the IRB that the PI is allowing adequate time for the participant to make an informed decision and minimize the possibility of coercion or undue influence.*

Name Description

Consent description | History

**17.11 Parental Permission and Youth Assent: Complete this question only if enrolling minors. How will parental permission and youth assent (if applicable) be obtained?**

Give details of assent process and assent form.

View: 17-02 Informed Consent Process II

**17.2 Informed Consent Process II:**

**17.12 What method will be used to document the consent process (i.e. a note in EPIC)? Not how you will get consent only how you will document consent has been obtained, i.e chart note, note in study file.**

i.e chart note, note in study file.

Chart note in EPIC

**17.13 What type of Informed Consent will be used in this study? (check all that apply):**

*Check all that apply*

Consent Type

Written/Signed Consent by Subject

*A non-return cover memo applies to a study in which you are sending out a questionnaire with a memo or letter that informs participants about the study but does not need to be signed and returned. If they complete and return the questionnaire they have given consent.*

**17.14 If other, please specify:**

If other, please give specifics.

****Attach all consent forms (Informed Consent, Genetic Consent and HIPAA) here:****

**17.15 Please attach a copy of each Informed Consent form(s) and HIPAA Authorization you are using for this study:**

Attach Consent form(s) and HIPAA Authorization here

| Name | Version |
|---|---|
| ICF & HIPAA ICET 18-Jun-2019- clean.docx | 0.02 |
| ICF & HIPAA ICET 18-Jun-2019- track changes.docx | 0.01 |

**17.16 Will non-English speaking subjects be enrolled?**

*Check one*

○ Yes ◉ No Clear

*Please give the IRB an explanation as to why non-English speaking subjects will not be enrolled.*

**If the answer to 17.17 is no we will not be enrolling non-English speaking subjects then tell the IRB why not?**

The informed consents are in English and it is not realistic given our small operation for us to translate this study into Spanish and expect sufficient and accurate follow up over the phone as our investigators do not speak Spanish.

**17.17 If non-English speaking subjects will be enrolled please provide information about the person(s) obtaining consent (what language they will speak)and how you will deal with written translation(s):**

Provide information about translating consents and having interpertative services available for consent.

View: 18-00 Data Safety Monitoring I

## Section 18.0 Data Safety Monitoring Plan

**DATA AND SAFETY MONITORING PLAN GUIDE**

WHEN DO YOU HAVE TO COMPLETE A DATA SAFETY MONITORING PLAN?

FOR THE IRB- **All interventional studies that are greater than minimal risk should have a Data Safety Monitoring Plan. The IRB reserves the right to require a Data Safety Monitoring Plan for any study.**

**Archived IRB Data Plans - prior to 9/28/2010**

FOR THE CRU- ALL CRU PROTOCOLS [**Recent NIH guidelines stipulate that all protocols that involve human subjects, a signed consent form and are conducted on, or use the resources of, the CTSA Clinical Research Unit - MHMC (CRU) are required to have a Data and Safety Monitoring Plan (DSM Plan).]**

**What is a Data and Safety Monitoring Plan (DSM Plan)?**

**A DSM Plan is a prospectively defined strategy to assess the assumptions made in the trial design while the study is in progress. Its main purpose is to ensure the safety of participants in clinical research studies and the validity and integrity of research data collection. A properly designed DSM Plan improves the scientific quality and yield from a clinical trial and the protection of human subjects.**

**The DSM Plan needs to address the nature of the safety monitoring and who will be conducting that monitoring. It may be reasonable for a single individual to perform the monitoring in a small trial with minimal/low risk while a local independent or an external data and safety monitoring board (DSMB) may be required for more complex/high risk trials.**

**Key elements to be incorporated in a DSM Plan**

- **Assessment of risks and monitoring level**
- **Safety contact: Who is responsible?**
- **Safety monitoring: Who will do it? How often?**
- **Informed consent process; consistency with the protocol**
- **Data collection process**
- **Adverse Events Monitoring: Anticipated and unanticipated**
  - **Description of anticipated adverse events**
  - **Grading and attribution method**
  - **Reporting of unanticipated adverse events**
  - **Plans for periodic reporting**
  - **Impact on termination of subjects from the study and study closure**

**Step 1 - only for Investigators Using the CRU:**

**1.A Is your protocol approved and supported by the Ireland Cancer Center?** ○ Yes ○ No

**If Yes - The Comprehensive Cancer Center Data and Safety Moniotoring Plan for Clinical Trials is on file. Proceed to Step 5.1.B If No, Proceed and complete Steps 2-5**

**********

**Step 2 - all Investigators - Provide Information in order to determine the level of safety monitoring required**

**2.A List all data collection types and study procedures (this information will pull from Section 8 Methods and Procedures questions 8.1, 8.2, 8.3)**

## Data Collection types:

Name

Chart Review - Prospective

Interviews, questionnaires or psychological tests

## Social-Behavioral Procedures:

Name
Surveys/Questionnaires

**Medical Procedures:**
Name
Investigation/Approved drugs
Clinical Assessments (EEG, EKG, SCID, etc.)

**********

***You must select the risk level Please read the information below, check the applicable boxes and select an appropriate risk level.***

**Level I: Minimal and Low Risk Studies (examples of studies that are minimal and low risk studies)**

**Types of Studies:**
Name
Chart Review, interview, questionnaire
Observational Studies

**Level II: Moderate Risk Studies (examples of studies with populations, drugs, and procedures that are moderate risk)**

**Types of Studies:**
Name
Elderly Population
Normal Population (Healthy Volunteers)

**Level III: High Risk Studies (examples of diagnostic procedures and drugs or device studies which are high risk)**

**Types of Studies:**
Name
There are no items to display

**2.B If you do not see your study procedures on the above list please add in the procedures being done for research purposes:**

**Add additional risk(s):**
Procedure DSMB Risk
There are no items to display

**Select the Appropriate Level of Risk for this study based on the criteria above:**

**Level of Risk:**
Risk Level II Moderate Risk Studies

**Now Select the appropriate Level of Monitoring and give your justification:**

**2.C Rank Level of Monitoring (select one by checking the box)**

**Minimal/Low/Moderate Levels of Monitoring** ☑

**Justification for selecting Minimal/Low/Moderate Level of Monitoring Required:**
The study does not meet criteria for Level III high risk studies but does use medications that are commonly prescribed in elderly and normal patient populations.

**High Level of Monitoring** ☐

**Justification for selecting Risk High Level of Monitoring**:

View: 18-01 Data Safety Monitoring II

**18.01 Data Safety Monitoring II**

**A designee will perform the safety monitoring:**

◉ **Yes** ○ No

**Identify the designee [provide contact information]:**
Dr. Robert Pollard (PI)

**A medical monitor or independent individual/safety officer will be performing the safety assessments.**

◉ **Yes** ○ No

**Identify who will be performing the safety assessments [provide contact information]:**
Dr. Sally MacPhedran is an independent attending physician in the Dept. of OB/GYN at MetroHealth who will be performing safety monitoring. She is unaffiliated with this study and is capable of performing the safety monitoring. She will be in charge of reviewing the findings
including adverse events, safety, and evaluating the outcomes.

**Has a Data Safety Monitoring Board or Committee been established for this study?**

○ Yes ◉ **No**

**Identify these members by name, title and qualifications. How often will the DSMB meet? How frequently will the DSMB report it's findings?) data prior to 9/28/2010 read only.**

**If there is a DSMB or DSMC is it a nationally constituted Data and Safety Monitoring Committee?** ○ Yes ◉ **No**

**Please enter the Name of Contact or Chair, Address and Phone or E-Mail:**

**Is there a locally constituted Data and Safety Monitoring Committee or Board that will perform the safety monitoring. Specify composition and responsibilities in the box below.** *Note: Board Members should not have conflicts with this study or with study personnel.* ○ Yes ○ No

**Names of Members of Local DSMB [provide contact information]:**

**3.B.1 Description of anticipated adverse events. Pulled from question 10.5.**

Overall, risk of dissemination of PHI is rare (1% or less).
Rare risk of feeling uncomfortable answering some questions.

Tylenol Risks:
Rare cause of liver toxicity (1% or less)
Rare cause of serious kidney disease (1% or less)
Rare risk of allergic reaction (1% or less)
Rare risk of overdose (1% or less)

ICE
Uncommon risk of hypothermia (>1% to 10%)
Uncommon risk of shivering (>1% to 10%)
Rare risk of wound infections/complications (<1%)

TORADOL
Rare risk of gastrointestinal complications, i.e. bleeding (<1%).
Rare risk of cardiovascular disease (<1%) and contraindicated in setting of coronary artery bypass graft (CABG).

Rare risk of renal disease (<1%) and contraindicated in patients with renal failure
Rare risk of bleeding (<1%) and contraindicated in patients with suspected or confirmed bleeding.
Rare risk of allergic reaction (<1%) and contraindicated in patients with previous reaction to NSAIDs
Neither of these medications are experimental in a postoperative setting as they are frequently used. The key here is their combination to limit postoperative opioid use.

Additional Comments on anticipated adverse events:

**3.B.2 Safety data/procedure used to preform evaluation:**

**Data to be evaluated:**
Name
Subject interview and/or contact
Subject's vital signs
Subject's physical exam
Subject's symptoms or performance status
Clinical Test(s) (e.g. labs, ECG)

**Who will evaluate safety data:**
PI and co-investigators

**Frequency of Monitoring:**
Name
6 Months

## 3.C. Grading method and attribution for adverse event reporting:

**Grading method and attribution for adverse event reporting**

**The PI must identify what scale will be used to grade adverse events (AEs) and indicate his/her attribution/assessment of the relationship between the adverse event and the protocol/intervention. Each protocol may have a unique approach to grading adverse events and the PI should consult the parent protocol and/or funding source for specific grading scales. Suggested guidelines for the grading of adverse events are available below:**

***Example A:*** *Cancer Therapy Evaluation Program (CTEP) Common Toxicity Criteria (CTC II) available for viewing at http://ctep.info.nih.gov (see "Reporting Guidelines, Common Toxicity Criteria")*

***Example B: Common grading scale***

| | |
|---|---|
| *0* | *No adverse event or within normal limits or not clinical significant* |
| *1* | *Mild AE, did not require treatment* |

*2 Moderate AE, resolved with treatment*
*3 Severe AE, resulted in inability to carry on normal activities and required professional medical attention*
*4 Life threatening or disabling AE*
*5 Fatal AE*

**3.C.1 Identify the scale to be used to Grade AEs in this study:**

**CRU Safety Scale:**
Name
AEs will be graded according to the 0-5 scale shown above.

**3.C.2 Identify the attribution scale to be used in this study:**

**CRU Attribution Scale:**
Name
The PI will determine the relationships of AEs to test procedure/device/agent as not related, possibly related, or definitely related, using standard criteria for clinical trials.

**3.D. Population being studied: (populated from your answers to Sections 11.00 and 12.00)**

**Vulnerable subject groups?** Yes

**Children?** No

**Decisionally Impaired Subjects?** No

**Pregnant Women and/or Fetuses?** No

**Will you be enrolling Prisoners?** No

**Other Populations being studied:**

Vulnerable Populations
Poor / Uninsured
Elderly
Employees
Students
Minorities

**** Note More Frequent monitoring intervals may be needed for vulnerable populations.***

**4.A. Plan for Adverse Event Reporting:**

**All Reportable Events (Anticipated and Unanticipated events) from this protocol must be submitted using the MHA eIRB Reportable event form in a timely maner consistent with MHS IRB SOPs.**

**In addition to the MHS IRB adverse events and Uanticipated problems will be reported to:**

**Reporting Institutions (check all that apply):**
Name
There are no items to display

**If other has been selected above please specify:**

**4.B Stopping Rules or Conditions under which Subjects can be removed from the Study [this information is from Section 10.01 of the Protocol Risks/Benefits Questions**

**Are there defined Stopping Rules?** Yes

**What are the stopping rules for the study?** If the investigators notice an in increase complications, >10% that are associated with the ICE-T postoperative pain regimen, the study will be terminated prematurely. This may include any of the complications listed in the previous section.
The study may be terminated by the clinical investigator for any reason. In the event of a serious adverse event (one that is fatal, life threatening, requiring inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is medically significant or requires intervention to prevent one or other of the outcomes listed above). Study will be stopped if there is a significant increase in pain scores and significantly higher rescue dilaudid use.

**What findings, events, or conditions would require a research subject to be removed from the study? (i.e. disease progression)**
Patients will be removed from the study at their request. Patients will be removed from the study if they experience any serious adverse events listed above. The event does not necessarily have to have a causal relation with the procedure.

**4.D. Additional Information (if Applicable):**

**Provide any other information relevant to the data and safety monitoring plan that was not already incorporated into this form.**

**Attach A copy of your Data Safety Monitoring Plan or other relevant information related to this form:**

| Name | Version |
|---|---|
| There are no items to display | |

View: 19-00 Use of Human Biological Materials In Research I

**19.0 Use of Human Biological Materials In Research I:**

| | | |
|---|---|---|
| **19.1** | **Will Human Biological Materials be collected as part of this study? (i.e. blood, tissue, fluids and substances etc.)**<br>No<br><br>If no, hit continue and you will be taken to the next page. | Check yes or no. |
| **19.2** | **Will the storage or transportation of study materials place anyone at a health risk? In other words, are these biohazardous materials? Will they put the staff collecting them or transporting them at risk?** | Check yes or no. |
| **19.3** | **If yes, please explain:** | Please explain the risks. Above and beyond universal precautions. |
| **19.4** | **Will information from the materials be stored in an electronic database?** | Check yes or no. |
| **19.5** | **If yes, list the database(s) where the information from the materials will be stored and who will have access to them:** | List the database(s) and who will have access to them. |
| **19.6** | **Human Biological Material Destruction: please describe the plan for materials destruction (when, where, how and by whom):** | Give the destruction plan i.e. shipped back to sponsor for destruction at end of study, incinerated by Browning Ferris 3 months after study ends. |
| **19.7** | **Storage of Human Biological Materials: please describe where, how and for how long the materials will be stored:** | Physical storage of materials where will it be, how will it be stored and for how long. |

View: 19-01 Use of Human Biological Materials in Research II

**19.1 Use of Human Biological Materials In Research II:**

**19.8** **Does this research involve human cell/lines and/or products that are made from human biological materials?** ○ Yes ◉ **No**

*Check Yes or No.*

**If yes, please explain:**

*Please explain.*

**19.9** **Will Human Biological Materials (tissue, blood or salavia) be collected in this study for genetic research?**
**No**

Check Yes or No.

**If Yes, please provide additional discussion of the genetic testing components including who will conduct the tests:**

**19.10** **If yes, can subject(s) decide not to participate in the genetic research and still participate in the study?**

Check Yes or No.

**Please submit the appropriate genetic consent/tissue storage form and attached at 17.15**
A template for this form can be found on the IRB Home Page. Note: if tissue storage is mandatory for participation in a study the subject consent must be included in the body of the consent form; if it is not mandatory it can be included as a separate page at the end of the consent form.

**19.11** **Will NIH Genome-Wide Association Studies (GWAS) be conducted?** ○ Yes ◉ **No**

Check Yes or No.

**19.12** **Will you be sending samples/data to the NIH GWAS?** ○ **Yes** ◉ **No**

Check Yes or No.

**19.13** **Will you be using sample/data obtained frm the NIH GWAS?** ○ Yes ◉ **No**

Check Yes or No.

**19.14** **Please provide justification for using NIH GWAS:**

*Please explain.*

If this is a GWAS study you will need to submit a **Patient Information Sheet (add at 17.16)**. This sheet should summarize the Genetic research component of this study and tell the subjects where their biological materials will be sent, what analysis they will undergo, who will have control of them and for how long and who to contact if they want to withdraw their permission. It must be clear to

subjects that these samples will not be housed at MHS nor will the MHS Investigator retain control over them.

View: 20-00 Drug Information I

**20.0 Drug Information I:**

**20.1** *** Does this study involve drugs?** Yes

If you check no and hit continue you will go to the next page.

If you are doing a drug study you may be required by law to register that study at Clinical Trials.gov Section 113 of the FDA Modernization Act mandates registration with ClinicalTrials.gov of investigational new drug efficacy trials for serious diseases or conditions. For more information click on the link below:
http://prsinfo.clinicaltrials.gov/registering.pdf

If you answer no and hit continue you will go to the next section.

**Does this study involve:**

**Is the study drug(s) FDA approved for this indication?** ◉ **Yes** ○ No

**Does this study involve use of a Placebo?** ○ Yes ◉ **No**

**Does this study have a drug washout period?** ○ Yes ◉ **No**

**Do you have an IND?** ○ Yes ◉ **No**

**If yes please give the IND: (include a copy of the FDA approval letter at 20.4)**

**Who is the sponsor or holder of the IND?**

**Does this study have an IND exemption? (include a copy of the FDA exemption letter at 20.4)** ○ Yes ◉ **No**

**20.2** **Fill in an entry for all drugs that will be used in the study:**

Please give a complete list.

| Drug Name | FDA Approved (yes, no) | IND Number | Supplied By |
|---|---|---|---|
| Acetaminophen (Tylenol) | Yes | | |
| Ketorolac (Toradol) | Yes | | |

**20.3 Manufacturer (name, address):**
Ketorolac-Roche Pharmaceuticals. 340 Kingsland St. Nutley NJ0 7110
Tylenol-Multiple manufacturers-Fresnius Kabi, Lake Zurich IL 60047

Answer only if produced commercially.

**20.4 Attach a copy of:**
**1.) Investigator Brochure and/or Package Insert**
**2. FDA Form 1571 Investigational new Drug Application Form**
**3.) FDA Form 1572 Statement of the Investigator Form**
**4.) FDA Correspondence (i.e. FDA Approval Letter for IND, FDA Exemption letter)**

*Attach the IB, 1572 and 1571 here.*

| Name | Description |
|---|---|
| Toradol \| History | |
| Tylenol \| History | |

View: 20-01 Drug Information II

**20.01 Drug Information:**

**20.5 Provide Drug Preparation and Administration information:**
At the end of surgery patients will receive 30mg of IV toradol.
Once out of the PACU patients will receive:

1. ICE PACKS applied to the surgical sites every hour for 20 minutes ATC until discharge.
2. 6 hours from the time of first dose of surgery patients will receive 30mg of IV toradol ATC until discharge.
3. Once out of the PACU will receive 1 gram of Tylenol every 6 hours for a total of 4
grams daily ATC until discharge
4. Patients will receive dilaudid 0.2mg IV Q3 hr PRN for breakthrough pain.
5. Patients will be discharged home with PO Tylenol and PO toradol PRN.

Regimen #2 STANDARD Postoperative Regimen
1. Once out of the PACU patients will receive “Standard” postoperative regimen
2. Motrin 600mg PO Q4h PRN pain 1-3
3. Percocet 1 tab PO Q4-6 hours PRN 4-6 pain
4. Percocet 2 tabs PO Q 7-10 hours PRN 7-10 pain
5. Patients will receive dilaudid 0.2mg IV Q3 hr PRN for breakthrough pain.
6. Patients will be discharged home with Motrin and Percocet for pain PRN.

*Please provide detailed information on how you will dose study subjects along with a dosing schedule and Pharmacy Manual.*

**Provide a Dosing schedule and a Pharmacy Manual:**

| Name | Description |
|---|---|
| There are no items to display | |

**20.6 Does this research study involve the dispensing of drugs on an outpatient basis?**

Please answer yes or no.

(●) **Yes** ( ) **No**

**IF you have answered No please hit continue and go to the next page.**

**20.7 Is the intent of the investigator to dispense and coordinate the drugs involved in this study?**

*If you do not plan to use the Research Pharmacy answer yes to this question.*

( ) **Yes** (●) **No**

**20.8 Where the drugs will be stored and who will have access to them?**

*Please tell the IRB where the drugs will be stored and who will have access to them.*

The drugs will be stored in the pharmacy and will be dispensed as per routine postoperative orders based on one of the two regimens prescribed.
Pharmacy staff will have access to the medications.

**20.9 IF Yes, The primary investigator or designated study staff must notify the MetroHealth Pharmacy Investigational Drug Service (MPIDS) by providing them with a copy of the investigator's brochure(s) and the study protocol. The MPIDS pharmacist will ensure the investigator can comply with the required storage and distribution plan and return a signed copy of the "Investigator Responsibility for Research Medication Form" The signed form must be provided to the IRB at the time of study submission.**

*Please review the Pharmacy Policies on the MIV Section Q on Investigational Drugs.*

*Link to form:*

*Print this form out and have it completed and signed by PI.*

**Attach Appendix A signed by Investigator: Link to Form Attachment A**

| Name | Description |
|---|---|
| There are no items to display | |

View: 21-00 Medical Device Information I rev

**21.0 Medical Device Information I:**

**Definition of a Medical Device:**

An instrument, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is

- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in man or other animals.
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

In short any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Medical devices include, among other things, surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for *in vitro* diagnosis (IVD) of disease and other medical conditions such as pregnancy.

**21.1** **Is this a Medical Device Study?** No — Answer yes or no.

If you are doing a device study you may be required by law to register that study at Clinical Trials.gov Section 113 of the FDA Modernization Act mandates registration with ClinicalTrials.gov of investigational new device efficacy trials for serious diseases or conditions. For more information click on the link below:

http://prsinfo.clinicaltrials.gov/registering.pdf

If you answer no and hit continue you will go to the next section.

**21.2** **Medical Device Generic Name:** — Give generic name.

**21.3** **Medical Device Brand Name:** — Give brand name.

**Medicare Code Number:**

**21.4**

**As stated in regulations 21 CFR 812.3(m), a device may be considered a, Significant Risk Device, if it meets any of the following criteria and a determination is made by the IRB that the device presents a potential for serious risk to the health, safety or welfare of a subject.**

**21.5** **Is this device intended as an implant?** — Check one

**21.6** **Is device to be used in supporting or sustaining human life?** — Check one

**21.7** **Is the device for use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health?** — Check one

| | | |
|---|---|---|
| **21.8** | **Does this device present a potential for serious risk to the health, safety, or welfare of a subject?** | Check one |
| **21.9** | **If you answered NO to all the above, or if an initial risk assessment has determined that this is a non-significant risk device (21CFR 812.3), attach the appropriate documentation for this justification:**<br>Name Description<br>There are no items to display | Attach justification. |
| **21.10** | **What is the regulatory status of the study device?** | Provide information on the regulatory status of the device. |
| **21.11** | **What is the long term plan for device management once the study closes?** | Provide information such as how you will communicate important information to subject; plan for maintenance/repairs; contact information besides the PI. |

View: 22-00 Clinical Trials Registration

**22.0 Clinical Trials Registration:**

*Note: Phase 2 - 4 trials of drugs and biologics (controlled clinical investigations other than Phase 1 investigations of a product subject to FDA regulation) AND trials of devices (controlled trials with health outcomes, other than small feasibility studies and pediatric post-marketing surveillance) must be registered per the Food and Drug Administration Act of 2007; NIH encourages registration of all trials, regardless of whether required under applicable law.*

***How are study protocols submitted to ClinicalTrials.gov?***
*The FDA Guidance Document (March 2002) (http://www.fda.gov/cder/guidance/4856fnl.htm) describes the submission criteria. The NLM has developed the Protocol Registration System (PRS), a Web-based tool for submitting information to ClinicalTrials.gov. Study sponsors or their representatives may register online to apply for a PRS account (http://prsinfo.clinicaltrials.gov/).*

| | | |
|---|---|---|
| **22.1** | Has this trial been registered on www.clinicaltrials.gov?<br>◉ **Yes** ○ No | Web link to clinical trails website. |
| **22.2** | If **Yes**, who registered the trial?(i.e. sponsor, investigator)<br>Investigator | Please respond |
| **22.3** | Please provide ClinicalTrials.gov Identifier (i.e. NCT00391872) | The sponsor can provide you with this information or you can look it up on the website. |

**22.4** If **No**, are there plans to register the study? ○ Yes ○ No

If you answer No you must provide an reason why this study will not be registered.

**22.5** If the answer to 22.4 is **No**, provide and explanation:

Provide a response if the answer to 22.4 is No.

View: 23-00 Interview/Focus Groups

**23.0 Interview/Focus Groups:**

**23.1 Does this study involve Interviews/Focus Groups?** No

Answer yes or no.

If you answer no and hit continue you will go to the next page.

**23.2 Attach copies of any scripts/or questions that will be used to guide the interview focus/groups:**

Attach scripts or questions.

| Name | Version |
|---|---|
| There are no items to display | |

**23.3 Idendtify all Staff conducting interviews on page 1 question 1.4 by selecting the correct role.**

**23.4 Is there any specific training or qualifications needed to conduct the interviews/focus groups?**

Describe training and/or qualifications.

View: 24-00 Psychological Testing

**24.0 Psychological Testing:**

**24.1 Does this study involve Psychological testing?** No

Answer yes or no.

If you answer no and hit continue you will go to the next page.

**24.2 First Please list all Psychological Tests that will be given:**

First please list the test(s)/measures to be used.

**24.3 Attach copies of all psychological test(s)/measures that will be used for this study:**

Second attach copies of all test(s)/measures.

| Name | Version |
|---|---|
| There are no items to display | |

**24.4 Is there any necessary training or licenses required of those administering the psychological testing?**

Describe any training or licenses required to administer test(s).

**Idendtify all Staff Administering tests on page 1 question 1.4 by selecting the correct role.**

View: 25-00 Surveys/Questionnaires

**25.0 Surveys/Questionnaires:**

**25.1 Does this study involve Surveys/Questionnaires?** Yes

Answer yes or no.

If you answer no and hit continue you will go to the next section.

**25.2 Please attach all questionnaires and/or surveys to be used in this study:**

Attach survey(s)/questionnaire(s).

| Name | Version |
|---|---|
| ICE T 24 hrs \| History | 0.01 |
| ICE T Day 4 \| History | 0.01 |
| ICE T Questionionnaire \| History | 0.01 |
| VAS \| History | 0.01 |

**25.3 Idendtify all Staff conducting Surveys on page 1 question 1.4 by selecting the correct role.**

View: 26-00 Deception

**26.0 Deception:**

**Deception is a research methodology. When deception is used in research the subject is not told, or is misled, about the true purpose of the research, such as in certain studies of group processes, contextual influences on cognition, etc.**

**26.1 Does this study involve the use of deception as a study design method for the research?**

Deception is defined as intentionally misleading or withholding information about the nature of the experiment.

No

If you checked no then hit the continue button and you will be taken to the next page.

**26.2 Describe in detail the nature of the deception and explain why this is necessary for the research:**

Please describe the nature of the deception.

**26.3 State how, when and by whom the research subjects will be debriefed:**

Briefly describe your plan to debrief subjects.

View: 27-00 Additional Documents

**27.0 Additional Documents:**

**27.1 Are there any additional study documents you wish to attach to this application?**

Attach any additional study documents i.e protocols supplied by sponsor.

| Name | Version |
| --- | --- |
| There are no items to display | |

View: The End

**To Finalize this application you must do two things:**

**1.)** As a final step you should click on Hide/Show Errors on the top of this page. If there are any required fields in the Application you have omitted they will show up in red. If you click on each item you will be taken to that page of the application so you can complete the question.

**Note:** Unless all named Co-investigators have agreed to participate you will not be able to submit your study. Co-Investigators have to press the Co-Investigators agree to participate button. You can send them an email message tellng them to do this by pressing

Notify Co-Investigators of Need to Agree to Participate. The minute you have selected your Co-Investigators you can press this button it is not advisable to wait until you have completed the application as it may hold up your submission.

When all error messages are gone then...

**2.)** Click Finish

Please click on the "Finish" button to finalize and exit the Study application. Doing so will **NOT** submit the application for review.

**3.)** The PI must press the Submit Study button (when they are ready to submit to the IRB)

Please note that a submission may only be forwarded to the IRB by the Principal Investigator. To do this, the Principal Investigator must push **" Submit Study"** in the blue area on the left hand side of the page under **My Activities**. Only the PI will have this button it will not be visible to any other study team members.

You can track the ongoing status of your submission by logging into the study workspace. On the top left hand side of the page in the light blue area there will be a box labeled with the **Current State** of your study.

Please contact the IRB with any questions or concerns. When calling the IRB Office Please direct your questions to the IRB staff named as the "Owner" of your study.

View: CCF Key Personnel Questions View
*** Name of Key Personnel Working on Study:** Sarah Sears

**Study Role:**
Name
Co-investigator

View: CCF Key Personnel Questions View
*** Name of Key Personnel Working on Study:** Rozina Aamir

**Study Role:**
Name
Study Coordinator
Co-investigator
Research Support Staff
Interviewer (Survey, Focus Group)
eIRB Notification Recipient

View: CCF Key Personnel Questions View
*** Name of Key Personnel Working on Study:** Ryan Darvish

**Study Role:**
Name
Co-investigator
DRA (only one)
Interviewer (Survey, Focus Group)
Obtaining Informed Consent
eIRB Notification Recipient

View: CCF Key Personnel Questions View
*** Name of Key Personnel Working on Study:** Linda-Dalal Shiber

**Study Role:**

Name
Co-investigator
Interviewer (Survey, Focus Group)
Obtaining Informed Consent
eIRB Notification Recipient

View: CCF Key Personnel Questions View
* **Name of Key Personnel Working on Study:** Nicole Findlay

**Study Role:**
Name
Co-investigator

View: CRU DSMP Data Collection Simple View
Name: Chart Review, interview, questionnaire
Level of Risk: Minimal and Low Risk Studies
Type: Data Collection
View: CRU DSMP Data Collection Simple View
Name: Observational Studies
Level of Risk: Minimal and Low Risk Studies
Type: Data Collection
View: CRU DSMP Data Collection Simple View
Name: Elderly Population
Level of Risk: Moderate Risk Studies
Type: Study Population
View: CRU DSMP Data Collection Simple View
Name: Normal Population (Healthy Volunteers)
Level of Risk: Moderate Risk Studies
Type: Study Population