Prospective Randomized Controlled Trial Comparing Resident Performance and Clinical Outcomes with Two Different Polypropylene Meshes for Laparoscopic Inguinal Hernia

NCT01825187

Study Protocol and Analysis Plan

Document Date: February 8, 2013

New Hanover Regional Medical Center
Institutional Review Board (IRB)
2131 South 17th Street/P.O. Box 9000
Wilmington, NC 28402-9000

RESEARCH APPLICATION

NHRMC: IRB ID#_____ ☐**Full Board** ☒**Expedited Review Category**_____

Check the appropriate boxes to indicate the documents you are submitting.	Submit application package copied double-sided & collated:
☒ IRB Application *(required for all studies)* ☒ Informed Consent ☐ Protocol ☒ Recruitment Materials ☐ Dated/Current CV for PI only (if not currently on file in IRB office) ☐ Professional License/Certifications (if required for study) ☒ Data Collection Tool (QOL, CRF, Surveys, etc.) ☐ Other (i.e. Investigator Brochure) ☒ Administrative Attachment ***(required, one copy for Clinical Research Officer)*** ☐ Human Participant Protection Certificate **(required all study staff if not currently on file in IRB office)**	• **Full Board: Original plus 13 copies** • **Expedited Review: Original Only** *Applications must "stand alone" and should provide all information requested, i.e., complete answers must be contained in the application. Application questions should be answered directly on the form. While you may reference other documents with supporting information, do not respond solely by stating "see attached".*

You must have administrative approval from the Clinical Research Officer prior to submission to the IRB as evidenced by a signature below.
To be completed by the Clinical Research Officer.
☐ Administrative Review Complete
☐ Administrative Approval Pending

_____ _____
Clinical Research Officer **Date**

Part I: Study Identification & Information

Complete the following information as it applies to your study.

Study Title (Use Title Case)	Prospective Randomized Controlled Trial Comparing Resident Performance and Clinical Outcomes with Two Different Polypropylene Meshes for Laparoscopic Inguinal Hernias	
Study ID	**Protocol Number:** **Version Date:**	**Amendment Date** (if applicable): **Consent Form Version Date:**

	Principal Investigator	**Primary Study Coordinator**
Name w/ Degrees	William Hope, MD	Chiquta Harris, BS
Practice/Company	SEAHEC Surgery	SEAHEC Research
Address	2131 S 17th St	2511 Delaney Ave.
City, State, Zip	Wilmington NC 28401	Wilmington, NC 28403
Phone	910.667.9233	910.667.9253
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Pager	910.341.5342	
E-mail	William.Hope@SEAHEC.net	Chiquta.Harris@seahec.net

A. Investigator Research Experience

1. Has the PI ever conducted research at NHRMC before?	☐ No ☒ Yes **Role:** ☒ PI ☐ Co-PI	☒ Currently have an open study(ies). ☐ Participated within last 2 years. ☐ Greater than 2 years.
2. Has any IRB ever taken corrective action for non-compliance including but not limited to issuance of a non-compliant closure of any of the PI's studies?	☒ No ☐ Yes	If yes, why?
3. Is any special or technical training required specific to the conduct of the study?	☒ No ☐ Yes	If yes, explain.
4. Name of course PI took for Human Participant Protection Education.	Name of course: NIH PHRP Cert. #129665 Completion Date: 11/05/2008 Expiration date:	
5. Name of course Study Coordinator took for Human Participant Protection Education.	Name of course: NIH PHRP Cert. #819035 Completion Date: Expiration date: NA	

**NOTE: If you have not completed a course in human participant protections, there is a link on the IRB webpage or go to http://phrp.nihtraining.com for an online tutorial course. If you have completed a course other than the NIH course, you will be required to provide a copy of the syllabus for the course.*

B. Nursing Research

*Complete this section **only if the PI or Co-PIs are nurses.*** ☒ **This section is not applicable to my study**

1. My research may be listed on the Nursing Research Committee intra-hospital webpage.	☐ Yes ☐ No ☐ Yes ☐ No	☐ PI ☐ Co-PI
2. My contact information may be given to the Nursing Research Committee to be listed on their intra-hospital webpage as a resource to other nursing researchers.	☐ Yes ☐ No ☐ Yes ☐ No	☐ PI ☐ Co-PI

C. Investigational Agent

*List investigational drugs/devices that are **not** FDA approved.*

☒ **This section is not applicable to my study**

Device **Complete section D below*	**Drug**
Name:	**Generic Name:**
Model #:	**Brand Name:**
IDE#:	**IND#:**

D. Research Involving Devices

Complete this section only if the study involves a device (both FDA and non-FDA approved).

☐ **This section is not applicable to my study**

1. Where will the devices be stored?	Explain. Devices are stored in the Operation Room (OR) and are in stock in the OR holding room at New Hanover Regional Medical Center.
2. Who will receive and manage inventory for the devices throughout the study?	Name: OR Staff Title: Nurses and Doctors
3. Who will have access to the devices?	Name: OR Staff Title: Nurses and Doctors
4. How will the devices be accounted for?	Explain. Devices that are availble on stock at the hospital will be used and the Lot number will be recorded.

5. What protections are in place to prevent loss or improper use?	Explain. These are devices are currently FDA approved and used on a daily basis at NHRMC so there are already precautions in place to protect them.

Part II: Study Subjects and Procedures

Complete the sections that apply to your study.

A. Subject Enrollment and Demographics:

This is a listing of the ***target*** study population. Check all that may apply.

You don't have to meet the anticipated subject enrollment number, but you can't exceed it without an amendment to increase the number anticipated at this site.

☒ Healthy Volunteers	☐ Chronically Ill	☐ Placebo (non active medicine)
☐ Employees	☐ Mentally Ill	☐ No Treatment Condition (control group is involved that receives no study-related treatment)
☐ Students	☐ Terminally Ill	
☒ Hospitalized Patients	☐ Use of Banked Specimens	
☒ Male	☐ Use of Fetus/Fetal Tissue	☐ Storage of Specimens for Future Use
☒ Female	☒ ***Indigent/Uninsured**	☐ Multi-center Study: Subject Enrollment anticipated subject enrollment # anticipated this site
☒ Adults	☒ ***Non-English Speaking**	
☐ Children (under 18) *(complete section V)*	☒ ***Limited or No Literacy**	☒ Single Site Study: Subject Enrollment # anticipated this site 511
☐ ***Pregnant** *(see below)*		

***The subject populations in bold font represent protected populations. If you are excluding subjects because they are pregnant, indigent/uninsured, non-English speaking, or limited or no literacy please explain why**: Pregnant women are excluded from the study because they are not usually operated on until after they have delivered.*

B. Research Involving Children

Complete this section only if study subjects are less than 18 years of age.

Special requirements: 45 CFR 46 Subpart D – Additional Protections for Children Involved as Subjects in Research

☒ **This section is not applicable to my study**

Age of Pediatric Subjects *(check all that apply)*

- ☐ Preterm Newborn Infants
- ☐ Term Newborn Infants (0—27 days)
- ☐ Infants and Toddlers (28 days to 23 months)
- ☐ Children (2—11 years)
- ☐ Adolescents (12—18 years)

Special Protections (answer as applicable to your study)

1. ☐ Yes ☐ No — Does the research have an identifiable prospect of direct benefit to the subjects? Explain:
2. ☐ Yes ☐ No — Can that benefit be achieved through alternative means? Explain:
3. ☐ Yes ☐ No ☐ N/A — If using a placebo control, does this place the subject at greater risk? Explain:
4. ☐ Yes ☐ No ☐ N/A — Will permission be sought from both parents? If not, why?
5. ☐ Yes ☐ No — Will you include children who are wards of the state? Explain:
6. ☐ Yes ☐ No ☐ N/A — Are there special issues that call for the presence of an advocate during

consent procedures? If so, what? Who? 7. ☐ Yes ☐ No ☐ N/A Will parents be present during the conduct of the research? If not, why? 8. ☐ Yes ☐ No ☐ N/A Are mechanisms in place to ensure the child's dignity is not undermined (obtaining their assent, honoring dissent, etc.)? Explain: 9. ☐ Yes ☐ No ☐ N/A Have you addressed the special needs of adolescents (protection of privacy {child abuse, sexual practices, drugs, alcohol, etc.}, counseling, appropriate resources, etc.)? Explain:	
10. How will parental permission be obtained?	☐ N/A Explain if applicable.
11. How will assent be obtained? This is generally a written consent for children who can read, ages 7 –17. A script can be used for children under 7 for verbal permission. **Attach copies to your submission.**	☐ N/A Explain if applicable.
12. For research involving children under 8 years of age, what non-verbal cues will you watch for to indicate the child is ready to end or pause participation?	☐ N/A Explain if applicable.

C. Confidentiality and Informed Consent: Be specific to protections that will be in place for subjects.

1. Where is study subject data kept? Check all that apply.	☐ Sponsor's Location ☒ Medical Record ☒ Principal Investigator/Local Research Office ☐ Other	
2. Will precautions be taken to protect subject information (e.g. locked file cabinet, password protected files, etc.).	☐ No ☒ Yes	Explain. All records will be coded and kept in a locked file cabinet. No patient or resident identifiers will appear on any coding sheets or electronic databases. Electronic databases will be password protected. Strict confidentiality will be maintained and no patient or resident will be identified in any report of our findings. A master list of patients and residents will be maintained separately from the coding sheets and databases.
3. Will the subject's personal health information be released with identifiers such as name, DOB, SSN?	☒ No ☐ Yes	If yes, explain.

4. Are you requesting a waiver of consent? If no, complete questions 5-12. ***Waiver can only be requested if it makes your study infeasible to conduct.*** Answer "No" and indicate in the explanation if you plan to use implied consent language for a survey, or a telephone consent script.	☒ No ☒ Yes	If yes, explain. A waiver of written consent is being requested for the residents involved in the study because 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. The normal consenting process will apply to the patients.
5. Who will obtain informed consent? Only the PI or Co-PIs may obtain consent. *Refer to NHRMC policy on informed consent.*	Name and credentials: William Hope, MD Study Role (PI / Co-PI): PI	

6. Describe how and where informed consent will be obtained?	If the subject is a potential candidate for the study, the subject will be approached by Dr. Hope. Dr. Hope will explain the study to the subject. If the subject decides to participate in the study, he/she will be given the informed consent document to review and sign. Once verbal consent is received, Dr. Hope will obtain written consent from the subject. All documents will be written and/or explained in a language to be understood by the subjects. Additional time to review the informed consent document will be provided if needed. Consent will be obtained by Dr. Hope during the patient's pre-operative appointment or during their visit to NHRMC. Patients will be consented by Dr. Hope at the Outpatient Surgery Clinic, SEAHEC Physicians' Office, Inpatient Surgical Units at NHRMC and/or the Emergency Department. Dr. Hope will review the surgical procedure and all of the steps associated with participating in the study. Dr. Hope will also review the informed consent documents with the patients. Patients will have a chance to ask Dr. Hope any questions they may have about the surgery and the study. Resident will be approached by Dr. Hope prior to the initiation of the study. Dr. Hope will give the residents the information sheet and will explain the study to the residents. Additional time to review the information sheet will be provided if needed. Dr. Hope will address and answer all concerns and questions of the residents pertaining to the study. If the residents agree to participate in the study, the study coordinator will obtain verbal consent from the consenting residents. The will be no repercussions to any residents that objects to being in the study. Will there be an opportunity for potential subjects to take the informed consent form home to consider the options and to discuss participation with family members? ☐ No ☒ Yes If no explain why:	
7. If you are enrolling non-English speaking subjects, will the consent form be in their native language? If not, explain the process for consent.	☐ No ☒ Yes ☐ N/A	Explain. If necessary, a Spanish interpreter will be used to explain the study and consent process.

8. If the subject is unable to provide consent, will consent be obtained from a legally authorized representative?	☒ No ☐ Yes	If yes, explain.
9. If yes to Q.7, if the subject becomes able to provide consent, will you re-consent?	☐ No ☐ Yes ☒ N/A	If no, explain.
10. How will you ensure that only the approved and current consent form is used *(e.g. only approved version will be available, will print original each time, etc.)*?	Explain. Study consent and information sheets will only be printed as needed and no additional copies will be printed. Only the approved version of the consent form and the information sheet will be provided to the patients and residents. The most current electronic version of the consent and information sheet will be kept in a separate electronic folder from prior consent forms and information sheets to avoid printing the wrong version. All previous drafts will be deleted.	
11. Where will the original signed and dated informed consent form be maintained?	Location: Dr. Hope's Office and/or SEAHEC Research Department A signed copy will be given to the subject? ☐ No ☒ Yes ☐ N/A A signed copy will be maintained in subject's medical record? ☐ No ☒ Yes ☐ N/A If no, explain.	
12. Will the informed consent process be documented in the subject's medical record? *(e.g. documented discussion of risks/benefits, alternatives to study participation, voluntary participation and measures of understanding)*	☐ No ☒ Yes ☐ N/A	Explain. The informed consent process will be documented in the subjects' medical records. There will be documentation of the discussion of the risks/ benefits associated with the study, any questions the subject had about the study, whether or not the subject chose to participate in the study, and evidence that the subject has a solid understanding of what participation in the study entails.

D. Recruitment: Tell how prospective subjects will be identified, referred, and contacted.

1. Is there any prior relationship with the subjects and the PI? *(one or both may be checked as applicable)*	☒ No ☒ Yes	If yes, explain. Patients may be current and/or previous patients of the investigator. Dr. Hope serves as the assistant professor to surgical residents.

2. If you as the PI are a clinician, will subjects be drawn exclusively from your own sample base?	☐ No ☒ Yes	If no, explain how subjects will be identified.
3. If no to Q2, will the subject's physician be consulted, contacted, or notified?	☐ No ☐ Yes	If no, explain.
4. Will recruitment materials be used (videos, ads, flyers, etc.)?	☒ No ☐ Yes	If yes, what types, and when and how will they be used?
5. Will subjects be paid for participating in the study, including but not limited to compensation for time, travel, etc.?	☒ No ☐ Yes	If yes, explain.
6. Describe how subjects will be initially contacted (i.e. recruitment materials, letter, office visit, etc.)? Subjects will be initially contacted by Dr. Hope at their preoperative visit.		

E. Benefits: Do not list monetary payments as a benefit.

1. Are there benefits to the subject? (What are the benefits, if any, to the subject by participating in the study?)	Explain. There are no direct benefits to research participants.
2. Are there benefits to society? (What potential benefits to future individuals may the study provide?)	Explain. Yes. Information gathered from the study may benefit future patients undergoing hernia surgery by determining which mesh is better for use during these procedures. The study will increase knowledge on the different types of hernia meshes and the length of time it takes residents to perform the procedure.

F. Costs to Subjects: Explain the financial liability to the study subject; distinguish study related costs vs. routine care costs.

1. Are there study related costs to subjects that are not paid by the study?	☐ No ☒ Yes	Explain. Participants will be responsible for covering routine care costs associated with doctor visits and the surgery. However, there are no extra costs associated with this study. The six (6) month and one (1) year follow-up visit are not routine, therefore, the patient will not be charged for any of these services (both clinic and professional fees will not be billed to the patients). For the 6 month and 1
2. Will the subject be financially responsible should insurance deny coverage of study-related costs?	☒ No ☐ Yes	
3. Will the subject be financially responsible should insurance deny coverage of routine care costs?	☐ No ☒ Yes	

4. Will the PI or a representative discuss with the subject the difference between study related costs and routine care costs, and that the subject or the subject's insurance provider will be responsible for routine care costs?	☐ No ☒ Yes	year follow-up the patient will be contacted by telephone or be asked to return to the SEAHEC Physician's Office. Dr. Hope will discuss this information with the patients.

G. Statistical Analysis

1. Who will provide statistical analysis?	SEAHEC Research Department
2. Is there a data safety monitoring board?	☒ No ☐ Yes ☐ N/A, this is not a clinical trial or treatment study

Part IV: Description of Proposed Research Study

NOTE: This portion of the application is not intended for a cut and paste from the protocol, but rather for a summary of why the study is needed and how the study will work at this institution. ***Please use lay terms or provide definitions.***

1. **Purpose and rationale**: Provide a brief summary of the background information to put the study in context, include references and prior research as appropriate. State the research question(s) and tell why the study is needed or important. Describe the primary objective and any secondary objectives. Document a clear, concise purpose statement. If the study is a clinical trial involving patients as subjects and use of placebo, please justify the use of these controls.	An inguinal hernia occurs when soft tissue, which is usually part of the lower intestine, bulges through a weak point in the lower abdominal wall. The bulge that occurs from this hernia can be extremely painful and does not go away on its own. Inguinal hernia repair is one of the most common operations performed by general surgeons in the world. There are two main ways to repair an inguinal hernia, open or laparoscopic. An open repair is done by making a single long incision in the groin (the fold or hollow on either side of the front of the body where the thigh joins the abdomen) so it is possible for the surgeon to see the entire area and perform the surgery without the use of a laparoscope (an instrument through which structures within the abdomen and pelvis can be seen). Open repairs lead to more scarring and a longer recovery period. A laparoscopic repair is done by making a small cut in or just below the belly button. The abdomen is then inflated with air to allow the surgeon to be able to see all of the organs. Then, a lighted scope called a laparoscope is inserted into the incision so the surgeon can see inside the abdomen during the surgery. Surgical instruments used to repair the hernia are inserted through other small openings in the abdomen and a mesh is placed over the bulge (hernia) to reinforce the abdominal wall. Laparoscopic repair has become an accepted standard for inguinal hernia repair and has become the technique of choice for recurrent inguinal hernias.

	One main part of the procedure to repair a hernia involves the placement of a prosthetic (a device that substitutes for missing parts or pieces) mesh to reinforce the abdominal wall and allow for a tension free repair. The use of the mesh also helps to lower the recurrence rate (the chance that the hernia will come back). The most common type of mesh prosthesis that is placed in laparoscopic inguinal hernias is a polypropylene (the substance the mesh is composed of) mesh which has been shown to be safe and effective. There is some emerging evidence that a "lighter weight" form of this mesh may improve quality of life outcomes following surgery and is the mesh currently being used at New Hanover Regional Medical Center for laparoscopic inguinal hernia repair. However, there are many different "light weight" polypropylene meshes on the market that are FDA approved and available for use. Currently, there are two different forms of the mesh being used interchangeably for the procedure at NHRMC. Both of these meshes have had good clinical outcomes. The purpose of this research study is to evaluate the clinical effectiveness of the two meshes currently being used. The study may provide evidence on whether one mesh is more effective than the other. A secondary goal of the study is to evaluate the ease of use and time it takes residents to place and perform the surgery using these two different meshes. This information may make it possible to determine if one mesh is easier for residents to use during surgery and therefore take them less time to perform the procedure. The effectiveness of the meshes will be measured by the patient's length of hospital stay, perioperative complications, recurrence rate, patient pain score and/or comfort level and the patient's postoperative quality of life.
2. **Description of study design, methods, and procedures, *describe the study in sequential order as it is to be conducted at this institution. The following should be included*:** ➢ type of experimental design ➢ study procedures: a sequential description of what will be asked of/done to subjects (to include identification and recruitment of subjects, consent process, treatment or intervention if applicable, length of participation, additional visits, follow-up, etc.) ➢ description and assignments of subjects to various arms of the study (if applicable)	This will be a prospective open-label randomized study conducted by Dr. Hope from the study's approval date to until December 31, 2015. Approximately five-hundred (500) subjects will be enrolled in this study. Patients presented to NHRMC, the Outpatient Surgery Clinic, SEAHEC Physicians' Office, Inpatient Surgical Units at NHRMC and/or the Emergency Department for abdominal wall hernia repair during their pre-operative visit and who meet the inclusion and exclusion criteria will be counseled by Dr. Hope on surgical options for repair to determine if they would

➢ doses, frequency, and route of administration of medication and other treatment ➢ data that will be collected ➢ primary outcome measurements ➢ follow-up procedures ➢ If the study involves clinical activities, distinguish routine care procedures from those that are study specific	rather undergo an open or laparoscopic repair. If the patient is a candidate and agrees with undergoing the laparoscopic repair, they will be asked if they would like to participate in a randomized trial comparing two different meshes. If the patient agrees, he/she will be presented with information regarding this study. The study will then be explained to the patient by Dr. Hope. Dr. Hope will give the patients the informed consent document at New Hanover Regional Medical Center, Outpatient Surgery Clinic, SEAHEC Physicians' Office, Inpatient Surgical Units at NHRMC and/or the Emergency Department. Dr. Hope will review the page-by-page informed consent document with the patients. A copy of the informed consent document explaining the objectives and associated risks and benefits of the study will be given to the patient. The patient will be allowed to read and review the elements of the informed consent document. Patients will have a chance to ask Dr. Hope any questions they may have about the surgery and the study. If necessary, the patient will be allowed additional time to review the document. After receiving verbal consent, Dr. Hope will obtain written consent from the patient. A copy of the signed informed consent document will be given to the patient and another copy will be placed into the patient's medical record. The original document will be placed into a separate secure file cabinet that will be locked at all times. On the day of surgery, patients agreeing to participate in the study will be randomized to receive either one of two meshes - ultrapro mesh (Ethicon) or bard 3d max (Bard). This randomization will occur with a random pattern being generated using an electronic random number generator. Then, the random assignments will be placed inside opaque, sequential envelopes. The envelopes will be opened, in order, which will guarantee a random assignment of subjects to each study arm. Prior to the surgery, patients will be given the Carolinas Comfort Scale (CCS) and Visual Analog Scale (VAS). These study specific scales will be used to access the patients' pain and/or comfort level prior to surgery and should take no longer than 5 minutes to complete. The CCS uses a patient questionnaire of 8 questions to establish a quality measure for pain. Patients are asked to rate, on a scale of 0 to 5, sensation of mesh, pain and movement limitations during the following activities: lying down, sitting up, activities of daily living, coughing or deep breathing, walking or standing, walking up or down stairs, and while performing non-work related exercising. The VAS

helps patients to say how good or bad their health state is. This scale uses a line with two different extremes. The extremes can vary in forms. Some VAS can ask the patient to range their pain level or current health status on a rating of either 0-10 (with 0 being no pain and 10 being the worst possible pain) or by choosing a picture of a happy or sad face.

Patients with bilateral inguinal hernias (an abnormal opening or defect that occurs on both sides of the groin), either found preoperatively or intra-operatively, will be treated as one hernia and will have the same mesh placed on both sides. Cases will be performed by one attending using his standard technique for laparoscopic inguinal hernia repair.

Data to be collected will include the patients' demographic information (age, sex, race), comorbidities (if present), smoking history, drinking history, medications, allergies and previous surgeries.

Operative data will include the following: type of anesthesia (all patients will undergo general), technique of laparoscopic access, type and side of hernia (direct or indirect), size of mesh used, type and number of tacks used to secure mesh, operative time, blood loss, urine output, and type and technique of closure.

Postoperative data will include: length of hospital stay, perioperative complications, recurrence rate, patient pain score and patient's postoperative quality of life. Further follow up data will include an assessment of the patient's recurrence rate, pain scale and quality of life during the patient's 1-2 weeks, 6 months, and 1 year follow-up. The patient will also be asked to rate their pain and/or comfort level by using the CCS and/or the VAS. During their 1-2 weeks visit, the patient will be informed of the 6 and 1 year follow-ups. For the six (6) month and one (1) year follow-up the patient will be contacted by telephone and/or be asked to return to the SEAHEC Physician's Office. The patient will not be charged for any of these services. Subjects will be tracked and identified with the use of the research record that will be set up in EPIC. Patients will be associated with the study and their surgery admission will be associated with the study for billing and coding compliance. In case the above system does not work, as a secondary system, patients will be tracked using an excel spreadsheet.

Resident will be approached by Dr. Hope prior to the initiation of the study. Dr. Hope will give the residents the information sheet and will explain the study to the

	residents. Additional time to review the information sheet will be provided if needed. Dr. Hope will address and answer all concerns and questions of the residents pertaining to the study. If the residents agree to participate in the study, the study coordinator will obtain verbal consent from the consenting residents. The will be no repercussions to any residents that objects to being in the study. Resident level (PGY level), participation in the case (percentage of resident involvement to be determined by attending physician), time to perform the three critical portions of the case (laparoscopic access and takedown of peritoneum, placement of mesh, closure of peritoneum, and closure) will all be documented. This is routinely done by the surgical residents. Following the case, the resident will be given a performance scale (NASA-TLX) to grade his/her performance in conducting the surgery. This is not routinely done but is done for some surgical cases. The NASA-TLX is a publically available, multi-dimensional scale designed to obtain workload estimates from one or more operators while they are performing a task or immediately afterwards. It contains 6 scales that will ask the residents to rate their mental demand, physical demand, temporal demand, performance, effort and frustration on a scale of very low to very high. This will take the resident no more than three (3) minutes to complete. Once the resident has completed the scale, they will return the scale to Dr. Hope. Dr. Hope will then give the scales to the study coordinator who will keep all the scales in a locked and secure place at SEAHEC. The scale will be linked to the study patient by entering the study patient's study ID number on the scale. The residents do not routinely complete the NASA-TLX for all surgeries but for some they do. The requirement for the completion of the NASA-TLX by the surgical residents will be new and specific for this study. Descriptive statistics will be performed and outcomes and resident performance will be compared based on resident level and type of mesh used. A p-value of <0.05 will be considered significant.
3. **Description of risks and measures to minimize risks:** Do not insert "No Risk", at minimal every study has a risk of breach of confidentiality. Include risk of: * breach of confidentiality, * known side effects of study medication, risk of pain, and/or physical injury,	This study has no additional health risks. The short and long physical risks associated with hernia repair of both meshes include very mild pain and awareness of mesh and/or stiffness in the groin respectively. However, these risks are similar to the risks seen in routine surgical hernia repairs.

* psychosocial harm (emotional distress, embarrassment, , etc.), * economic harm (loss of insurability), * legal jeopardy (disclosure of illegal activity) ***Describe the measures taken to minimize each risk.***	As an additional safety precaution, once the first one hundred (100) subjects have been entered into the study by the PI, an interim analysis (analysis of data collected at a certain time during the study in order to detect any trends of adverse events or to see if the study has negative effects on the patient's safety) will be conducted by the statistician. Any negative trends or adverse events will be reported to the IRB by the study coordinator. Another interim analysis will be collected by the statistician after the first two hundred and fifty (250) subjects have been entered into the study. Any negative trends or adverse events will be reported to the IRB by the study coordinator.The possible side effects and complications of the surgery relate to the procedure itself and will not be related to the data collection. A possible risk may be the loss of privacy and the confidentiality of patient information. Access to the database is protected by password and is only accessible to the study and research staff. Every effort will be made to protect the privacy of patient information in the database, but this cannot be guaranteed.
4. **Inclusion/exclusion criteria**: List required elements of potential subjects and those that preclude enrollment. *(Exclusion criteria are not opposite of inclusion criteria, but rather elements within the already identified subject population that would be a cause for exclusion from the study.)*	The inlcusion criteria for patients in this study will include all of Dr. Hope's patients undergoing laparoscopic repair for the treatment of either single or bilateral inguinal hernias from the study's approval date to December 31, 2015. The inclusion criteria for residents in this study will include all surgery residents. The exclusion criteria for patients in this study will include patients requiring emergency surgery, pregnant patients and patients under 18 years of age. There is no exclusion criteria for residents in this study.

Part V: Financial Conflict of Interest

This section is to be completed for all financially sponsored studies.

Are you being paid to conduct this study? ☐ ***Yes*** ☒ ***No***

If yes, complete questions below, if no skip to next section.

If financially sponsored indicate source:

Indicate by marking YES or NO if any of the financial interests or arrangements described below apply to you, your spouse, or dependent children.		
Yes ☐	**No** ☐	Compensation for services (e.g. consulting fees or honoraria), or in-kind payments, other than from the Investigator's primary employer, in the prior calendar year or project over the next twelve months.
		Royalty income or the right to receive future royalties under the patent license or copyright,

☐	☐	where the research is directly related to the licensed technology or work.
☐	☐	Equity interests (e.g. stocks, stock options or other ownership interests, including equity holdings where the value cannot readily be determined by reference to public prices).
☐	☐	Intellectual property rights (e.g. patents, copyrights, and royalties from such rights).
☐	☐	Gifts or funds available to the researcher from this sponsor beyond the current research project.
☐	☐	Funding expected to significantly exceed the projected costs of conducting the current research project.
☐	☐	Any other financial or personal interest which presents an actual or perceived conflict of interest.

If the response to any item is yes, please provide below a full description of the financial interest (including amount of compensation and other information related to compensation) and how the financial interest might affect or be affected by the proposed research.

I certify that the above information is complete and accurate, in accordance with 21 CFR Part 54. Furthermore, if changes occur in my financial arrangements and interests, or those of my spouse or dependent children, during the course of this study, I am required to update this form.

WILLIAM HOPE
Principal Investigator *(Printed Name)*

1/24/13
Date

Signature Principal Investigator

Agreement of the Principal Investigator

- I certify that I have reviewed the information in this document and it is correct and complete.
- I certify that each of the named study personnel has accepted his/her role in this study.
- I agree to a continuing exchange of information with the New Hanover Regional Medical Center's (NHRMC) Institutional Review Board (IRB) as required by NHRMC IRB Policy and Procedure and the FDA Regulations and Guidelines.
- I agree to conduct this study according to the Good Clinical Practice Guidelines and regulations (FDA).
- Under non-emergent conditions, I agree to obtain IRB approval before making any changes or additions to the project. I will provide progress reports as required.
- I agree to report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects.
- A signed and dated copy of the consent form will be given to each subject and the original will be retained in the study files. If the study involves NHRMC patients, I will be responsible for placing a copy of the signed consent in the patient's medical record.
- I will notify the IRB in the event the study closes.

- I agree to use the patient health information as specified in this research study application and to:
  - Only view and obtain the information necessary to complete the scope of this study.
  - Only release information as it is specified in an approved and signed informed consent form.
  - Store the collected information in a confidential manner.
  - Comply with the standards and regulations set forth by the Health Information Management Department to acquire and use the medical records.
  - Be responsible for the study staff listed in this application or required attachments and ensure that they will abide by the rules of confidentiality outlined above.

WH
Signature

WILLIAM HOPE
Printed Name

1/24/13
Date

NOTE: Your signature must be legible for submission to be accepted.