Improvement in Wound Healing with Negative Pressure Wound Therapy for Postoperative Total Hip Arthroplasty

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General Information

1. General Information

1. Project Title

   Improvement in Wound Healing with Negative Pressure Wound Therapy for Postoperative Total Hip Arthroplasty

2. **Brief Summary**. Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content. PLEASE NOTE: THIS SECTION MAY BE EDITED BY THE IRB FOR CLARITY OR LENGTH.

   For the target population of adult patients following primary total hip arthroplasty, the randomized clinical trial will be used to evaluate the efficacy of the use of a mobile negative pressure wound therapy(NPWT) device compared to a standard absorptive dressing in the immediate postoperative period. We will apply two dressing types and evaluate the postoperative wounds with a wound scoring system (ASEPSIS) that incorporates multiple variables of wound infection risk.

3. Is this new study similar or related to an application already approved by a UNC-Chapel Hill IRB? Knowing this will help the IRB in reviewing your new study.

   No

2. Project Personnel

1. Will this project be led by a STUDENT (undergraduate, graduate) or TRAINEE (resident, fellow, postdoc), working in fulfillment of requirements for a University course, program or fellowship?

   No

2. List all project personnel beginning with principal investigator, followed by faculty advisor, co-investigators, study coordinators, and anyone else who has contact with subjects or identifiable data from subjects.

   - List ONLY those personnel for whom this IRB will be responsible; do NOT include collaborators who will remain under the oversight of another IRB **for this study**.
   - If this is Community Based Participatory Research (CBPR) or you are otherwise working with community partners (who are not functioning as researchers), you may not be required to list them here as project personnel; consult with your IRB.
   - If your extended research team includes multiple individuals with limited roles, you may not be required to list them here as project personnel; consult with your IRB.

   The table below will access campus directory information; if you do not find your name, your directory listing may need to be updated.

Last Name	First Name	Department Name	Role	Detail
Eskildsen	Scott	Orthopaedics	Co-investigator	view
Del Gaizo	Daniel	Orthopaedics	Principal Investigator	view
Healy	Kaitlin	Orthopaedics	Project Manager or Study Coordinator	view
Laux	Jeff	Biostatistics Operations	Research Assistant	view

NOTE: The IRB database will link automatically to UNC Human Research Ethics Training database and the UNC Conflict of Interest (COI) database. Once the study is certified by the PI, all personnel listed (for whom we have email addresses) will receive separate instructions about COI disclosures. The IRB will communicate with the personnel listed above or the PI if further documentation is required.

3. If this research is based in a center, institute, or department (Administering Department) other than the one listed above for the PI, select here. Be aware that if you do not enter anything here, the PI's home department will be AUTOMATICALLY inserted when you save this page.

Department	Orthopaedics

3. Funding Sources

1. Is this project funded (or proposed to be funded) by a contract or grant from an organization EXTERNAL to UNC-Chapel Hill?

   Yes

Funding Source(s) and/or Sponsor(s)

Sponsor Name	UNC Ramses Number	Sponsor Type	Prime Sponsor Name	Prime Sponsor Type	Sponsor/Grant Number	Detail
Kinetic Concepts, Inc. (KCI)	Currently Not Available	Industry		Industry	15-0451	view

2. Is this study funded by UNC-CH (e.g., department funds, internal pilot grants, trust accounts)?

   No

3. Is this research classified (e.g. requires governmental security clearance)?

   No

4. Is there a master protocol, grant application, or other proposal supporting this submission (check all that apply)?

- ✖ Grant Application
- ✖ Industry Sponsor Master Protocol
- ✖ Student Dissertation or Thesis Proposal
- ✖ Investigator Initiated Master Protocol
- ✖ Other Study Protocol

4. Screening Questions

The following questions will help you determine if your project will require IRB review and approval.

The first question is whether this is RESEARCH

1. Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge? PLEASE NOTE: You should only answer yes if your activity meets all the above.

Yes

The next questions will determine if there are HUMAN SUBJECTS

2. Will you be obtaining information about a living individual through direct intervention or interaction with that individual? This would include any contact with people using questionnaires/surveys, interviews, focus groups, observations, treatment interventions, etc. PLEASE NOTE: Merely obtaining information FROM an individual does not mean you should answer 'Yes,' unless the information is also ABOUT them.

   Yes

3. Will you be obtaining identifiable private information about a living individual collected through means other than direct interaction? This would include data, records or biological specimens that are currently existing or will be collected in the future for purposes other than this proposed research (e.g., medical records, ongoing collection of specimens for a tissue repository).

   Yes

The following questions will help build the remainder of your application.

4. Will subjects be studied in the Clinical and Translational Research Center (CTRC, previously known as the GCRC) or is the CTRC involved in any other way with the study? (If yes, this application will be reviewed by the CTRC and additional data will be collected.)

   No

5. Does this study directly recruit participants through the UNC Health Care clinical settings for cancer patients **or** does this study have a focus on cancer or a focus on a risk factor for cancer (e.g. increased physical activity to reduce colon cancer incidence) **or** does this study receive funding from a cancer agency, foundation, or other cancer related group? (If yes, this application may require additional review by the Oncology Protocol Review Committee.)

   No

6. Are any personnel, organizations, entities, facilities or locations in addition to UNC-Chapel Hill involved in this research (e.g., is this a multi-site study or does it otherwise involve locations outside UNC-CH, including foreign locations)? You should also click "Yes" if you are requesting reliance on an external IRB, or that UNC's IRB cover another site or individual. See guidance.

   No

Exemptions

Request Exemption

Some research involving human subjects may be eligible for an exemption which would result in fewer application and review requirements. This would not apply in a study that involves drugs or devices, involves greater than minimal risk, or involves medical procedures or deception or minors, except in limited circumstances.

Additional guidance is available at the OHRE website. Exemptions can be confusing; if you have not completed this page before, please review this table with definitions and examples before you begin.

1. Would you like your application evaluated for a possible exemption?

   No

Part A. Questions Common to All Studies

A.1. Background and Rationale

A.1.1. Provide a summary of the background and rationale for this study (i.e., why is the study needed?). If a complete background and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here. If there is no proposal, provide a more extensive background and literature review, including references.

Periprosthetic joint infections are a devastating complication due to their difficulty in treating, burden on the system, and patient morbidity and occurs in approximately 0.5% to 3% of primary total joint arthroplasties.[1–4] Revision total knee has both a detrimental physical and economic burden. Patients require treatment with intravenous antibiotics, multiple surgeries, and prolonged hospital courses. The clinical outcome of revision surgery for infection is also worse compared to other reasons for revision.[5] Periprosthetic infections also place a significant burden on hospitals. Increased blood loss, complications, and operative time lead to higher total hospital costs, longer hospital stays and increased outpatient visits. Revision arthroplasty compared to aseptic revision can cost more than $60,000 more.[4] The cost of revision total joint arthroplasty is expected to be 1.6 billion in 2020.[6]

Periprosthetic infections can be related to a number of different factors both patient and environmental. Patient factors such as rheumatologic disease and obesity increase the risk of infection.[7–9] There is also evidence that surgical factors can increase a patient's risk. Time in the operating room, increased traffic, and protective clothing can also impact a patient's chance of developing a SSI.[10,11] Postoperative wound dressings have also been targeted as a means for reducing infection risk. Standard dressings generally consist of sterile absorptive dressings over the incision. Changes in dressing duration and type have yielded varying results. Recently, the use of Negative Pressure Wound Therapy (NPWT) has been investigated for the use on postoperative clean wounds.[12–18]

NPWT was developed for the use on open wounds. Granulated foam is placed over the wound and negative pressure through the form of suction is applied. The benefit of this therapy is hypothesized to be multifactorial including increasing blood flow, reduction of hematoma, and sequestering of the wound from the outside environment.[19] NPWT has been used successfully in orthopaedics for traumatic wounds and surgical infections. Due to this success the use of NPWT expanded to postoperative infection prevention. A study by Pachowsky et al. used a NPWT device specifically designed for closed wounds to reduce post operative seromas in total hip arthroplasty.[15] The study used the PREVENA™ system from Kinetic Concepts Inc. (KCI) to reduce seromas in size from 5.08ml to 1.97ml after 10 days post-op. The PREVENA™ system is a mobile wound therapy device that operates through a battery-powered pack allowing the patient greater mobility than a standard suction device. [20]

Given the success of the system in reducing postoperative seromas it may help reduce the risk of postoperative surgical site infection (SSI). Evaluation of SSI in total joint arthroplasty is difficult given the low incidence in primary arthroplasty. Comparing the incidence of infection with two dressings is difficult given the large amount of patients required to obtain a statistically significant difference. Therefore, evaluating a method that can reduce risk factors for infection such as seroma development becomes more achievable. However, the risk of SSI postoperatively is not limited to the development of a seroma. Wound dehiscence and drainage are also indicated as potential risk factors for SSI. Patients that develop drainage, erythema or dehiscence require increased concern for infection and can lead to additional procedures including diagnostic aspirations, scar revision and irrigation and debridement. The previous study's evaluation of seroma did not evaluate many of these factors that can lead to SSI.

Another method of evaluating wounds for SSI risk that incorporates multiple wound healing factors such as erythema, drainage, and dehiscence is the ASEPSIS (**A**dditional treatment, presence of **S**erous discharge, **E**rythema, **P**urulent exudate, **S**eparation of the deep tissue, **I**solation of bacteria, and duration of inpatient **S**tay) wound scoring system.[21] Originally developed and validated for cardiac surgery sternal wounds, ASEPSIS evaluates the wound for the severity of multiple factors linked with surgical site infection.[22–25] This includes dehiscence, exudate/discharge, and erythema. The scoring system also includes secondary procedures that increase patient morbidity such as surgical procedures and the use of antibiotics. The higher the score, the more likely a surgical site infection will be present. This score will give us a more diverse picture of postoperative wound healing and the influence of NPWT.

ASEPSIS Scoring System

Characteristic	Percent of Wound Affected					
	0	<20	20-39	40-59	60-79	>80
Serous Exudate	0	1	2	3	4	5
Erythema	0	1	2	3	4	5
Purulent Exudate	0	2	4	6	8	10
Separation of Deep Tissue	0	2	4	6	8	10

Additional Points for: Antibiotic Treatment- 10 Local Debridement- 5 OR Debridement- 10 Isolation of Bacteria- 10 Hospitalization >14 days- 10

The scoring system is designed to translate the appearance of the wound with the clinical appearance. Stricter methods of evaluating wounds (such as evaluating for pus) can miss lesser degrees of infection. This score helps to overcome the challenge of a small incidence of grossly infected wounds by identifying the skin changes associated with infection. Wilson et al. identified an ASPESIS score >20 as being more sensitive and as specific as the presence of pus as an indicator of changes in management resulting from infection [24]. The scoring method has also been shown to be both repeatable (intraobserver reliability of 0.96 and coefficient of repeatability of 4.1) and validated against the CDC criteria in general surgery procedures.[22,25]

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A.1.2. State the research question(s) (i.e., specific study aims and/or hypotheses).

Does the use of a negative pressure wound therapy system improve wound healing as measured by the ASEPSIS score on postoperative primary total hip arthroplasty patients?

Aim 1. Wound Healing. Compare the two dressings in terms of their ASEPSIS wound healing score after 1 week, 2 weeks and 6 weeks post operatively. The anticipated result is that the NPWT will show improved wound healing.

Aim 2. Secondary Procedures. Compare the two dressings in terms of requirements for secondary events such as aspirations, ER visits for wound concerns, and return to the operating room. The anticipated result is that the NPWT will decrease secondary events.

Aim 3. Safety. Compare the two dressings in terms of frequencies of adverse events. The anticipated result is that the research subjects will experience no significant difference in the number of adverse events relative to the standard regimen.

A.2. Subjects

A.2.1. Total number of subjects proposed across all sites by all investigators (provide exact number; if unlimited, enter 9999):

90

A.2.2. Total number of subjects to be studied by the UNC-CH investigator(s) (provide exact number; if unlimited, enter 9999):

90

A.2.3. If the above numbers include multiple groups, cohorts, or ranges or are dependent on unknown factors, or need any explanation, describe here:

All patients will be adult patients undergoing primary total hip arthroplasty. Patients will be randomly and evenly divided into two groups. One receiving the NPWT treatment and the other receiving our standard post surgical dressing.

A.2.4. Do you have specific plans to enroll subjects from these vulnerable or select populations:
Do not check if status in that group is purely coincidental and has no bearing on the research. For example, do not check 'UNC-CH Employees' for a cancer treatment study or survey of the general public that is not aimed at employees.

✘ Children (under the age of majority for their location)
Note that you will be asked to provide age ranges for children in the Consent Process section.
✘ Non-English-speaking
✘ Prisoners, others involuntarily detained or incarcerated (this includes parolees held in treatment centers as a condition of their parole)
✘ Decisionally impaired
✘ Pregnant women
✘ HIV positive individuals
✘ UNC-CH Students
Some research involving students may be eligible for waiver of parental permission (e.g., using departmental participant pools). See SOP 32.9.1
✘ UNC-CH Employees
✘ UNC-CH Student athletes, athletic teams, or coaches
✘ People, including children, who are likely to be involved in abusive relationships, either as perpetrator or victim. This would include studies that might uncover or expose child, elder or domestic abuse/neglect. (See SOP Appendix H)

A.2.5. If any of the above populations are checked, describe how you plan to confirm status in one or more of those groups (e.g., pregnancy, psychological or HIV testing)

No Answer Provided

A.2.6. If any of the above populations are checked, please describe your plans to provide additional protections for these subjects

No Answer Provided

A.2.7. Age range of subjects:

Minimum age of subject enrolled	18
	years
Maximum age of subject enrolled	99
» If no maximum age limit, indicate 99	
	years

A.3. Inclusion/exclusion criteria

A.3.1. List required characteristics of potential subjects (i.e., inclusion and exclusion criteria). If not covered, list also characteristics that would preclude their involvement.

Inclusion Criteria:

Adult patients undergoing primary total hip arthroplasty.

Exclusion Criteria:

- age less than 18 y/o
- Total hip arthroplasty for fracture
- Revision or conversion total hip arthroplasty
- inability to personally consent to participation due to cognitive impairment, intoxication or sedation
- multiple surgical procedures
- Patients taking immune modulating medication(prednisone, methotrexate, anakinra, etc...)
- skin hypersensitivity to acrylic adhesive or silver.
- Inability to care for dressing due to physical or mental incapacitation

A.3.2. Justify any exclusion based on race, gender or ethnicity

Individuals will have equal opportunity to participate in the study regardless of gender, race and ethnicity.

A.3.3. Will pregnant women or women who become pregnant be excluded?

No

A.4. Study design, methods and procedures

Your response to the next question will help determine what further questions you will be asked in the following sections.

A.4.1. Will you be using any **methods or procedures commonly used in biomedical or clinical research** (this would include but not be limited to drawing blood, performing lab tests or biological monitoring, conducting physical exams, administering drugs, or conducting a clinical trial)?

Yes

A.4.2. Describe the study design. List and describe study procedures, including a sequential description of what subjects will be asked to do, when relevant.

Patients will undergo primary total hip arthroplasty with identical preoperative and intraoperative care. The patients will then be divided into two groups depending on their randomization. All postoperative care will remain the same other than the choice of dressing placed postoperatively. They will remain in the hospital for 2-3 days(standard of care). On Post op day two they will receive a dressing change regardless of their regimen(standard of care). Patients will be discharged home or to a skilled nursing facility with instructions regarding wound care in both regimens. They will receive assistance through home health or through their nursing facility in case of dressing issues although there will be no intended dressing change or other alteration of the dressing until their next followup. Instructions for the study will be included in the discharge instructions and

include a phone number for questions, these instructions are provided on another attachment. The patients will return to clinic on Post op day seven. They will have their wound evaluated and the dressing changed with their wound evaluated for ASEPSIS (the details of the scoring system and references are provided in the background). They will return on post op day 14 and again have their wound evaluated. Their staples will also be removed. They will be monitored until their 6 week visit for any complications.

Standard Regimen.

Post Op Dressing	Staples over surgical incision, Adaptic® dressing, Abdominal Dressing pad, Tape
POD2	All dressings removed, staples remain in place, Island dressing placed
1 Week Post Op	Island dressing removed and new sterile island dressing placed *Wound evaluated
2 Weeks Post Op	Island dressing removed and staples removed, no dressing placed *Wound evaluated

Experimental Regimen.

Post Op Dressing	Staples over surgical incision, NPWT dressing
POD2	Dressing removed, staples remain in place, New sterile NPWT dressing placed

1 Week Post Op	NPWT dressing removed and sterile island dressing placed *Wound evaluated
2 Weeks Post Op	Island dressing removed and staples removed, no dressing placed *Wound evaluated

The evaluations to be recorded, and the occasions of evaluation, are detailed in **Table 1a** and **Table 1b**.

Table 1a. Measurements Recorded: Patient Profile Data

Domain	Name of Variable	Description of the Variable	When Recorded
Identifiers	patient_ID	unique patient ID for this study	All occasions
	date	Date of each occasion	All occasions
	treatment_group	Treatment regimen assigned	Enrollment
Patient Factors	age	age in years	Enrollment
	gender	sex(male, female)	Enrollment
	allergies	list of allergies	Enrollment
	medical_history	medical history	Enrollment
	side	Side(left, right)	Enrollment
	co-morbidities	List of co-morbidities	Enrollment
Compliance	adherence	Self-reported adherence to protocol	All visits

Table 1b. Measurements Recorded: Treatment and Response Data

Measurement	1 Week Post op	2 Weeks Post op
Serous Exudate	X	X
Erythema	X	X
Purulent Exudate	X	X

Separation of Deep Tissue	X	X
Antibiotic Treatment	X	X
Local Debridement	X	X
Operative Debridement	X	X
Positive Bacterial Culture	X	X
Hospitalization >14 days	X	X
Adverse Events	X	X

A.4.3. If subjects are assigned or randomized to study "arms" or groups, describe how they are assigned.

- *Describe the methods of computing the randomization schedule (if any) and maintaining blinding (if any).*
- *Who will perform these computations?*
- *How will you verify each subject's eligibility prior to randomization?*

Treatment regimen will be assigned to research subjects by a randomization procedure performed through the REDCap software. An independent member of the TraCS team and software manager (Clarence Potter) will assist in developing the randomization. Prior to surgery the research team will be informed of the selected treatment group and provide the dressing to the surgeon intraoperatively. Subsequently, the assigned treatment may be adaptively modified in some ways to protect the well-being of the subject. Such modifications may create a departure from protocol.

Randomization procedure. The randomization procedure will assign the research subjects (i.e., the experimental units) to the two treatment regimens in a 1:1 ratio. De

Blinding. This will be an unblinded, open-label study. Both patients and their respective care teams will be aware of the treatment regimen to which each patient has been randomized at the time of enrollment, at the time of informed consent and throughout treatment.

Protocol Departures. Although early termination of the subject's dressing is not anticipated, it is possible that some research subjects will require modifications of their dressing or care that constitute departure from the assigned treatment regimen. A case by case decision will be made to either continue the protocol or to drop the patient from the study and make needed changes. Protocol departures will be carefully documented. Subjects whose medical care departs from the protocol will continue to be evaluated per protocol and the resulting data will be recorded in the database for use in intent-to-treat (ITT) statistical analyses.

A.4.4. Describe any follow up procedures.

Followup is standardized and in keeping with normal postoperative care. Evaluation of the wound will occur during followup, however no additional procedures will be required.

A.4.5. Once this study has been approved by the IRB, for how many months or years will this study be active (you are collecting data or have access to identifiers)?

Start:Following IRB approval

Stop:1 year from start date or earlier depending on number enrolled

A.4.6. Will this study use any of the following methods?

- ✖ Audiotaping
- ✖ Videotaping or filming
- ✖ Behavioral observation - (e.g., Participant, naturalistic, experimental, and other observational methods typically used in social science research)
- ✖ Pencil and paper questionnaires or surveys
- ✖ Electronic questionnaires or surveys
- ✖ Telephone questionnaires or surveys
- ✖ Interview questionnaires or surveys
- ✖ Other questionnaires or surveys
- ✖ Focus groups
- ✖ Diaries or journals
- ✖ Photovoice
- ✖ Still photography

A.4.7. If there are procedures or methods that require specialized training, describe who (role/qualifications) will be involved and how they will be trained.

Physical examination will be performed by 2 orthopaedic clinic members that do not require additional training. Dressing care will be provided by nursing staff, home health, and skilled nursing facilities with proper training. The nurses involved in patient care are not required to do any additional tasks. They can monitor the status of the dressing and will inform the clinic team if a dressing is malfunctioning. They will not be asked to do dressing changes. The device is designed to not require any daily maintenance.

A.4.8. Are there cultural issues, concerns or implications for the methods to be used with this study population?

No

A.4.A. Biomedical methods and procedures

A.4.A.1. Is this an interventional study that involves treatment, evaluation or diagnosis of a medical disease or condition?

Yes

If yes, distinguish what is being done specifically for this research from procedures that would be done anyway for clinical care:

The standard treatment is the placement of an absorptive dressing postoperatively after total hip arthroplasty. The patient receives a dressing change on Post op day 2. On POD7 there wound will be evaluated and dressing replaced and their staples removed on post op day 14.

The study group will have a negative pressure suction device place postoperatively(This will be the only difference). They will also receive a dressing change on postop day 2. On POD7 they will be

changed to an absorptive dressing and their staples removed on post op day 14.

The difference will be treatment for seven days postoperatively with a negative pressure suction device.

A.4.A.2. Is this a Clinical Study?
Check YES if this study involves research using human volunteers that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials and observational studies. Do NOT check yes merely because you are conducting research in a clinical setting or using clinical data.
Click here for additional definition of "Clinical Study"

Yes

Will this clinical trial be listed in ClinicalTrials.gov, either by you or the sponsor?

Yes

Choose the appropriate Phase designation for this clinical trial.

- ✗ Pilot Study
- ✗ Phase I
- ✗ Phase I/II
- ✗ Phase II
- ✗ Phase III
- ✓ Phase IV
- ✗ Other

A.4.A.3. If the study involves the use of placebo control, provide justification

No Answer Provided

A.4.A.4. Will this study involve drugs, biologics or other substances (such as a botanical or dietary supplement)?
For guidance on dietary supplements, see Section VI, C FDA guidance document UCM229175.pdf

No

A.4.A.5. Is there an Investigational New Drug application (IND) for this study?

No

Please check below:

This study does not involve drugs, biologics or other substances.

A.4.A.6. Will this study involve investigational devices, instruments, machines or software?

No

A.4.A.7. Does your study involve any of the following? (check all that apply)

- ✗ Embryonic stem cells
- ✗ Fetal tissue
- ✗ Genetic testing (see GINA and GWAS)
- ✗ Clinical laboratory tests

If McLendon Labs will do the testing, you must complete the appropriate form found at UNC Health Care and submit to them for review.

✖ Testing for communicable diseases that have mandated reporting requirements (link to state guidance)

✖ Point of Care Testing (POCT), which is CLIA-approved testing done at the "bedside" or site of care by hospital or clinic personnel (not by subject). Examples include urine pregnancy testing, glucose monitoring, etc.

If McLendon Labs will do the testing, you must complete the POCT form found at UNC Health Care and submit to them for review.

✖ Diagnostic or therapeutic ionizing radiation, or radioactive isotopes, which subjects would not receive otherwise if not participating in this research study. Do not check if all radiation is administered as standard of care. (Human Use of Radiation in Research)

✖ Gadolinium administered as a contrast agent

✖ Recombinant DNA or gene transfer to human subjects

A.4.A.8. Will your study involve storage of specimens for future unspecified research?

No

A.5. Benefits to subjects and/or society

A.5.1. Describe how this study will contribute to generalizable knowledge that will benefit society.

NPWT has been increasing in utility in both orthopaedics and general surgery. Originally designed for open wounds the use of NPWT on clean surgical incisions for wound healing and the prevention of infection is relatively new. No study has been done evaluating multiple aspects of wound healing on clean incisions. This study will further evaluate the use of NPWT on closed incisions and their role in improving wound healing. We anticipate that the proposed study will provide further evidence to support NPWT on clean, closed incisions in primary total hip arthroplasty.

The prevention of infection is extremely important in total joint surgery.Periprosthetic joint infections are a devastating complication due to their difficulty in treating, burden on the system, and patient morbidity and occurs in approximately 0.5% to 3% of primary total joint arthroplasties. Revision total knee has both a detrimental physical and economic burden. Patients require treatment with intravenous antibiotics, multiple surgeries, and prolonged hospital courses. The clinical outcome of revision surgery for infection is also worse compared to other reasons for revision. Periprosthetic infections also place a significant burden on hospitals. Increased blood loss, complications, and operative time lead to higher total hospital costs, longer hospital stays and increased outpatient visits. Revision arthroplasty compared to aseptic revision can cost more than $60,000 more. The cost of revision total joint arthroplasty is expected to be 1.6 billion in 2020. Any method that can help reduce the risk of infection stands to benefit both the patient and society.

A.5.2. Does this study have the potential for direct benefit to individual subjects in this study?

Yes

Consider the nature, magnitude, and likelihood of any direct benefit to subjects. If there is no direct benefit to the individual subject, say so here and in the consent form, if there is a consent form. Do not cite monetary payment or other compensation as a benefit.

Explain

The negative pressure device may decrease the risk of infection which is a devastating complication of total hip arthroplasty. Although it may decrease risk the incidence of infection is low(0.5 to 3%)

of the population so it is unlikely that any one individual has a change in outcome. However, the decrease in risk can be seen as a substantial benefit over the entire total hip arthroplasty population.

A.5.3. Are there plans to communicate the results of the research back to the subjects?

No

A.6. Risks and measures to minimize risks

For each of the following categories of risk you will be asked to describe any items checked and what will be done to minimize the risks.

A.6.1. Psychological

- ✗ Emotional distress
- ✗ Embarrassment
- ✗ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✗ Other

A.6.2. Describe any items checked above and what will be done to minimize these risks

A.6.3. Social

- ✗ Loss of reputation or standing within the community
- ✗ Harms to a larger group or community beyond the subjects of the study (e.g., stigmatization)
- ✓ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✗ Other

A.6.4. Describe any items checked above and what will be done to minimize these risks

. Research data will be identified only by study identification numbers (IDs). These study IDs will be used to maintain relationships in the data between various tables. All consent forms and any paper data collection instruments will be stored in a locked cabinet in a secure location. The list identifying subjects with their contact information will be kept separate from the scientific study data. Data will be managed with REDCap software to help with data security and remain on password protected hardware.

A.6.5. Economic

- ✗ Loss of income
- ✗ Loss of employment or insurability
- ✗ Loss of professional standing or reputation
- ✗ Loss of standing within the community

- ✘ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✘ Other

A.6.6. Describe any items checked above and what will be done to minimize these risks.

No Answer Provided

A.6.7. Legal

- ✘ Disclosure of illegal activity
- ✘ Disclosure of negligence
- ✘ Consequences of breach of confidentiality (Check and describe only once on this page)
- ✘ Other

A.6.8. Describe any items checked above and what will be done to minimize these risks

No Answer Provided

A.6.9. Physical

- ✘ Medication side effects
- ✘ Pain
- ✘ Discomfort
- ✘ Injury
- ✘ To a nursing child or a fetus (either through mother or father)

A.6.10. Describe any items checked above, including the category of likelihood and what will be done to minimize these risks. Where possible, describe the likelihood of the risks occurring, using the following terms:

- Very Common (approximate incidence > 50%)
- Common (approximate incidence > 25%)
- Likely (approximate incidence of 10-25%)
- Infrequent (approximate incidence of 1-10%)
- Rare (approximate incidence < 1%)

Potential Risks. The potential risks to the research subjects include

INFREQUENT/RARE -- surgical site infection(known risk factor that we are evaluating)-Patients will undergo surgery with sterile technique. They will be monitored throughout the postoperative course for signs of infection.

RARE -- unanticipated adverse events, allergic reaction- -- Screening to exclude patients with known contraindications to the study dressing including silver and adhesive and obtaining care early for any adverse events or allergic reactions, departing from protocol to provide care as necessary to address side effects and adverse events that are not expected

INFREQUENT -- skin sensitivity to the dressing, Taking care to decrease the pain with dressing removal including the use of rubbing alcohol as needed

A.6.11. Unless already addressed above, describe procedures for referring subjects who are found, during the course of this study, to be in need of medical follow-up or psychological counseling

Any study device leading to serious allergies or adverse side effects will be discontinued. Research related injuries will be treated at UNC Hospitals if desired by the patient. The subject or their insurance company will be billed for this treatment, in the usual manner.

A.6.12. Are there plans to withdraw or follow subjects (or partners of subjects) who become pregnant while enrolled in this study?

No

A.7. Data and safety monitoring

A.7.1. When appropriate, describe the plan for monitoring the data to ensure the safety of participants. These plans could range from the investigator monitoring subject data for any safety concerns to a sponsor-based data and safety monitoring board or committee (DSMB, DSMC, DMC), depending on the study. For studies that do not raise obvious safety concerns, you may still describe your plans for monitoring the study as it progresses.

The investigator and the attending's nurse will be monitoring the patients continuously as the study progresses. Patients will be in the hospital for 2-3 days following surgery and will return to clinic around post op day 7 and 14. During that time they will be maintained on a monitoring list to identify any readmissions and to ensure appropriate followup. They will have a number for any issues and these will be provided to the research team to ensure appropriate care.

A.7.2. If not already addressed above, describe the plans for aggregate review of unanticipated problems (including but not limited to adverse events) across all sites, in order to monitor subject safety.

Any adverse event/unanticipated problem will result in disclosure to the IRB and proper response by the PI and investigator team.

A.7.3. What are the criteria that will be used to withdraw an INDIVIDUAL SUBJECT from this study or halt the research intervention (e.g., abnormal lab tests, allergic reactions, failure or inability to comply with study procedures, etc.)?

Patients that sustain allergic reactions, complications necessitating further treatment, or other unanticipated adverse event will be withdrawn from the study and proper care initiated.

A.7.4. Are there criteria that will be used to stop the ENTIRE STUDY prematurely (e.g., safety, efficacy, unexpected adverse events, inability to recruit sufficient number of subjects, etc.)?

Yes

Please explain

If a significant percentage of patients in the treatment group have unanticipated adverse events or any concern for their short/long term safety the project will be halted immediately. If it does not appear that we will be able to establish our numbers in 1 year, the project will be halted.

We anticipate being able to sign up 2 patients a week. If we are averaging less than 1 patient a week for a month we will stop the study. As this will likely be difficult to recover from.

Any noticeable increase in significant postoperative complications would lead us to stop the study early however specific numbers will likely depend on the type of adverse event. For instance if 3 hips require surgical irrigations that would be a signiifcant increase. However 3 surgical wounds that have significant erythema would not be a significant increase. We will have to remain aware of the status of these patients and be willing to be cautious if any noticeable increase in adverse events beyond what is expected occurs.

Adverse events will be graded on a 1-5 grading scale in line with the NIH adverese outcomes grading. Most relevant to our study will be adverse outcomes related to allergic reactions although any adverse outcome will be applied.

Grade 1 Mild AE, no intervention required

Grade 2 Moderate AE, local or noninvasive intervention required

Grade 3 Severe AE, invasive or hospitalization may be required

Grade 4 Life-threatening or disabling AE, urgent intervention may be required

Grade 5 Death due to AE

Grade 1 –Transient allergic reaction, such as itching, mild pain

2 – Localized rash or erythema, skin damage

3 – Full body urticarial, edema, excessive bleeding

4 – Bronchospasm, hypotension

5 – Death due to adverse event

If a significant number of adverse events occur we will discontinue the study immediately. Given the very low likelihood of adverse events related to this study we will have a low threshold to discontinue the study. Therefore, if 3 cases (This would then be 3% of the final number of participants) of serious adverse events (greater than grade 3) this will result in discontinuation of the study. This threshold was set due to the reported rate of allergic reaction and adverse events of this product being less than 1%. If 3% of patients are experiencing severe effects, than this would be over 3 times the expected percentage. This may be due to chance because of our low number of subjects. But given the severity and the possibility that this increase may be due to our specific institutions care routine, specific device, or other problems associated with our care it is reasonable to set this low threshold.

A.7.5. Will this study involve a data and safety monitoring board or committee?

No

A.8. Data analysis

A.8.1. Summarize the statistical analysis strategy for each specific aim.

Our primary goal is to test the difference between two independent groups at one week post op. Our feasible total sample size is 80 subjects. The progression of the ASEPSIS score over the six week post op recovery period will not be rectilinear. All patients are expected to be infection free with very low ASEPSIS scores immediately following the operation and are likely to be fully healed at six weeks. Attempting to model the timecourse of the ASEPSIS score with splines or multiple dummy variables and including all potential covariates would require considerable degrees of freedom and model tweaking based on intermediate assessments of model fit. Such a model would likely be too saturated to yield meaningfully narrow standard errors and holds considerable danger for overfitting. This modeling process does have some value for exploratory purposes, and we will employ it as such, but it will not be appropriate for confirmatory hypothesis testing. Instead, we note that the timepoint when differences in wound healing are most pronounced is after one week. Because subjects will be randomized to the two arms, we can consider the relevant population to be balanced on their covariates. The null hypothesis is simply that the treatments do not differ in ASEPSIS score at one week post op. Thus, we have a two independent groups t-test as a valid test

of our a-priori hypothesis.

A biostatistician (Jeffrey Laux, NC TRACS) has been recruited and will provide the statistical computations and interpretive analyses required for the exploratory model-based analyses of the data. Estimates of effect magnitude, confidence intervals and sensitivity analyses will augment the exploratory modeling that will be conducted.

A.8.2. What are the practical objectives of the study? Examples: pilot study to obtain data for a grant proposal, train junior investigators, create a registry, develop new assay methods, pilot-test procedures, evaluate feasibility, generate hypotheses, estimate parameters, test hypotheses.

To determine the statistical difference in wound healing of patients treated with a standard dressing compared to the PREVENA dressing. We plan on publishing these results at completion of the study. We are unable to determine a difference in infection rate due to the small sample size, however the use of the ASEPSIS score allows us to identify differences in wound healing in this small study size.

A.8.3. If this is a pilot study, please describe the future study and say how its study design, aims, sample size, and methods differ from the pilot study you are proposing.

No Answer Provided

A.8.4. Provide a compelling justification for the proposed sample size in terms of the likelihood of achieving each aim.

Over the course of the study period, there will be a finite number of possible enrolled subjects. We expect to enroll a total target sample size of N = 80 eligible subjects. Our funding will provide for 40 patients to undergo the new treatment plan with 40 standard dressing subjects as a comparison. We anticipate that about 10 subjects will have incomplete data due to compliance, drop-out, and other causes. This will result in a recruitment of up to 90 subjects in order to result in 80 subjects completing the trial.

Our primary goal is to test the difference between two independent groups at a specific time point (namely, one week post op). We can think of this as a two independent groups t-test. With n1=40 vs n2=40, we will have 80% power to reject the null if the difference between the means of the two conditions were 0.63 standard deviations apart (and with greater power if the differences were bigger). Any difference of less than 0.63 SDs would be seen as not clinically significant. Small differences in the score of 1-2 points would fall within this and can be attributed to observer differences and would likely not be sensitive for detecting any risk for surgical infection.

The experimental dressing is expected to have benefit by reducing wound healing characteristics related to complications (ASEPSIS score) and subsequently reducing postoperative infections. There is an extremely low rate of infections in primary total hip arthroplasty surgeries and infection cannot be measured with this limited population (0.5% to 3.0% of the population). Adverse secondary events also have a low incidence and our study is not designed or powered to identify a statistically significant difference in these events, although such events will be recorded and examined for exploratory purposes. The ASEPSIS score allows a lower sample size that is within our reach to detect changes and will be used to identify infection risk.

In summary, the proposed target sample size was based on the number of enrollable subjects we believe we would plausibly have access to, based on the availability of eligible subjects, conjectures about the feasible rate of recruitment, and the length of time available to conduct the study. A sensitivity-type power analysis shows that our sample size will have adequate power (80%) to detect a clinically meaningful improvement (.63 SDs) in the ASEPSIS score, which is intrinsically beneficial and a predictor of more serious adverse outcomes.

A.8.5. Summarize the plans for data management.

Management of the research data for this study will involve collection, entry, processing, storage, retrieval, archival, distribution and documentation of information collected according to a written protocol. The overall strategy for quality assurance in data management will be assisted by the use of REDCap software and the TraCS institute(Clarence Potter).

REDCap and TraCS Research Management. The TraCS Clinical Research Data Management Service is a key initiative of the Biomedical Informatics core of the UNC-Chapel Hill CTSA. The purpose is to provide a system, and associated support resources, to enable efficient and high quality collection and management of research data that is standards-based in design, development and implementation. Standard features of electronic clinical research data management systems are available in the web-based systems provided with the service. These include interactive data entry with real-time field validation, lab data imports, audit logs to record database modifications, database integrity checks, security (in logins, permissions based on need, and encryption), reporting, forms inventory, and exports to common statistical packages for analysis.

The database system provides for secure web-based data entry with the data stored on servers that we maintain. The data is encrypted during transmission. The servers are located in a secure campus area with all the appropriate physical security measures in place. The web and database servers are monitored by the TraCS IT staff, patched frequently, and scanned by a third party vendor to ensure that they are protected against known vulnerabilities. The scanning application is the standard service for the entire campus. Access is by individual user id, and is restricted to the forms and/or functions that the user needs to have. The applications themselves are written using open source tools, and have also been scanned by campus security office to ensure that the applications also are protected from known exploits. The data is backed up to electronic media on a daily basis. The electronic media is secured by ITS stored in a secure area separate from the servers.

Quality Assurance. The P.I. will have overall responsibility for ensuring quality in the data and in the procedures that produce the data. The P. I. will have overall responsibility for the definition and production of the documents necessary to describe all aspects of the study in sufficient detail to insure the study can be conducted in a scientifically sound, standardized manner. The P.I. will be assisted by members of the research team in monitoring adherence to protocol.

Database Security. The database will be created within centralized files and maintained on University approved; password protected, encrypted, shared research drives in the orthopaedic surgery department and viewed only on approved devices by approved study personnel.

PHI Security. Procedures to maintain privacy and confidentiality will be followed rigorously. For each subject, identifying information and protected health information (PHI; e.g., demographic information, medical history, laboratory results, insurance information) will be collected along with scientific study data (e.g., treatment group assignment, medical chart data, responses to treatment). Each research subject will be assigned a study identification number (ID) and applied within REDCap. The scientific study data will be stored in a digital file that does not include patient identifiers or PHI. A separate data file will contain identifiers and PHI. A master file linking patient identifiers to the study data will be kept by the principal investigator. The database will be password protected and will be stored on servers housed in a secure location.

Confidentiality. Research data will be identified only by study identification numbers (IDs). These study IDs will be used to maintain relationships in the data between various tables. All consent forms and any paper data collection instruments will be stored in a locked cabinet in a secure location. The list identifying subjects with their contact information will be kept separate from the scientific study data.

Case Report Forms (CRFs). As it is not unusual for revisions to the CRFs to occur in clinical studies, each form will be clearly labeled with a set number. Transition to an updated version of a CRF will be communicated to all members of the research team.

Data Collection. Study data will be recorded at the point of care using data collection instruments provided by the study team. Paper forms will be stored in a designated folder securely maintained at the point of care and will be retrieved by the study team on a daily basis. The subjects' medical records will be reviewed to obtain study data and the patient characteristics at admission (e.g., age, sex, race, BMI). The medical record data will be recorded on a patient-specific CRF. Data collection will adhere to precise written instructions and will be monitored to insure adherence to the protocol.

Data Entry. All data entered into the database from the CRFs will be verified by comparing the original CRFs to the values in the database.

Data Editing. The P.I. will be responsible for reviewing data-monitoring results and investigating questions raised (i.e., "queries") about remarkable or questionable data values.

Database Documentation. The names of the variables and their valid ranges or categorical values will be listed in a "data book". Documentation will also include an index of computer programs and an index of reports. All programming for statistical computation will include comments providing internal documentation.

Pilot Testing of Operations. All aspects of data management and project operation will be pilot tested prior to the commencement of the study in order to verify adequacy of the methods, materials and systems prepared. Every clinical study collects such pilot data -either intentionally prior to commencement of the study, or unintentionally after recruitment has begun.

Risk of Deductive Disclosure. We will minimize the risk of unauthorized persons using the database to figure out a subject's identity and responses.

(1) The database will comprise two separate files: a TRACKING FILE (containing sensitive patient identifiers such as name, birthdate, date and time of admission to the ER, and Subject_ID) and a de-identified RESEARCH FILE containing non-sensitive data such as Subject_ID, age, treatment assignment, ASEPSIS data, etc. Both database files contain Study_ID. This allows the two sets of information to be linked together if necessary, but prevents linkage as long as the two files are kept safely separated.

(2) The database will be secured on encrypted storage media to guard against hacking or other unauthorized access. Paper forms will be stored in locked locations.

(3) Data will be retrieved from the RESEARCH FILE and distributed to specific personnel (e.g., the P.I., or co-investigators) for purposes of statistical computations for preparation of publications. Storage, retrieval and distribution will be carefully and securely controlled. Digital transmission of the data will be encrypted. Transportation of the data will use secure media.

A.9. Identifiers

A.9.1. Check which of the following identifiers you already have or will be receiving, or select "None of the above."

- ✔ Names (this would include names/signatures on consent forms)
- ✔ Telephone numbers
- ✔ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older

✔ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes (e.g. GPS coordinates), except for the initial three digits of a zip code

✘ Fax numbers

✘ Electronic mail addresses

✘ Social Security numbers

✔ Medical record numbers

✘ Health plan beneficiary numbers

✘ Account numbers

✘ Certificate/license numbers

✘ Vehicle identifiers and serial numbers (VIN), including license plate numbers

✘ Device identifiers and serial numbers (e.g., implanted medical device)

✘ Web universal resource locators (URLs)

✘ Internet protocol (IP) address numbers

✘ Biometric identifiers, including finger and voice prints

✘ Full face photographic images and any comparable images

✔ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

✘ None of the above

A.9.2. For any identifiers checked, how will these identifiers be stored in relationship to the research data?

✘ with the research data (i.e., in the same data set and/or physical location)

✔ separate from the research data (i.e., coded with a linkage file stored in a different physical location)

Provide details about the option you selected above:
(1) The database will comprise two separate files: a TRACKING FILE (containing sensitive patient identifiers such as name, birthdate, date and time of admission to the ER, and Subject_ID) and a de-identified RESEARCH FILE containing non-sensitive data such as Subject_ID, age, treatment assignment, ASEPSIS data, etc. Both database files contain Study_ID. This allows the two sets of information to be linked together if necessary, but prevents linkage as long as the two files are kept safely separated. (2) The database will be secured on encrypted storage media to guard against hacking or other unauthorized access. Paper forms will be stored in locked locations. (3) Data will be retrieved from the RESEARCH FILE and distributed to specific personnel (e.g., the P.I., or co-investigators) for purposes of statistical computations for preparation of publications. Storage, retrieval and distribution will be carefully and securely controlled. Digital transmission of the data will be encrypted. Transportation of the data will use secure media.

A.9.3. Are you collecting Social Security Numbers to be used as a unique identifier for study tracking purposes for national registry or database? (Do not check yes if collecting SSN *only* for payment purposes; this will be addressed later.)

No

A.10. Confidentiality of the data

A.10.1. Describe procedures for maintaining confidentiality of the data you will collect or will receive (e.g., coding, anonymous responses, use of pseudonyms, etc.).

. Research data will be identified only by study identification numbers (IDs). These study IDs will be used to maintain relationships in the data between various tables. All consent forms and any paper data collection instruments will be stored in a locked cabinet in a secure location. The list identifying subjects with their contact information will be kept separate from the scientific study data.

Database Security. The database will be created within centralized files and maintained on University approved; password protected, encrypted, shared research drives in the orthopaedic surgery department and viewed only on approved devices by approved study personnel.

PHI Security. Procedures to maintain privacy and confidentiality will be followed rigorously. For each subject, identifying information and protected health information (PHI; e.g., demographic information, medical history, laboratory results, insurance information) will be collected along with scientific study data (e.g., treatment group assignment, medical chart data, responses to treatment). Each research subject will be assigned a study identification number (ID). The scientific study data will be stored in a digital file that does not include patient identifiers or PHI. A separate data file will contain identifiers and PHI. A master file linking patient identifiers to the study data will be kept by the principal investigator. The database will be password protected and will be stored on servers housed in a secure location.

Confidentiality. Research data will be identified only by study identification numbers (IDs). These study IDs will be used to maintain relationships in the data between various tables. All consent forms and any paper data collection instruments will be stored in a locked cabinet in a secure location. The list identifying subjects with their contact information will be kept separate from the scientific study data.

A.10.2. Describe how data will be transmitted among research team (i.e., personnel listed on this application).

Digital transmission of the data will be encrypted. Transportation of the data will use secure media.

A.10.3. Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/physical abuse, immigration status, etc?

No

A.10.4. Do you plan to obtain a federal Certificate of Confidentiality for this study?

No

A.10.5. If relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs).

We will minimize the risk of unauthorized persons using the database to figure out a subject's identity and responses.

(1) The database will comprise two separate files: a TRACKING FILE (containing sensitive patient identifiers such as name, birthdate, date and time of admission to the ER, and Subject_ID) and a de-identified RESEARCH FILE containing non-sensitive data such as Subject_ID, age, treatment assignment, ASEPSIS data, etc. Both database files contain Study_ID. This allows the two sets of information to be linked together if necessary, but prevents linkage as long as the two files are kept safely separated.

(2) The database will be secured on encrypted storage media to guard against hacking or other unauthorized access. Paper forms will be stored in locked locations.

(3) Data will be retrieved from the RESEARCH FILE and distributed to specific personnel (e.g., the P.I., or co-investigators) for purposes of statistical computations for preparation of publications. Storage, retrieval and distribution will be carefully and securely controlled. Digital transmission of the data will be encrypted. Transportation of the data will use secure media.

A.10.6. Will any of the groupings or subgroupings used in analysis be small enough to allow individuals to be identified?

No

A.11. Data sharing and transmission

A.11.1. Check all of the following who will receive **identifiable data** (contains any of the 18 identifiers listed above) outside the immediate research team (i.e., not listed as personnel on this application)? *

- ✔ No one
- ✘ Coordinating Center
- ✘ Statisticians
- ✘ Consultants
- ✘ Other researchers
- ✘ Registries
- ✘ Sponsors
- ✘ External labs for additional testing
- ✘ Journals
- ✘ Publicly available dataset
- ✘ Other

A.11.2. For any recipients checked above, explain the confidentiality measures to be taken

No Answer Provided

A.12. Post-study disposition of identifiable data or human biological materials

A.12.1. Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. If you plan to destroy linkage codes or identifiers, describe how and when this will be done.

Following publication Identifiable information will be deleted from UNC Secure servers and physical data will be shredded. Data with non identifiable data (e.g. patient_1, patient_@, etc...) and study data will be kept on a secure drive for further research needs and planning of future studies.

Part B. Direct Interaction

B.1. Methods of recruiting

B.1.1. Check all the following means/methods of subject recruitment to be used:*

- ✔ In person
- ✘ Participant pools
- ✘ Presentation to classes or other groups
- ✘ Letters
- ✘ Flyers
- ✘ Radio, TV recruitment ads
- ✘ Newspaper recruitment ads
- ✘ Website recruitment ads
- ✘ Telephone script
- ✘ Email or listserv announcements
- ✘ Follow up to initial contact (e.g., email, script, letter)
- ✘ Other

B.1.2. Describe how subjects will be identified

Patients will be patients previously scheduled for primary total hip arthroplasty in Dr. Del Gaizo's clinic.

B.1.3. Describe how and where subjects will be recruited and address the likelihood that you will have access to the projected number of subjects identified in A.2.

All patients will be previously scheduled for primary total hip arthroplasty in Dr. Del Gaizo's clinic. Dr. Del Gaizo performs approximately 10 primary total hip arthroplasties per month.

B.1.4. Describe how you will protect the privacy of potential subjects during recruitment

All patient data will remain on secured servers.

B.1.5. Describe how subjects will be contacted, if not addressed above

Subjects will be previously scheduled for clinic visits in preparation of total hip arthroplasty surgery.

B.1.6. Describe who will do the recruiting

Recruiting will be performed by the resident surgeon during clinic visits.

B.1.7. Describe efforts to ensure equal access to participation among women and minorities

All patients regardless of demographics will be recruited. No difference in recruiting efforts will be made.

B.2. Protected Health Information (PHI)

Protected Health Information (PHI) is any identifiable information about the subject's health that relates to their participation in this research and is obtained from sources other than the subject, such as medical records, health care providers, insurance plans, etc. more

B.2.1. Are you requesting a limited waiver of HIPAA authorization?
If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a limited waiver of HIPAA authorization (see SOP 29.3). This does not apply to situations where you will never contact subjects directly (e.g., retrospective chart review), in which case you should request a full waiver under section D.

Yes

Will you access the records of 50 or more patients under this limited waiver?

Yes

Please provide a response to each of the following questions:

Under this limited waiver, you are allowed to access and use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects. Describe the information you are planning to collect for this purpose

Name, Age, Medical comorbidites, surgical plan, surgical history

Describe how confidentiality/privacy will be protected prior to ascertaining the patient's willingness to participate

No patient information will be recorded prior to participation, prior to recruitment the patient's will be identified before clinic and highlighted for recruitment.

Describe when and how you will destroy the contact information if an individual declines participation

Patient's that decline to participate will have no information previously recorded and all schedules with identification for study enrollment will be shredded securely.

B.2.2. Will you need ongoing access to PHI (e.g., medical records) to conduct the study, beyond the identification of potential subjects as addressed above? In this case you will need to obtain a signed HIPAA Authorization from each subject.

Yes

In order to access patient records you are required to provide a copy of the IRB approval letter and copies of signed HIPAA authorization forms for each patient whose record you will access, to Healthcare Information Management (HIM).

B.3. Subject Contact, Duration and Privacy

B.3.1. Number of contacts per subject

6

B.3.2. Duration of each contact. If multiple contacts, provide the range or average time for each contact.

Contact will be limited to outpatient clinic visits that will involve the recruitment and wound checks. No more than 10 minutes of each visit will be devoted to research other than recruitment.

B.3.3. Total duration of individual subject's participation, including follow up evaluation, if applicable

8 weeks

B.3.4. Where are you studying subjects or obtaining their data?

Healthcare setting

Please check all that apply:

- ✔ UNC Medical Center (N.C. Memorial Hospital, N.C. Children's Hospital, N.C. Womens' Hospital, N.C. Cancer Hospital, N.C. Neurosciences Hospital, Ambulalory Care Center (ACC))
- ✘ Rex Healthcare
- ✘ Chatham Hospital
- ✘ Johnston Memorial
- ✘ Pardee Hospital
- ✘ High Point Regional Health
- ✘ Caldwell Memorial Hospital
- ✘ UNC Physician Network - affiliated site(s)
- ✘ Other

B.3.5. Provide more information about the location(s) where research will be conducted (e.g., if UNC Medical Center is checked in #4 above and study visits will be conducted in the CTRC, enter “CTRC” here.)

All subjects will be studied at the UNC Orthopaedic clinic.

102 Mason Farm Rd.

Chapel Hill 27599

B.3.6. Describe procedures that will ensure privacy of the subjects in this study. Examples include the setting for interviews, phone conversations, or physical examinations; communication methods or mailed materials (e.g., mailings should not indicate disease status or focus of study on the envelope)

All patient contact will occur in outpatient clinic rooms that will only contain the individual involved in the research study.

B.4. Incentives for participation

B.4.1. Are there incentives (monetary or non-monetary) for subjects to participate?

No

B.4.2. Are you collecting Social Security numbers for payment and/or tax-related purposes?

No

B.5. Costs to be borne by subjects

B.5.1. Will there be any costs that subjects will incur related to participation in the study? Do not include costs for standard care for which patients would be billed if they were not in this study. Also do not include the time spent participating in the study.

No

Part C. Existing Data, Records, Specimens

C.1. Data Sources

C.1.1. What existing records, data or human biological specimens will you be using? (Indicate all that apply or select 'None of the above'): *

✘ Data already collected from another research study

Were the investigators for the current application involved in the original collection? --

✗ Patient specimens (tissues, blood, serum, surgical discards, etc.)

Has the clinical purpose for which they were collected been met before removal of any excess? --

✗ Data already collected for administrative purposes

✗ Student records (You will need to satisfy FERPA requirements: see SOP 24.6.2 for guidance)

✗ UNC Health Care System Medical records in any format.

If you access the records of fewer than 50 patients under a full or limited waiver of HIPAA, submit a copy of your IRB approval letter and a completed Research Disclosure Form to Health Information Management (HIM). Do not submit this information to the IRB. For additional information about this process, you should contact HIM directly at 919-595-5691 or 919-966-1255.

✗ UNC Dental Records

✗ Data coming directly from a health plan, health care clearinghouse, or health care provider?

✗ Publicly available data

✗ Other

✓ None of the above

For EACH data source checked above, provide a description of the data, proposed use, how data were collected (including consent procedures), and where data currently reside.
--

C.1.2. Describe your plans for obtaining permission from the custodians of the data, records or specimens (e.g., pathology dept, tissue bank, original researcher):

N/A

C.1.3. Do the custodians of the data, records or specimens require a data use agreement?

No

C.2. Coding and Data Use Agreements

C.2.1. When you receive these data, records or human biological specimens will they be coded? Coded means identifying information that would enable the research team to readily ascertain the individual's identity has been replaced with a number, letter, symbol, or combination thereof (i.e., a code). If you will not be using existing materials, check "No."

No

Part D. The Consent Process

D.1. Obtaining informed consent from subjects

The standard consent process is for all subjects to sign a document containing all the elements of informed consent, as specified in the federal regulations. Some or all of the elements of consent, including signatures, may be altered or waived under certain circumstances. If you will be requesting a waiver answer "not applicable" for any of the following questions that will not pertain to this study. You will be asked to provide relevant information in the section below on waivers.

D.1.1. Will children under the age of majority in their locale (18 years in NC) be enrolled?

No

D.1.2. Will adult subjects be enrolled in your study?

Yes

Explain the process for obtaining consent from the subject or the subject's legally authorized representative, if relevant

Patient's will be consented during their preoperative clinic visits. These visits have been previously scheduled for their surgery.

D.1.3. Will decisionally-impaired subjects be enrolled in your study? (includes unconscious patients, some psychiatric disorders, others who lack the capacity to give consent)

No

D.1.4. Are you planning to obtain consent from any Non-English speaking subjects?

No

D.1.5. Describe who (by role) will be obtaining consent or parental permission.

The resident orthopaedic surgeon will obtain consent.

D.1.6. Discuss the potential for influencing the subject's decision to participate. Describe steps that will be taken to minimize undue influence during the consent process. These might include a waiting period between the initial consent discussion and obtaining consent, or obtaining consent by someone other than a person with perceived authority (e.g., professor, employer, treating physician).

Consent will occur after the patient has consented and scheduled for surgery as to eliminate any perception that care is dependent on agreement. The resident physician will obtain consent and will allow the patient any questions and the ability to refuse randomization.

D.1.7. Has the sponsor of this study provided a model consent form?

No

D.2. Waiver of written documentation of informed consent

The default is for subjects to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived by the IRB. For example, this might occur for phone or internet surveys, when a signed consent form is either impractical or unnecessary, or in circumstances where a signed consent form creates a risk for the subject.

D.2.1. Are you requesting a waiver of any aspect of written (signed) documentation?

No

D.3. Full or partial waiver of consent

The default is for subjects to give informed consent. A waiver might be requested for research involving only existing data or human biological specimens. More rarely, it might be requested when the research design requires withholding some study details at the outset (e.g., behavioral research involving deception). In limited circumstances, parental permission may be waived. This section should also be completed for a waiver of HIPAA authorization if research involves Protected Health Information (PHI) subject to HIPAA regulation, such as patient records.

D.3.1. Are you requesting any of the following:

- ✘ a waiver of informed consent in its entirety
- ✘ a waiver or alteration of some of the elements of informed consent
- ✘ a waiver of HIPAA authorization (If you are accessing patient records for this research, you must

also request a waiver of HIPAA authorization)

D.3.2. If your request for a waiver applies to some but not all of your subject groups and/or consent forms, please describe and justify

No Answer Provided

D.3.3. Does this request for waiver support a study design that involves deception or withholding of information?

No

Consent Forms

This submission requires the following consent forms

Template Type
Adult Consent Form
HIPAA Authorization

This submission includes the following consent forms

File Name	Document Type
Suction_Dressing_Consent3.docx	Adult Consent Form
Suction Dressing HIPAA authorization.docx	HIPAA Authorization

view consent forms

Attachments

This submission requires the following attachments

Document Type

This submission includes the following attachments

File Name	Document Type
Device Description.docx	Device Description
document.pdf	Investigator Brochure and/or Drug Package Insert
suction_dressing_instructions3.docx	Other

view attachments

Addenda

Data Security Requirements

view addenda

By certifying below, the Principal Investigator affirms the following:

I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

This study proposes research that has been determined to include Security Level 3 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

If PI is a Student or Trainee Investigator, the Faculty Advisor also certifies the following:

I accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI.

Certifying Signatures:

Signature: Electronic Signature Received **Date:** 9/17/2014 08:29:50 PM
Daniel Del Gaizo

The expectation is that this approval is being given on behalf of the head of the Department, Division, or Center. If the chair or director is an investigator on this project or otherwise conflicted in approving it, the Vice-Chair or Chair's designee should review it. By approving, you are certifying the following on behalf of your department, division or center:

- This research is appropriate for this Investigator and our department
- The investigator(s) are qualified to conduct the research
- There are adequate resources (including financial, support and facilities) available
- For units that have a local review committee for pre-IRB review, this requirement has been satisfied
- I support this application, and hereby submit it for further review

This study proposes research that has been determined to include Security Level 3 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

If you are approving for other purposes (e.g., CTRC, DSMB, IBC, PRC, RSC, or other review committees), you affirm the following:

- The proposed submission is approved and may be forwarded for IRB review.

This study proposes research that has been determined to include Security Level 3 data security requirements. I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security Requirements addendum can be reviewed here.

Department Approval Signatures:

By signing in the appropriate space, the Department Chairperson(s) is indicating only that he/she has seen and reviewed this submission

Department: Orthopaedics
Signature: Electronic Signature Received **Date:** 9/18/2014 07:50:55 AM
Name & Title: Philip Clark, Associate Chair for Administration