PennState

HRP-591 - Protocol for
Human Subject Research

Protocol Title:

Provide the full title of the study as listed in item 1 on the "Basic Information" page in CATS IRB (http://irb.psu.edu).

Suture Repair of Lacerations in the Emergency Department: Comparison between Absorbable and Non-absorbable Suture Material

Principal Investigator:
Name: Kenneth Taylor, MD
Department: Department of Orthopaedics and Rehabilitation
Telephone: 717-531-5638
E-mail Address: ktaylor3@pennstatehealth.psu.edu

Version Date:

Provide a version date for this document. This date must be updated each time this document is submitted to the IRB office with revisions. DO NOT revise the version date in the footer of this document.

November 30, 2022

Clinicaltrials.gov Registration #:

Provide the registration number for this study, if applicable. See "HRP-103- Investigator Manual", under "ClinicalTrials.gov" for more information.

NCT05281666

Important Instructions for Using This Protocol Template:

This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.

1. **GENERAL INSTRUCTIONS:**
   - Prior to completing this protocol, ensure that you are using the most recent version by verifying the protocol template version date in the footer of this document with the current version provided in the CATS IRB Library.
   - Do not change the protocol template version date located in the footer of this document.
   - Some of the items may not be applicable to all types of research. If an item is not applicable, please indicate as such or skip question(s) if indicated in any of the instructional text.
   - **GRAY INSTRUCTIONAL BOXES:** Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.
     - **Do NOT delete the instructional boxes from the final version of the protocol.**
   - Add the completed protocol template to your study in CATS IRB (http://irb.psu.edu) on the "Basic Information" page.

2. **CATS IRB LIBRARY:**
   - Documents referenced in this protocol template (e.g. SOP's, Worksheets, Checklists, and Templates) can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

3. **PROTOCOL REVISIONS:**
   - When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the guides available in the Help Center in CATS IRB (http://irb.psu.edu) for using track changes.
   - Update the Version Date on page 1 each time this document is submitted to the IRB office with revisions.

If you need help…

All locations:
Human Research Protection Program
Office for Research Protections
The 330 Building, Suite 205
University Park, PA 16802-7014
Phone: 814-865-1775
Fax: 814-863-8699
Email: irb-orp@psu.edu
https://www.research.psu.edu/irb

Table of Contents

1.0 Objectives

1.1 Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

The purpose of the study is to evaluate the use of absorbable and non-absorbable suture material in hand lacerations repaired in the Penn State Health Milton S. Hershey (PSHMC) Emergency Department.

1.2 Primary Study Endpoints

State the primary endpoints to be measured in the study.

Clinical trials typically have a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

The primary endpoints of this study consist of evaluating wound healing using the Patient and Observer Scar Assessment Scale[1] (POSAS). This scale includes assessment by the observer (vascularization, pigmentation, thickness, relief, and pliability), as well as by the patient (scar pain, itching, color, stiffness, irregularity, and stiffness). There will be a single observer for this study to eliminate any interrater bias, and this observer will be a clinician different from the one who removes the sutures.

1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

The secondary study endpoints will measure patient reported pain of the scar itself as well as suture removal for those with non-absorbable sutures through the use of the visual analogue pain scale (VAS), a commonly used scale to judge patients' pain levels. We will also record the following:

- Hematoma rate
- Infection rate (requiring either antibiotics or operative intervention)
- Time off of work

2.0 Background

2.1 Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

For clinical research studies being conducted at Penn State Health/Penn State College of Medicine, and for other non-PSH locations as applicable, describe the treatment/procedure that is considered standard of care (i.e., indicate how patients would be treated in non-investigational setting); and if applicable, indicate if the study procedure is available to patient without taking part in the study.

There has been limited data published on suture type in traumatic hand wounds. The only study we found in our literature review was a retrospective study comparing vicryl vs. nylon suture, and found no difference in scar appearance, tenderness, retraction, or complications as far as 6 months after repair[2]. There have been no prospective studies on this topic. The theoretical advantage of absorbable suture for these wounds is they do not require suture removal, thereby removing the discomfort of suture removal as well potentially decreasing the burden of follow up.

At Penn State Hershey Medical Center, either suture choice included in this study is considered standard of care and is routinely used. Selection as to whether absorbable or non-absorbable suture is used is based on the preference and discretion of the resident and attending surgeon involved in the patient care. As such, if patient were to present to the emergency department with a forearm or hand laceration and hand surgery were consulted, regardless of whether the patient opts to participate in this research study, their laceration would be repaired with either absorbable or non-absorbable suture depending on provider preference and the patient would be scheduled follow up.

2.2 Previous Data

Describe any relevant preliminary data.

There have been multiple prospective clinical trials on suture type in the context of planned surgical incisions, specifically carpal tunnel release, with variable outcomes. One clinical trial looking at a total of 40 incisions found no difference in pain, tenderness, inflammation, or outcomes postoperatively[3]. Certain clinical trials favored non-absorbable sutures, reporting higher rate of infection[4] or inflammation[5] with vicryl suture as compared to non-braided, non-absorbable sutures. On the other hand, other clinical trials favored absorbable sutures, describing reduction in pain scores[6] and pain associated with absorbable suture removal in the setting of other equivalent outcomes[7].

2.3 Study Rationale

Provide the scientific rationale for the research.

This study aims to determine whether the use of non-absorbable (i.e. nylon) versus absorbable (i.e. chromic gut) sutures in traumatic hand lacerations affects wound healing, patient perception, and development of complications.

3.0 Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.).

Vulnerable Populations:

Indicate specifically whether you will include any of the following vulnerable populations in this research. You MAY NOT include members of these populations as subjects in your research unless you indicate this in your inclusion criteria because specific regulations apply to studies that involve vulnerable populations.

The checklists referenced below outline the determinations to be made by the IRB when reviewing research involving these populations. Review the checklists as these will help to inform your responses throughout the remainder of the protocol.

- **Children –**Review “HRP-416- Checklist - Children”
- **Pregnant Women** – Review “HRP-412- Checklist - Pregnant Women”
- **Cognitively Impaired Adults-** Review “HRP-417- Checklist - Cognitively Impaired Adults”
- **Prisoners-** Review “HRP-415- Checklist - Prisoners”
- **Neonates of uncertain viability or non-viable neonates-** Review “HRP-413- Checklist - Non-Viable Neonates” or “HRP-414- Checklist - Neonates of Uncertain Viability”

[Do not type here]

3.1 Inclusion Criteria

Create a numbered list of the inclusion criteria that define who will be included in your final study sample (e.g., age, gender, condition, etc.)

- Subject seen in PSHMC Emergency Department for hand or forearm lacerations (i.e. laceration below the level of the elbow) that require suture repair, in which hand surgery is consulted
- CDC surgical wound classification grades I-IV (Table 1)
- Age ≥18 years of age
- Gender: male or female (non-pregnant)
- Fluent in written and spoken English
- Subject is able to provide voluntary, written informed consent
- Subject, in the opinion of the clinical investigator, is able to understand the clinical investigation and is willing to perform all study procedures and follow-up visits
- Non-Prisoners

3.2 Exclusion Criteria

Create a numbered list of the exclusion criteria that define who will be excluded in your study.

- Known allergy to suture material
- History of immunosuppression (i.e. concurrent chemotherapy, steroid use or immunomodulatory therapy)
- History of diabetes mellitus
- Pregnancy
- Current Tobacco use
- Age < 18 years old
- Previous skin laceration at same location
- History of previous hypertrophic or keloid scar
- Concurrent tendon, nerve or bone injury requiring trip to the operating room
- Non-English speaking patients
- Cognitive impairment
- Prisoners

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

Subjects will be withdrawn from the study for safety reasons including failure of subject to adhere to protocol requirements, safety concerns related to the study, or subject consent withdrawal.

3.3.2 Follow-up for withdrawn subjects

Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

If a subject is withdrawn from the study, data collection will be terminated from that time point forward. All prior data collected will be included in the analysis. These subjects will not be replaced, but instead more subjects may need to be enrolled. These new data will be recorded and analyzed as would any other new enrollee.

4.0 Recruitment Methods

- Upload recruitment materials for your study in CATS IRB (http://irb.psu.edu). **DO NOT** include the actual recruitment wording in this protocol.
- StudyFinder: If StudyFinder (http://studyfinder.psu.edu) is to be used for recruitment purposes, separate recruitment documents do not need to be uploaded in CATS IRB. The necessary information will be captured from the StudyFinder page in your CATS IRB study.
- Any eligibility screening questions (verbal/phone scripts, email, etc.) used when contacting potential participants must be uploaded to your study in CATS IRB (http://irb.psu.edu).

[Do not type here]

4.1 Identification of subjects

Describe the source of subjects and the methods that will be used to identify potential subjects (e.g., organizational listservs, established recruitment databases, subject pools, medical or school records, interactions during a clinic visit, etc.). If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.

StudyFinder:

- If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, include this method in this section.
- Information provided in this protocol needs to be consistent with information provided on the StudyFinder page in your CATS IRB study.

For Penn State Health submissions using Enterprise Information Management (EIM) for recruitment, and for non-Hershey locations as applicable, attach your EIM Design Specification form on in CATS IRB (http://irb.psu.edu). See "HRP-103- Investigator Manual, What is appropriate for study recruitment?" for additional information. **DO NOT** include the actual recruitment material or wording in this protocol.

Subjects will be identified through their clinical encounter in the Emergency Department. The Emergency Department staff will contact the hand surgery resident on call to inform them of a patient who requires a laceration repair that requires hand surgery consultation. Subjects who meet the inclusion criteria will be offered participation in the study at the time of their Emergency Department visit by a hand surgery resident who is a study team member.

4.2 Recruitment process

Describe how potential subjects first learn about this research opportunity or indicate as not applicable if subjects will not be prospectively recruited to participant in the research. Subject recruitment can involve various methods (e.g., approaching potential subjects in person, contacting potential subjects via email, letters, telephone, ResearchMatch, or advertising to a general public via flyers, websites, StudyFinder, newspaper, television, and radio etc.). **DO NOT** include the actual recruitment material or wording in this protocol.

[Do not type here]

4.2.1 How potential subjects will be recruited.

Subjects will be recruited after they are identified and a diagnosis is made. Inclusion/exclusion criteria will then be reviewed to confirm eligibility.

4.2.2 Where potential subjects will be recruited.

Subjects will be recruited at time of visit in the PSHMC Emergency Department.

4.2.3 When potential subjects will be recruited.

Subjects will be recruited by a study team member prior to laceration repair.

4.2.4 Describe the eligibility screening process and indicate whether the screening process will occur before or after obtaining informed consent. Screening begins when the investigator obtains information about or from a prospective participant in order to determine their eligibility. In some studies, these procedures may not take place unless HIPAA Authorization is obtained OR a waiver of HIPAA Authorization when applicable for the screening procedures is approved by the IRB. [*For FDA regulated studies, consent for any screening activities would need to be obtained prior to screening unless specifically waived by the IRB.]*

Adult subjects presenting to the PSHMC Emergency Department will be evaluated as part of standard of care. Those subjects meeting eligibility requirements will be presented with the opportunity to participate in the research study by a member of the study team.

5.0 Consent Process and Documentation

Refer to the following materials:

- The "HRP-090- SOP - Informed Consent Process for Research" outlines the process for obtaining informed consent.
- The "HRP-091– SOP - Written Documentation of Consent" describes how the consent process will be documented.
- The "HRP-314- Worksheet - Criteria for Approval" section 7 lists the required elements of consent.
- The "HRP-312- Worksheet - Exemption Determination" includes information on requirements for the consent process for exempt research. In addition, the CATS IRB Library contains consent guidance and templates for exempt research.
- The CATS IRB library contains various consent templates for expedited or full review research that are designed to include the required information.
- Add the consent document(s) to your study in CATS IRB (http://irb.psu.edu). Links to Penn State's consent templates are available in the same location where they are uploaded. **DO NOT** include the actual consent wording in this protocol.

[Do not type here]

5.1 Consent Process:

Check all applicable boxes below:

☒ **Informed consent will be sought and documented with a written consent form *[Complete Sections 5.2 and 5.6]***

☐ **Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent) *[Complete Sections 5.2, 5.3 and 5.6]***

☐ **Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception). *[Complete section 5.2, 5.4 and 5.6]***

☒ **Informed consent will not be obtained – request to completely waive the informed consent requirement. *[Complete Section 5.5]***

The following checkbox is for all locations EXCEPT Penn State Health and College of Medicine:

☐ **Exempt Research at all Locations Except Penn State Health and the College of Medicine: If you believe that the research activities outlined meet one or more of the criteria outlined in "HRP-312- Worksheet- Exemption Determination." Please verify by checking this box that if conducting an exempt research study, the consent process will disclose the following (all of which are included in "HRP-590- Consent Guidance for Exempt Research"):**

Penn State affiliation; name and contact information for the researcher and advisor (if the researcher is a student); the activities involve research; the procedures to be performed; participation is voluntary; that there are adequate provisions to maintain the privacy interests of subjects and the confidentiality of the data; and subjects may choose not to answer specific questions.

If the research includes the use of student educational records include the following language in this section (otherwise delete):

Note: If this box has been checked, skip the remainder of section 5 and proceed to section 6 of this protocol. If the investigator's assessment is inaccurate, an IRB Analyst will request revision to the protocol and that an informed consent form be submitted for review and approval. Except for exemptions where Limited IRB Review (see "HRP-312- Worksheet- Exemption Determination") is required or where otherwise requested by the IRB, informed consent forms for research activities determined to be exempt without Limited IRB Review are generally not required to be submitted for review and approval by the University Park IRB.

5.2 Obtaining Informed Consent

5.2.1 Timing and Location of Consent

Describe where and when the consent process will take place.

Subjects presenting to the PSHMC Emergency Department for evaluation will be given the opportunity to participate in the research study. Subjects will be given information about the study and asked to participate. If eligible, based on inclusion and exclusion criteria, Informed Consent will be obtained at the time of the screening visit and the subject will be enrolled in the study.

5.2.2 Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

Study procedures will be fully explained, voluntariness will be emphasized as well as the fact that no care will be denied regardless of the subjects decision. Subjects will be given ample time to read and review the consent form on their own. All questions the subject may have will be answered, and written consent will be obtained. A member of the research team will assist in the explanation and obtaining of the written consent. A copy of the signed consent will be given to the subject and another copy sent to Medical Records.

5.3 Waiver of Written Documentation of Consent

Review "HRP – 411 – Checklist – Waiver of Written Documentation of Consent."

5.3.1 Indicate which of the following conditions applies to this research:

☐ The research presents no more that minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

OR

☐ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (*Note: This condition is not applicable for FDA-regulated research. If this category is chosen, include copies of a consent form and /or parental permission form for participants who want written documentation linking them to the research.)*

OR

☐ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. (*Note: This condition is not applicable for FDA-regulated research.)*

Describe the alternative mechanism for documenting that informed consent was obtained:

N/A

5.3.2 Indicate what materials, if any, will be used to inform potential subjects about the research (e.g., a letter accompanying a questionnaire, verbal script, implied consent form, or summary explanation of the research)

N/A

5.4 Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.4.1 Indicate the elements of informed consent to be omitted or altered

N/A

5.4.2 Indicate why the research could not practicably be carried out without the omission or alteration of consent elements

N/A

5.4.3 Describe why the research involves no more than minimal risk to subjects.

N/A

5.4.4 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

N/A

5.4.5 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

N/A

5.4.6 Debriefing

Explain whether and how subjects will be debriefed after participation in the study. If subjects will not be debriefed, provide a justification for not doing so. Add any debriefing materials to the study in CATS IRB.

N/A

5.5 Informed consent will not be obtained – request to completely waive the informed consent requirement

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.5.1 Indicate why the research could not practicably be carried out without the waiver of consent

A waiver is necessary for prescreening purposes only to determine subject eligibility. Patient identifiers are necessary for identification and review of the patient's medical records.

5.5.2 Describe why the research involves no more than minimal risk to subjects.

Access to the patient's medical records for prescreening purposes presents no more than minimal risk.

5.5.3 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

Subjects will not be adversely affected by this alteration/omission. The waiver is to review the patient's medical records for prescreening/study eligibility purposes only.

5.5.4 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

Patient identifiers are necessary for identification and review of the patient's medical records. A unique study code number will be used for identification of study data.

5.5.5 Additional pertinent information after participation

Explain if subjects will be provided with additional pertinent information after participation. If not applicable, indicate "not applicable."

N/A

5.6 Consent – Other Considerations

5.6.1 Non-English-Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review "HRP-091 –SOP- Written Documentation of Consent" and "HRP-103 -Investigator Manual" to ensure that you have provided sufficient information.

N/A

5.6.2 Cognitively Impaired Adults

Refer "HRP-417 -CHECKLIST- Cognitively Impaired Adults" for information about research involving cognitively impaired adults as subjects.

5.6.2.1 Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

N/A

5.6.2.2 Adults Unable to Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual's authority to consent to research.

For research conducted in the state of Pennsylvania, review "HRP-013 -SOP- Legally Authorized Representatives, Children and Guardians" to be aware of which individuals in the state of Pennsylvania meet the definition of "legally authorized representative."

For research conducted outside of the state of Pennsylvania, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or

authority review your protocol along with the definition of “children” in “HRP-013 - SOP- Legally Authorized Representatives, Children, and Guardians.”

N/A

5.6.2.3 Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

N/A

5.6.3 Subjects who are not yet adults (infants, children, teenagers)

5.6.3.1 Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual’s authority to consent to each child’s general medical care.

For research conducted in the state of Pennsylvania, review “HRP-013-SOP- Legally Authorized Representatives, Children and Guardians” to be aware of which individuals in the state of Pennsylvania meet the definition of “children.”

For research conducted outside of the state of Pennsylvania, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “HRP-013-SOP- Legally Authorized Representatives, Children, and Guardians.”

N/A

5.6.3.2 Assent of subjects who are not yet adults

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

N/A

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See "HRP-103 -Investigator Manual" for a list of the 18 identifiers.

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

[Do not type here]

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☐ **Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☒ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

☒ **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver of authorization. **If the section is <u>not</u> applicable, <u>remove</u> the statement and <u>indicate as not applicable</u>.**

Information is included in the "Confidentiality, Privacy and Data Management" section of this protocol.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.

Linking code list will be destroyed upon completion of the study.

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide an explanation for why the research could not practicably be conducted without access to and use of PHI.

Patient identifiers are necessary for identification and review of the patient's medical records. A unique study code number will be used for identification of study data.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide an explanation for why the research could not practicably be conducted without the waiver or alternation of authorization.

PHI is required during the recruitment process to determine subject eligibility.

6.3 Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver or alteration of authorization. **If the section is not applicable, remove the statement and indicate as not applicable.**

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the 'Minimum Necessary' standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

7.0 Study Design and Procedures

Data collection materials that will be seen or used by subjects in your study must be uploaded to CATS IRB (http://irb.psu.edu). **DO NOT** include any actual data collection materials in this protocol (e.g., actual survey or interview questions)

[Do not type here]

7.1 Study Design

Describe and explain the study design.

This study is a prospective, randomized, single observer blinded study evaluating the use of absorbable and non-absorbable suture material in lacerations below the level of the forearm. Both types of suture

material are current standard of care. Prior to washout and repair, the patient's wound will be classified according to the surgical wound classification system and sent home with 1 week of antibiotics (Keflex, unless an allergy precludes this option) as part of their standard of care treatment[8]. Subjects will then be seen back in clinic at 2, 6, and 12 weeks as part of their standard of care treatment. At two weeks, sutures will be removed.

Recruitment → Randomization → Wound suture (absorbable vs non-absorbable material) → Return to clinic site at 2, 6, and 12 weeks

ED*	2 weeks (Hand Clinic)*,**	6 weeks (Hand Clinic)*,**	12 weeks (Hand Clinic)*,**
Initial Visit	Follow-up visit	Follow-up visit	Follow-up visit
Suture of wound	Suture removal	VAS (research)	VAS (research)
Inclusion/Exclusion Criteria (research)	VAS (research)	POSAS (research)	POSAS (research)
Informed Consent (research)	POSAS (research)		
Randomization (research)			

* All visits are standard of care
**Study team member at 2, 6, and 12 weeks is a blinded, single observer

7.2 Study Procedures

Provide a step by step description of all research procedures being conducted (broken down by visit, if applicable) including such information as below (where and when applicable); describe the following:

- HOW: (e.g., data collection via interviews, focus groups, forms such as surveys and questionnaires, medical/school records, audio/video/digital recordings, photographs, EKG procedures, MRI, mobile devices such as electronic tablets/cell phones, observations, collection of specimens, experimental drug/device testing, manipulation of behavior/use of deception, computer games, etc.)
- WHERE: (e.g., classrooms, labs, internet/online, places of business, medical settings, public spaces, etc.)

7.2.1 Visit 1 – Enrollment (ED Visit)

Provide a description of what procedures will be performed on visit 1 or day 1 or pre-test in order of how these will be done. If your study only involves one session or visit, use this section only and indicate 7.2.2 as not applicable.

Visit 1: Subject presents to Emergency Department with lacerations below the level of the forearm. Subjects that meet inclusion criteria will be identified and consented. Ample time will be allowed for informed consent. The risk of keeping the wound open the additional time to obtain informed consent is considered low. Subjects will be randomized utilizing the National Cancer Institute Clinical Trial Randomization Tool (https://ctrandomization.cancer.gov/home/) and placed into one of two study groups – absorbable or non-absorbable suture material. Prior to washout and repair, the patient's wound will be classified according to the CDC surgical wound classification system. The washout and laceration repair will then be done in a standard fashion using 1 liter of normal saline to irrigate the wound, and closure of the wound using a horizontal mattress type of stitch.

Information will be collected from the subject's EMR and entered into a data collection form – age, gender, laterality, comorbidities, wound classification, location of laceration, mechanism, contamination, tissue involved, and antibiotics given.

There is not a classification that would indicate the use of either of the two suture materials. There is also not a classification that would put a subject at greater risk if randomized to one material versus another. Both sutures are used in multiple classification settings per physician preference.

Both suture types are appropriate in nearly any setting aside from those who meet exclusion criteria. There is little concern that taking away the physician or participant choice to suture material could make the risk greater than the physician just seeing the patient and using whatever material is preference.

The treatment of any adverse event would not be affected by suture type. If an event were to occur prior to suture removal, the subject may be seen by the on-call or clinic team (non-study personnel). This would be recorded as an adverse event and treated accordingly. If seen by the blinded observer prior to suture removal, the observer would be unblinded, treat the event accordingly, and record it as an AE.

7.2.2 Visit 2 – 2-weeks following ED Visit (Hand Clinic)

Provide a description of what procedures will be performed on visit 2 or day 2 or post-test in order of how these will be done. If your study involves more than two sessions or visits replicate this section for each additional session or visit (e.g., 7.2.3, 7.2.4, etc.).

Visit 2: Subjects will be seen in the Hand Clinic approximately 2 weeks after their initial Emergency Department visit. At this time, subjects in the non-absorbable suture material group will have their sutures removed. All subjects will have their wound assessed by a blinded single observer, utilizing the POSAS and VAS.

7.2.3 Visit 3 - 6-weeks following ED Visit (Hand Clinic)

Provide a description of what procedures will be performed on visit 2 or day 2 or post-test in order of how these will be done. If your study involves more than two sessions or visits replicate this section for each additional session or visit (e.g., 7.2.3, 7.2.4, etc.).

Visit 3: At the subject's 6-week follow-up clinic appointment, all subjects will have their wound assessed by a blinded single observer, utilizing the POSAS and VAS.

Visit 4 - 12-weeks following ED Visit (Final Visit in Hand Clinic)

Provide a description of what procedures will be performed on visit 2 or day 2 or post-test in order of how these will be done. If your study involves more than two sessions or visits replicate this section for each additional session or visit (e.g., 7.2.3, 7.2.4, etc.).

Visit 4: At the subject's 12-week follow-up clinic appointment, all subjects will have their wound assessed by a blinded single observer, utilizing the POSAS and VAS.

7.3 Duration of Participation

Describe how long subjects will be involved in this research study. Include the number of sessions and the duration of each session - consider the total number of minutes, hours, days, months, years, etc.

Approximately 12 weeks from time of initial Emergency Department encounter until last clinic follow-up visit.

7.4 Test Article(s) (Study Drug(s) and/or Study Device(s))

7.4.1 Description

Provide a brief description of all test articles (drugs (including any foods and dietary supplements), devices and/or biologics used in the research including the purpose of their use and their approval status with the Food and Drug Administration (FDA). Include information about the form of the drug product (e.g., tablets, capsules, liquid).

The two suture materials used in this study are chromic gut (absorbable) and nylon suture (non-absorbable). Both are products of Ethicon and FDA approved. Both are monofilament sutures used as standard practice as suture material. Chromic gut suture loses its tensile strength in approximately 10-21 days and fully dissolves over the course of three months.

7.4.2 Treatment Regimen

Describe dose, route of administration and treatment duration. Include information about dose adjustments.

N/A – This study involves suture material that is applied to a wound once. The nylon suture (non-absorbable) will be removed at the subject's 2-week follow-up appointment. There is no drug administration.

7.4.3 Method for Assigning Subject to Treatment Groups

Describe the randomization process and how the associated treatment assignment will be made.

Subjects will be randomized utilizing the National Cancer Institute Clinical Trial Randomization Tool (https://ctrandomization.cancer.gov/home/) and placed into one of two study groups – absorbable or non-absorbable suture material.

7.4.4 Subject Compliance Monitoring

Insert the procedures for monitoring subject compliance.

Subject compliance will be determined based on whether subjects come to their follow-up appointments where sutures will be removed (in the nylon suture group) and assessments will be made, as described previously. Subjects in the absorbable suture group are also asked to return for follow-up to assess wound healing and subject compliance is determined in the same manner.

7.4.5 Blinding of the Test Article

Describe how the test article is blinded.

The single observer who sees subjects at the 2, 6, and 12-week follow-up visits will be blinded.

7.4.6 Receiving, Storage, Dispensing and Return

7.4.6.1 Receipt of Test Article

Describe how the test article will be obtained and from what source. Describe how the study test article will be packaged along with amounts (e.g., number of tablets/capsules or volume of liquid) and labeling. If drug kits are used, describe all the contents of the kit and associated labeling.

Both suture materials are current standard of care treatment and available in the Emergency Department. A study device log will be utilized to record details of each suture device that is used for the study.

7.4.6.2 Storage

Describe the plans to store, handle the test article so they will be used only on subjects and only by authorized investigators. Describe storage temperature requirements and how temperature will be monitored and recorded.

All suture material used in the Emergency Department is obtained from the Emergency Department laceration carts. They are stored at room temperature.

7.4.6.3 Preparation and Dispensing

Describe how the test article will be assigned to each subject and dispensed. Describe the steps necessary to prepare the test article. Include where the test article preparation will be done and by whom. Fully describe how the study treatment is to be administered and by whom.

Subjects will be assigned to groups based on methods previously described.

7.4.6.4 Return or Destruction of the Test Article

Describe the procedures for final reconciliation of the test article supply at the end of the study and whether the test article is to be shipped back to a source or destroyed on site.

Absorbable sutures dissolve on their own without intervention. The non-absorbable sutures will be removed at the subject's two-week follow-up visit and disposed of at the practice site per standard of care.

7.4.6.5 Prior and Concomitant Therapy

Describe what prior and/or concomitant medical therapy will be collected. Describe which concomitant medicines/therapies are permitted during the study. Describe which concomitant medicines are not permitted during the study.

There will be no prior or concomitant medical or surgical therapy.

8.0 Number of Subjects and Statistical Plan

8.1 Number of Subjects

Indicate the maximum number of subjects to be accrued/enrolled. Distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures if applicable (i.e., numbers of subjects excluding screen failures.)

A maximum of 32 subjects, 16 in each group will be enrolled.

8.2 Sample size determination

If applicable, provide a justification of the sample size outlined in section 8.1 to include reflections on, or calculations of, the power of the study.

Minimum sample size required to detect a difference in a normalized POSAS score of 1 between two groups is 16 subjects/group, at a standard deviation of 1 (power 80%, p-value <0.05). Therefore, we plan to enroll a total of 32 subjects, 16 in each group.

8.3 Statistical methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

We will utilize a trained statistician to conduct our statistical analysis. We will likely use a paired T test for quantitative values and a Mann-Whitney U test for scaled values, though this will ultimately be determined by our statistician at time of analysis following data collection.

9.0 Data and Safety Monitoring Plan

This section is required when research involves more than Minimal Risk to subjects as defined in "HRP-001 SOP- Definitions."

Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Please complete the sections below if the research involves more than minimal risk to subjects, otherwise indicate each section as not applicable.

[Do not type here]

9.1 Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

N/A

9.2 Data that are reviewed

Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

N/A

9.3 Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

N/A

9.4 Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

N/A

9.5 Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

N/A

9.6 Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

N/A

9.7 Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

N/A

9.8 Suspension of research

Describe any conditions that trigger an immediate suspension of research.

N/A

10.0 Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration and reversibility of the risks. Consider all types of risk including physical, psychological, social, legal, and economic risks. Note: Loss of confidentiality is a potential risk when conducting human subject research.

- If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
- If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
- If applicable, describe risks to others who are not subjects.

- Loss of confidentiality will be minimized as the research team will only have access to the research data and all information will be kept on a password-protected computer or in a locked filing cabinet.

- Subjects will be assigned to a treatment program by chance. The treatment received may prove to be less effective or to have more side effects than the other research treatment(s) or other available treatments.

- Risks related to the laceration repair, independent of the study, include hematoma, infection, and wound healing issues including wound breakdown or dehiscence.

- Non-absorbable suture risks: Adverse reactions associated with the nylon suture material include wound dehiscence, gradual loss of tensile strength over time, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infection, minimal acute inflammatory tissue reaction, and transitory local irritation at the wound site. Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in transmission of bloodborne pathogens.

- Absorbable suture risks: Adverse reactions of the plain and chromic suture material include wound dehiscence, calculi formation in urinary and/or biliary tracts and prolonged contact with salt solutions such as urine and bile occurs, and transitory local irritation at the wound site. Patients with allergy or hypersensitivity to collagen or chromium may experience reactions resulting in inflammation, tissue granulation, fibrosis, wound suppuration, bleeding, sinus formation, secondary infection or inflammatory response characteristic of foreign body response.

  This suture may have variable rates of absorption over time (depending on such factors as the type of suture used, the presence of infection, and the tissue site). This may result in failure to provide adequate wound support in closure of sites where expansion, stretching or distension etc. may occur, unless additional support is supplied through the use of nonabsorbable suture material. Failure to provide adequate wound support in elderly, malnourished, or debilitated patents or in patients suffering from cancer, anemia, obesity, infection or other conditions may delay wound healing.

11.0 Potential Benefits to Subjects and Others

11.1 Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 13.0.

There is no direct benefit to subjects.

11.2 Potential Benefits to Others

Include benefits to society or others.

Data gathered from this study could help providers determine the best suture material for their patients and reduce complications of suture repairs.

12.0 Sharing Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how information will be shared.

N/A

13.0 Subject Payment and/or Travel Reimbursements

Describe the amount, type (cash, check, gift card, other) and timing of any subject payment or travel reimbursement. If there is **no** subject payment or travel reimbursement, indicate as not applicable.

Extra or Course Credit: Describe the amount of credit **and** the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered. It is not acceptable to indicate that the amount of credit is to be determined or at the discretion of the instructor of the course.

Approved Subject Pool: Indicate which approved subject pool will be used; include in response below that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

Each study participant will be paid $25.00 upon completion of the study. This will be payable at their final 12-week follow-up visit in the form of a Greenphire debit card.

14.0 Economic Burden to Subjects

14.1 Costs

Describe any costs that subjects may be responsible for because of participation in the research.

The research related tests and procedures that will be provided at no cost include:

- Patient and Observer Scar Assessment Scale (POSAS)
- Visual Analog Scale (VAS)

14.2 Compensation for research-related injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

N/A

15.0 Resources Available

15.1 Facilities and locations

Identify and describe the facilities, sites and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator's experience conducting research at these locations and familiarity with local culture.

Penn State Health Milton S. Hershey Medical Center

15.2 Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

The study team has access to all patients with hand and forearm lacerations who come through the Penn State Health Hershey Emergency Department requiring hand surgery consultation who meet inclusion criteria. It is unknown the exact percentage of those patients needed for recruitment as the number who come into the Emergency Department in which hand surgery is consulted is variable.

15.3 PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Please consider outside responsibilities as well as other on-going research for which the PI is responsible.

Sufficient time will be devoted to conducting the research and reviewing the data.

15.4 Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subjects might need as a result of their participation in the study, if applicable.

Penn State Health Milton S. Hershey Medical Center

15.5 Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties, if applicable.

All team members are provided copies of all IRB approved documents – protocol, data collection tools, approval memos, etc. Updates are provided regularly.

16.0 Other Approvals

16.1 Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from engaged cooperating institutions IRBs who are also reviewing the research and other required review committees, community leaders, schools, research locations where research is to be conducted by the Penn State investigator, funding agencies, etc.).

N/A

16.2 Internal PSU Committee Approvals

Check all that apply:

☐ Anatomic Pathology – **Penn State** Health **only** – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of "HRP-902 - Human Tissue For Research Form" in CATS IRB.

☐ Animal Care and Use – **All campuses** – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – **All campuses** – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

☐ Clinical Laboratories – **Penn State Health only** – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes but are no longer needed for clinical use. Upload a copy of "HRP-901 - Human Body Fluids for Research Form" in CATS IRB.

☐ Clinical Research Center (CRC) Advisory Committee – **All campuses** – Research involves the use of CRC services in any way.

☐ Conflict of Interest Review – **All campuses** – Research has one or more of study team members indicated as having a financial interest.

☐ Radiation Safety – **Penn State Health only** – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of "HRP-903 - Radiation Review Form" in CATS IRB.

☐ IND/IDE Audit – **All campuses** – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

☒ Scientific Review – **Penn State Health only** – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Health Cancer Institute (PSCI) Protocol Review Committee or the PSCI Disease Team is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website.

☐ St. Joseph Administrative Review – **Penn State Health only** – Penn State Health Research that will be conducted at St. Joseph Medical Center or St. Joseph Community Medical Groups.

17.0 Multi-Site Study

If this is a multi-site study (i.e., a study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol) and the Penn State PI is the lead investigator, describe the processes to ensure communication among sites in the sections below.

[Do not type here]

17.1 Other sites

List the name and location of all other participating sites. Provide the name, qualifications and contact information for the principal investigator at each site and indicate which IRB will be reviewing the study at each site.

N/A

17.2 Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site's IRB of record). Describe the process for communication of problems with the research, interim results and closure of the study.

N/A

17.3 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

N/A

17.4 Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

N/A

17.5 Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

N/A

17.6 Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

N/A

18.0 Adverse Event Reporting

18.1 Adverse Event Definitions

For device studies, incorporate the following definitions into the below responses, as written:	
Unanticipated adverse device effect	Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or IDE application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

18.2 Recording of Adverse Events

Address the frequency and process for eliciting adverse event information from research subject, e.g., "Research subjects will be routinely questioned about adverse events at study visits."

In the response, incorporate the following as written:
All adverse events (serious or non-serious) and abnormal test findings observed or reported to study team believed to be associated with the study drug(s) or device(s) will be followed until the event (or its sequelae) or the abnormal test finding resolves or stabilizes at a level acceptable to the investigator.

An abnormal test finding will be classified as an adverse event if one or more of the following criteria are met:

- The test finding is accompanied by clinical symptoms
- The test finding necessitates additional diagnostic evaluation(s) or medical/surgical intervention; including significant additional concomitant drug treatment or other therapy
  NOTE: Simply repeating a test finding, in the absence of any of the other listed criteria, does not constitute an adverse event.
- The test finding leads to a change in study drug dosing or discontinuation of subject participation in the clinical research study
- The test finding is considered an adverse event by the investigator.

All adverse events (serious or non-serious) and abnormal test findings observed or reported to study team believed to be associated with the study drug(s) or device(s) will be followed until the event (or its sequelae) or the abnormal test finding resolves or stabilizes at a level acceptable to the investigator.

An abnormal test finding will be classified as an adverse event if one or more of the following criteria are met:

- The test finding is accompanied by clinical symptoms
- The test finding necessitates additional diagnostic evaluation(s) or medical/surgical intervention; including significant additional concomitant drug treatment or other therapy
  NOTE: Simply repeating a test finding, in the absence of any of the other listed criteria, does not constitute an adverse event.
- The test finding leads to a change in study drug dosing or discontinuation of subject participation in the clinical research study
- The test finding is considered an adverse event by the investigator.

18.3 Causality and Severity Assessments

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will promptly review documented adverse events and abnormal test findings to determine 1) if the abnormal test finding should be classified as an adverse event; 2) if there is a reasonable possibility that the adverse event was caused by the study drug(s) or device(s); and 3) if the adverse event meets the criteria for a serious adverse event.

If the investigator's final determination of causality is "unknown and of questionable relationship to the study drug(s) or device(s)", the adverse event will be classified as associated with the use of the study drug(s) or device(s) for reporting purposes. If the investigator's final determination of causality is "unknown but not related to the study drug(s) or device(s)", this determination and the rationale for the determination will be documented in the respective subject's case history.

18.4 Reporting of Adverse Reactions and Unanticipated Problems to the FDA

18.4.1 Written IND/IDE Safety Reports

For a drug study under an IND, incorporate the following from 21 CFR 312.32 as written – DO NOT ALTER OR DELETE:
The Sponsor-Investigator will submit a written IND Safety Report (i.e., completed FDA Form 3500A) to the responsible new drug review division of the FDA for any observed or volunteered adverse event that is determined to be a serious and unexpected, suspected adverse reaction. Each IND Safety Report will be prominently labeled, "IND Safety Report", and a copy will be provided to all participating investigators (if applicable) and sub-investigators.

Written IND Safety Reports will be submitted to the FDA as soon as possible and, in no event, later than 15 calendar days following the Sponsor-Investigator's receipt of the respective adverse event information and determination that it meets the respective criteria for reporting.

For each written IND Safety Report, the Sponsor-Investigator will identify all previously submitted IND Safety Reports that addressed a similar suspected adverse reaction experience and will provide an analysis of the significance of newly reported, suspected adverse reaction in light of the previous, similar report(s) or any other relevant information.

Relevant follow-up information to an IND Safety Report will be submitted to the applicable review division of the FDA as soon as the information is available and will be identified as such (i.e., "Follow-up IND Safety Report").

If the results of the Sponsor-Investigator's follow-up investigation show that an adverse event that was initially determined to not require a written IND Safety Report does, in fact, meet the requirements for reporting; the Sponsor-Investigator will submit a written IND Safety Report as soon as possible, but in no event later than 15 calendar days, after the determination was made.

For a device study under an IDE, incorporate the following from 21 CFR 812.150 as written – DO NOT ALTER OR DELETE:
The Sponsor-Investigator will submit a completed FDA Form 3500Ato the FDA's Center for Devices and Radiological Health for any observed or volunteered adverse effect that is determined to be an unanticipated adverse device effect. A copy of this completed form will be provided to all participating sub-investigators.

The completed FDA Form 3500Awill be submitted to the FDA as soon as possible and, in no event, later than 10 working days after the Sponsor-Investigator first receives notice of the adverse effect.

If the results of the Sponsor-Investigator's follow-up evaluation show that an adverse effect that was initially determined to not constitute an unanticipated adverse device effect does, in fact, meet the requirements for reporting; the Sponsor-Investigator will submit a completed FDA Form 3500Aas soon as possible, but in no event later than 10 working days, after the determination was made.

For each submitted FDA Form 3500A, the Sponsor-Investigator will identify all previously submitted reports that that addressed a similar adverse effect experience and will provide an analysis of the significance of newly reported adverse effect in light of the previous, similar report(s).

Subsequent to the initial submission of a completed FDA Form 3500A, the Sponsor-Investigator will submit additional information concerning the reported adverse effect as requested by the FDA.

N/A

18.4.2 Telephoned IND Safety Reports – Fatal or Life-threatening Suspected Adverse Reactions

For a drug study under an IND, incorporate the following from 21 CFR 312.32 into the response, as written:
In addition to the subsequent submission of a written IND Safety Report (i.e., completed FDA Form 3500A), the Sponsor-Investigator will notify the responsible review division of the FDA by telephone or facsimile transmission of any unexpected, fatal or life-threatening suspected adverse reaction.

The telephone or facsimile transmission of applicable IND Safety Reports will be made as soon as possible but in no event later than 7 calendar days after the Sponsor-Investigator's receipt of the respective adverse event information and determination that it meets the respective criteria for reporting.

N/A

18.5 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

18.6 Unblinding Procedures

Describe the procedures for unblinding study therapy on a subject, including documentation of this in the subject's source document. Include example(s) here why someone might unblind a study. In most cases, the unblinding will be part of managing a serious adverse reaction and will be reported with the serious adverse event. However, in cases where unblinding was not associated with a serious adverse event, such actions should be reported in a timely manner.

Unblinding should be rare as subjects will be treated per standard of care practices. Subject unblinding would only occur if the single observer needed to evaluate the wound prior to suture removal. This would likely only occur between the ED visit and 2-week follow-up visit. However, a non-study team

clinical provider will likely remove any sutures, if necessary, prior to the single observer assessing the wound. If unblinding occurs, it will be documented in the subject's source document. The subject will not be withdrawn from the study.

18.7 Stopping Rules

In studies with a primary safety endpoint or studies with high risk to study subjects, provide the rules that define the circumstances and procedures for interrupting or stopping the study. If an independent Data and Safety Monitoring (DSMB) or Committee (DSMC) is set up for the study, the same stopping rules should be incorporated into the safety analysis plan as well.

There will be no stopping rules in this study, as both suture materials are FDA approved and safe for patient use.

If a subject, at any point in the study, demonstrates adverse reactions to the suture material, they will be treated accordingly. Subjects in the absorbable suture material group will be treated with an antihistamine. Subjects in the non-absorbable suture material group will have their sutures removed and treated with an antihistamine if needed. These subjects will not be removed from the study, but will be included in a subgroup analysis.

19.0 Study Monitoring, Auditing and Inspecting

19.1 Auditing and Inspecting

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

20.0 Future Undetermined Research: Data and Specimen Banking

If this study is collecting **identifiable** data and/or specimens that will be banked for future **undetermined research**, please describe this process in the sections below. This information should not conflict with information provided in section 22 regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly). If **NOT applicable**, indicate as such below in all sections.

[Do not type here]

20.1 Data and/or specimens being stored

Identify what data and/or specimens will be stored and the data associated with each specimen.

N/A

20.2 Location of storage

Identify the location where the data and/or specimens will be stored.

N/A

20.3 Duration of storage

Identify how long the data and/or specimens will be stored. If data and/or specimens will be stored indefinitely, indicate as such.

N/A

20.4 Access to data and/or specimens

Identify who will have access to the data and/or specimens.

N/A

20.5 Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

N/A

20.6 Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

N/A

21.0 References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

1. Draaijers, L., Tempelman, F., Botman, Y., Tuinebreijer, W., Middelkoop, E., Kreis, R. and van Zuijlen, P., 2004. The Patient and Observer Scar Assessment Scale: A Reliable and Feasible Tool for Scar Evaluation. *Plastic and Reconstructive Surgery*, 113(7), pp.1960-1965.
2. Shetty, P., Dicksheet, S. and Scalea, T., 1997. Emergency department repair of hand lacerations using absorbable vicryl sutures. *The Journal of Emergency Medicine*, 15(5), pp.673-674.
3. KHARWADKAR, N., NAIQUE, S. and MOLITOR, P., 2005. Prospective Randomized Trial Comparing Absorbable and Non-Absorbable Sutures in Open Carpal Tunnel Release. *Journal of Hand Surgery*, 30(1), pp.92-95.
4. Menovsky, T., Bartels, R., van Lindert, E. and André Grotenhuis, J., 2004. SKIN CLOSURE IN CARPAL TUNNEL SURGERY: A PROSPECTIVE COMPARATIVE STUDY BETWEEN NYLON, POLYGLACTIN 910 AND STAINLESS STEEL SUTURES. *Hand Surgery*, 09(01), pp.35-38.
5. EREL, E., PLEASANCE, P., AHMED, O. and HART, N., 2001. Absorbable Versus Non-Absorbable Suture in Carpal Tunnel Decompression. *Journal of Hand Surgery*, 26(2), pp.157-158.
6. Bæk Hansen, T., Kirkeby, L., Fisker, H. and Larsen, K., 2009. Randomised controlled study of two different techniques of skin suture in endoscopic release of carpal tunnel. *Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery*, 43(6), pp.335-338.
7. Theopold, C., Potter, S., Dempsey, M. and O'Shaughnessy, M., 2011. A randomised controlled trial of absorbable versus non-absorbable sutures for skin closure after open carpal tunnel release. *Journal of Hand Surgery (European Volume)*, 37(4), pp.350-353.
8. Onyekwelu, I., Yakkanti, R., Protzer, L., Pinkston, C., Tucker, C. and Seligson, D., 2017. Surgical Wound Classification and Surgical Site Infections in the Orthopaedic Patient. *JAAOS: Global Research and Reviews*, 1(3), p.e022.

22.0 Confidentiality, Privacy and Data Management

IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete "HRP-598 Research Data Plan Review Form." In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all other sub-sections of section 22.

For research being conducted at Penn State Health or by Penn State Health researchers only: The research data security and integrity plan is submitted using "HRP-598 – Research Data Plan Review Form."

Refer to Penn State College of Medicine IRB's "Standard Operating Procedure Addendum: Security and Integrity of Human Research Data," which is available on the IRB's website. In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all sub-sections of section 22.

For all other research: complete the following section. Please refer to PSU Policy AD95 for information regarding information classification and security standards and requirements. It is recommended that you work with local IT staff when planning to store, process, or access data electronically to ensure that your plan can be carried out locally and meets applicable requirements. If you have questions about Penn State's Policy AD95 or standards or need a consultation regarding data security, please contact security@psu.edu.

See the Research Data Plan Review Form