Cover Page

Official Title: Conservative Versus Suture Repair of Hand and Feet Lacerations in Children

Unique Protocol ID: IRB 26912

NCT Number: NCT03321721

Current Protocol Submitted for Review: 06/09/2020

Current Protocol and Continuing Review Form Withdrawn: 06/21/2020

Protocol Title:	Conservative versus Suture Repair of Hand and Feet Lacerations in Children
Protocol Status:	WITHDRAWN
Date Submitted:	06/09/2019
Approval Period:	Draft
Important Note:	**This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol. Questions that appear to not have been answered may not have been required for this submission. Please see the system application for more details.**

* * * Continuing Review * * *

Continuing Review Request

WHAT TO UPLOAD WITH YOUR CONTINUING REVIEW APPLICATION

For studies where research activities are limited to data analysis, upload subject safety information and publications (e.g., manuscripts, abstracts) since the last IRB approval, if applicable.

NOTE: if activities are limited to data analysis of de-identified/anonymous data (data that can no longer be linked to subject identifiers directly or through use of a code with master list kept), the study can likely be closed via the Final Report Form. See the SLU IRB Guidance for Closure of Human Subjects Research Studies.

For all other studies, upload:

- Subject safety information including the most current Serious Adverse Event (SAE) cumulative table and data safety monitoring reports since the last IRB approval, if applicable.
- Any publications (e.g., manuscripts, abstracts) since the last IRB approval.

Any changes, updated and/or new study materials should be uploaded and questions 19 - 24 of this form should be completed.

1. **Please indicate the status of the study:**

a) **The study has not started but will become active.**
Please explain why the study has not started.

b) X **The study is ACTIVE (please check the appropriate box below):**
X **Study is open to accrual.**
Study is on hold or halted.
Please explain what needs to occur before accrual can resume.

Study is permanently closed to accrual.

i. Have all subjects completed all research related activities/interventions?

ii. Will the research only remain active for long-term follow-up of subjects?

iii. Are remaining research activities limited to data analysis only? (See instructions above).

iv. For studies that are closed to subject accrual, do any subjects need to be re-consented (to inform them about changes to study procedures, study risks, study personnel, etc.)?

For IRB office use: * may qualify for expedited review

c) **The study has expired and needs to be re-initiated.**
Explain any research activities occurring during lapse in IRB approval.

2. **Date the study was initially approved by the IRB:** 06/21/2016

3. **Approval date of previous continuing review:** 06/05/2018

4. **Total number of participants/records/specimens you are approved to enroll.** 50

5. **Total number of subjects that have given consent (verbal or written) to date.** 26

6. **Total number of subjects that failed screening (if not applicable, state N/A).** 0

7. **Total number of participants accrued since the beginning of the project.** 26

8. **For multi-center studies, number of subjects approved for accrual study-wide (SLU site plus all other sites).**

9. **For multi-center studies, number of subjects enrolled study-wide (SLU site plus other sites).**

10. **Number of withdrawals from the research and explanation/reasons for withdrawals.**

N=9; Due to lack of patient returns at 4 months post repair for digital pictures to be obtained and for wound check

11. **Description and number of:**

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

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a) Reportable Protocol Deviations/Violations since the last approval date:

none

b) Unanticipated Problems (UPs) since the last approval date:

none

c) Serious Adverse Events (SAEs) since the last approval date:Note: Information here should be consistent with the cumulative table, which should also be attached in section #16.

none

12. Have there been any complaints about the research during the last year? N

If yes, please describe.

13. Briefly describe the progress of the study to date. Provide a status of participants in study, for example, where is the most recently accrued participant in terms of timeline in the study? If participants are in long-term follow-up, explain what this consists of in terms of data collection and/or intervention. Provide any new information in regard to risks. Summarize or attach publications or presentations.

Lack of patient follow up has hampered the progress of the study

14. Is there a Data Safety Monitoring (DSM) plan for this study?

Y No

Yes, a copy of the DSM report(s) for the last approval period is attached.

Yes, but a copy of the DSM reports(s) for the last approval period is not attached. Please explain below.

15. FDA Regulated Studies

Is this a Food and Drug Administration (FDA) Regulated Study, (i.e., involves drugs, devices, biologics)? If yes, please answer the following questions: N

a) Have there been any changes in the FDA status of any drug or device used in the study?

If yes, please explain:

b) Have any of the investigational drugs or devices used in this study received FDA approval?

If yes, please explain:

c) Have any new alternative drugs or devices been approved for treatment of the study condition that may affect subjects willingness to participate?

If yes, please explain:

Have current subjects been notified? Please explain:

d) Has there been a change in the standard care that may be considered as an alternative to the investigational drug or device or that would affect the original study design?

If yes, please explain:

Have current subjects been notified? Please explain:

e) Is there any new information that might affect the risk/benefit ratio and the willingness of current study subjects to participate or to continue to participate in the research?

If yes, please explain:

Have current subjects been notified? Please explain:

f) Does the study include an investigator's brochure (IB)?

If yes, what is the current version date?

(If study has multiple IBs, attach current versions in Attachments section (#16))

16. Provide a summary of any recent findings, literature, or other relevant information (especially pertaining to risks), if applicable.

none

17. Have there been any significant amendments or revisions to the protocol during the past approval period? (Significant amendments N

include changes in study design or risk level including those that resulted in a change in consent).

If yes, please briefly summarize the changes:

18. Y The consent materials attached to this eIRB application (including consent documents, assent documents, recruitment statements or other materials used to obtain consent) are the versions being used in the conduct of this study and all enrolled subjects have signed consent forms on file, if required. (If the requirement to obtain consent was waived or if no participants have enrolled since last continuing review, check N/A).

NOTE: The IRB routinely monitors consent document usage and may request copies of redacted participant consent forms.

19. Are any changes (amendments) requested with this Continuing Review?

Y Yes, please complete the remainder of this form.

No, form is complete. Please submit.

20. Summarize the proposed changes to the protocol in lay terms, including the type of change AND what the change involves.

If this is a change in PI a new Department Chair review is required. Please upload the signed document in the Attachments section.

In order to salvage this study may have to look at crowd sourcing evaluation tools such as Amazon's Mechanical Turk(1) where photos of repaired wounds of the hand and feet (suture vs no suture) at 4 months could be compared and rated by the lay public. This would be a form of data analysis and does not violate the study protocol

1. Crump MJ, McDonnell JV, Gureckis TM. Evaluating Amazon's Mechanical Turk as a tool for experimental behavioral research

21. Provide justification/explanation for the proposed changes.

Amazon Mechanical Turk (MT) is a crowd sourcing evaluation tool. For this study, sets of photographs of hands and feet lacerations (repaired/ no repaired) could be assessed as to cosmetic outcome or scar formation. Photographs would be grouped in terms of repair vs no repair but the crowd source would be blinded to the method of repair. In this way, we would use existing digital photographs of extremities already obtained by the study to evaluate the cosmetic outcome of extremity lacerations repaired vs no repair. In the original protocol, physician performed the evaluation of the digital images, with MT hundreds perhaps thousand of individuals will be evaluating the cosmetic outcome of the repair (or no repair) using a likert scale, assuming most participants are likely non-physician, this may result in a more accurate evaluation of a child's wound repair. MT participants are paid a few cents for their efforts since there are many surveys being conducted by Amazon.

22. Will currently accrued subjects need to be notified of changes? N

If no, please justify why not.

No changes in the original IC only the way the data is being used. No confidential information is being used only digital images of subject repairs (ie hand and feet)

If yes, please explain how AND when notification or re-consenting will occur.

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

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23.	**Does the SLU IRB Protocol need to be modified?**	N
24.	**Are consent documents modified?**	N

Proceed to the appropriate section(s) of the protocol and make your changes. Also make necessary changes in the Consent Form(s), Assent Form(s), Recruitment Statement, Questionnaire, or other attachments, as applicable. Upload any revised IRB materials. Please provide the entire revised document (not just revised pages). Use track changes or highlight (in yellow) changes to documents being revised. Please upload a tracked/highlighted copy of each revised document to be stamped upon IRB approval. NOTE: Upload a clean copy (changes or highlights removed) of documents in file formats other than Microsoft Word (i.e., the IRB will remove the tracked changes/highlights on uploaded Word documents).

NOTE: Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the subjects.

Sponsored Studies: Remember to update the Sponsor's Protocol version number and date in the Funding section of the protocol (this information will appear on the approval letter).

List of changed sections:
Personnel Information
Attachments (16)

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* * * Personnel Information * * *

Study Personnel Roles:
-Principal Investigator: accepts responsibility for study, must sign obligations, can edit protocol and submit to IRB
-Administrative Contact: additional study contact, may or may not also be member of research team, can edit/prepare protocol and submit to IRB
-Key Personnel (Research Team): SLU member of research team, can view protocol (not edit)
-Non-SLU Collaborator: member of research team from another institution or organization outside of SLU, has no access to system, must be provided with PDF of protocol. NOTE: SLUH/SSM employees who collaborate regularly may obtain a guest SLU account if access to system is needed.
-Department Chair: Official Department Chair, may or may not also be a member of research team, can view the protocol (not edit). NOTE: a proxy may be listed if the Chair is the PI.

IMPORTANT NOTE: Human Subjects Protection Training is mandatory for all research team personnel.

Principal Investigator (PI) Mandatory

PI must be SLU affiliate.

Name of Principal Investigator (Faculty, Staff or Student)	Degree (MD/PhD)	Title
Nakanishi, Albert	MD	Associate Professor

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

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Email nakanimk@slu.edu

Phone (314) 440-4272

Fax

Department Name
Peds-Emergency Medicine

Human Subjects Training Completed? Y
WARNING: Proof of training must show below or the application will be returned. If your training information isn't showing, upload a copy in the Attachments section.

Research Experience ***?HELP?***

The PI has conducted extensive clinical research with both intra-mural and extra-mural support leading to publications and presentations at local and national meetings.

Research Team Member Duties Picklist

1.	X	Recruitment	2.	X	Obtains consent
3.	X	Determine Subject Eligibility for Accrual	4a.	X	Subject Physical Examinations
4b.	X	Follow-up Visits including physical assessments	5.	X	Perform study procedures or Specimen Collection
6a.		Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.		Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.		Subject Randomization or Registry	8.	X	Collection of Subject Data
9.	X	Report Data (CRFs, e-CRFs, Spreadsheets)	10.		Data Analysis
11a.	X	Review Adverse Events	11b.	X	Treat and Classify Adverse Events
12.		Other (Please insert explanation below.)			

UserID	CourseCompletionDate	Course
nakanimk	09-09-2001	NIH/NCI Certification
nakanimk	04-24-2018	Good Clinical Practice (GCP)
nakanimk	03-12-2018	CITI Biomedical Research Basic Training

Administrative Contact

Name of Administrative Contact	Degree	Title
Gerard, James	MD	Associate Professor
Kociela, Vikki	RN, BSN	Research Coordinator

Key Personnel (Research Team)

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

Name of Key Personnel (Research Team)	Degree	Title	Department Name
Laffey, Steven	MD	Associate Professor	Pediatrics
Flood, Robert	MD	Associate Professor	Pediatrics
Charney, Rachel	MD	Assistant Professor	Pediatrics
Tredway, Trevor	MD	Assistant Professor	Pediatrics
Peter, John	MD	Professor	Pediatrics
Braun, Colleen	M.D.	Assistant Professor	Pediatrics
Hartman, Neal	MD	Housestaff Resident	Pediatrics
Oriaifo, Irene	MD	Housestaff Resident	Pediatrics
Velasco Masson, Jaime	MD	Assistant Professor	Pediatrics
Rivera Sepulveda, Andrea	MD	Housestaff Resident	Pediatrics
Forrester, Katherine	MD	Housestaff Resident	Graduate Medical Education
Gadiparthi, Rekha	MD	Housestaff Resident	Pediatrics
Arwikar, Neel	MD	Housestaff Resident	Pediatrics

Department Chair Mandatory

The official Department Chair should be listed here. If the Department Chair is the PI, a proxy may be listed.

Name of Department Chair	Degree	Title
Wilmott, Robert	MD	Professor
Email	**Phone**	**Fax**
wilmottr@slu.edu	(314) 577-5606	

Department Name
Pediatrics

Is this individual also a member of the research team? N

Human Subjects Training Completed?
WARNING: Proof of training must show below or the application will be returned. If your training information isn't showing, upload a copy in the Attachments section.

Research Experience *?HELP?*

Research Team Member Duties Picklist

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

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1.	Recruitment	2.	Obtains consent
3.	Determine Subject Eligibility for Accrual	4a.	Subject Physical Examinations
4b.	Follow-up Visits including physical assessments	5.	Perform study procedures or Specimen Collection
6a.	Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.	Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.	Subject Randomization or Registry	8.	Collection of Subject Data
9.	Report Data (CRFs, e-CRFs, Spreadsheets)	10.	Data Analysis
11a.	Review Adverse Events	11b.	Treat and Classify Adverse Events
12.	Other (Please insert explanation below.)		

UserID	CourseCompletionDate	Course
wilmottr	10-14-2001	Protecting Study Volunteers in Research

Research Team Roles

Name(s), Degree	Department	Experience	Duties
Nakanishi, Albert, MD	Peds-Emergency Medicine	The PI has conducted extensive clinical research with both intra-mural and extra-mural support leading to publications and presentations at local and national meetings.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations, Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Review Adverse Events, Treat and Classify Adverse Events
Gerard, James , MD	Peds-Emergency Medicine	Participated in and has been the PI on other clinical trials. Experienced in obtaining research informed consent both as PI and research team member in ongoing clinical study in the ED	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Data Analysis, Review Adverse Events, Treat and Classify Adverse Events
Tredway, Trevor, MD	Pediatrics	Participated in and has been the PI on other clinical trials. Experienced in obtaining research informed consent both as PI and research team member in ongoing	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Perform study procedures or

		clinical study in the ED	Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Review Adverse Events, Treat and Classify Adverse Events
Peter, John, MD	Pediatrics	Participated in other clinical trials. Experienced in obtaining research informed consent as a research team member in ongoing clinical study in the ED	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Review Adverse Events, Treat and Classify Adverse Events
Braun, Colleen, M.D.	Pediatrics	Participated in and has been the PI on other clinical trials. Experienced in obtaining research informed consent both as PI and research team member in ongoing clinical study in the ED	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Review Adverse Events, Treat and Classify Adverse Events
Hartman, Neal, MD	Pediatrics	Currently a fellow in PEM and involved in the research experience. Part of training includes receiving clinical research experience (research design and IRB submissions). He will be mentored by ED research faculty on this protocol.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data
Oriaifo, Irene, MD	Pediatrics	Currently a fellow in PEM and involved in the research experience. Part of training includes receiving clinical research experience (research design and IRB submissions). She will be mentored by ED research faculty on this protocol.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data
Velasco Masson, Jaime, MD	Pediatrics	Has conducted clinical research as a fellow in PEM and now an attending	Recruitment, Obtains consent, Determine Subject Eligibility for

		physician in the Division of PEM	Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Collection of Subject Data
Rivera Sepulveda, Andrea, MD	Pediatrics	is a fellow in the division of pediatric emergency medicine and involved in clinical research Will be mentored by senior research team members.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Review Adverse Events, Treat and Classify Adverse Events
Forrester, Katherine, MD	Graduate Medical Education	is a fellow in the division of pediatric emergency medicine and involved in clinical research Will be mentored by senior research team members.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Perform study procedures or Specimen Collection, Collection of Subject Data, Review Adverse Events, Treat and Classify Adverse Events
Gadiparthi, Rekha, MD	Pediatrics	is a fellow in the division of ped emergency medicine and involved in clinical research Will be mentored by senior research team members.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Perform study procedures or Specimen Collection, Collection of Subject Data, Review Adverse Events, Treat and Classify Adverse Events
Arwikar, Neel, MD	Pediatrics	is a fellow in our div of ped emergency medicine and involved in clinical research CITI form to be attached to this document Will be mentored by senior research team members.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Perform study procedures or Specimen Collection, Review Adverse Events, Treat and Classify Adverse Events
Laffey, Steven, MD	Pediatrics	Participated in and has been the PI on other clinical trials. Experienced in obtaining research informed consent both as PI and research	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Perform

		team member in ongoing clinical study in the ED	study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Review Adverse Events, Treat and Classify Adverse Events
Flood, Robert, MD	Pediatrics	Participated in and has been the PI on other clinical trials. Experienced in obtaining research informed consent both as PI and research team member in ongoing clinical study in the ED	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Review Adverse Events, Treat and Classify Adverse Events
Charney, Rachel, MD	Pediatrics	Participated in and has been the PI on other clinical trials. Experienced in obtaining research informed consent both as PI and research team member in ongoing clinical study in the ED	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Review Adverse Events, Treat and Classify Adverse Events

* * * Subject Population * * *

Subject Population(s) Checklist

Select All That Apply :

- [ ] Adults
- [ ] Cognitively Impaired Subjects
- [ ] Employees (specifically targeted)
- [ ] Fetuses
- [X] Minors (under 18)
- [ ] Neonates
- [ ] Non English Speaking Subjects
- [ ] Pregnant Women
- [ ] Prisoners
- [ ] Students (specifically targeted)
- [ ] Terminally Ill Subjects

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

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Wards of the State

Other (any population that is not specified above)

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* * * Study Location * * *

Study Location(s) Checklist

Indicate where the study will be conducted. Select all that apply:

Saint Louis University, Medical Center Campus

Saint Louis University, Frost Campus

Saint Louis University, Madrid Campus

Saint Louis University, SLUCare Practice Locations

SSM STL (DePaul Hospital, St. Mary's Health Center, St. Joseph (St. Charles, Wentzville, Lake Saint Louis), St. Clare)

X Cardinal Glennon Children's Medical Center

Saint Louis University Hospital (SSM Health- SLU Hospital)

SLU-SSM Cancer Center Research Alliance Sites

Other (In the box below, list any off-campus institutions or locations and describe the activities being conducted there. Please provide letters of cooperation and/or IRB approvals from each location to document support/approval of the study. You may provide such documentation as it becomes available, but you may not begin work at those sites until documentation of support is provided to the IRB.) Please refer to the Guidance for involving non-SLU institutions in human subject research.

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* * * General Checklist * * *

General Checklist

Select All That Apply :

Collection of Specimens

Data collection via e-mail or the Internet

Deception/Incomplete Disclosure

Dietary Supplements, Vitamins, and Other Food Agents

FDA Approved Device

FDA approved drugs, reagents, other chemicals administered to subjects (even if they are not being studied), or biologic products

Genetic Testing

HIV Testing

Human blood, cells, tissues, or body fluids

International Research or Research on International Populations

Investigational drugs, reagents, chemicals, or biologic products

Investigational Device

X Investigator Initiated Study *?HELP?*

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

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X Medical Records
X Photography, Video, or Voice-Recording Subjects
X Questionnaires and/or tests
Radioisotopes/radiation-producing machines, even if standard of care
rDNA/Gene Transfer Therapy
Registry(ies)
Specimens to be stored for future research projects (must be in consent form)
X Study of existing data or specimens
X University Indemnified Study (SLU is responsible for liability coverage) *?HELP?*
Other (clarify in text box to the right)

Single Use. Provide a brief summary and justification for the Single Use Therapy. Note: This application will refer to research. For Single Use applications it is understood that 'research' will mean 'therapy'.

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* * * Funding * * *

Funding Checklist

NONE

Funding - Saint Louis University

What type of Saint Louis University funding?	SLU eRS #
Departmental	61599

NOTE: Applicable grant application, contract or subcontract, investigator's brochure, and sponsor's protocol (for all industry sponsored clinical trials) must be attached. You will be prompted for these in section #16 (Attachments).

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* * * Expedited Paragraphs * * *

To request an Expedited Review, check the appropriate category(ies) below. Provide justification for your request for Expedited Review.

To qualify for expedited review, research activities must (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories below.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

a) **Research on drugs for which an investigational new drug application (21 CFR Part 31, 32) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)**

b) **Research on medical devices for which**

(i) An investigational device exemption application (21 CFR Part 812) is not required; or

(ii) **The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a) **From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or**

From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

Children are "persons who 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 the research will be conducted."

3. Prospective collection of biological specimens for research purposes by non-invasive means.

EXAMPLES: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra-and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

EXAMPLES: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiology; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. [FOR IRB use only]. Continuing review of research previously approved by a convened IRB only when condition (a), (b), or (c) is met.

   a) Previously approved research where
      (i) The research is permanently closed to the enrollment of new subjects;
      (ii) All subjects have completed all research-related interventions; and
      (iii) The research remains active only for the long term follow-up of subjects.

   b) Previously approved research where no subjects have been enrolled and no additional risks have been identified.

   c) Previously approved research where the remaining research activities are limited to data analysis.

9. [FOR IRB use only]. Continuing review or research not conducted under an investigational new drug application or investigational drug exemption where expedited categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research

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involves no greater than minimal risk and no additional risks have been identified.

*** * * Background, Purpose, Study Procedures * * ***

Title

Conservative versus Suture Repair of Hand and Feet Lacerations in Children

Complete Sections 1 - 16. In sections that allow reference to sponsor protocol or grant, clearly state section and page numbers. Any information that is different or specific to the local site should be in the SLU application. Specify N/A as appropriate.

1. Background

Page numbers from a sponsor's protocol/grant may be referenced in 1a and 1b.

a) **Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of the study, if applicable. Investigator initiated studies must cite references in the response provided or attach a bibliography. *?HELP?***

Lacerations and accidental incisions are a common presenting complaint in Emergency Departments (EDs). According to the CDC, there were over 4 million ED visits in 2010 that involved suturing or stapling (1). A wound registry created by faculty at SUNY Stony Brook compiled a cohort of 1000 patients with wounds requiring sutures. Of their cohort, they found that 28% of these wounds were located on either the finger or hand (2). These numbers suggest that there are over 1 million hand and feet lacerations repaired at EDs in America every year. Traditional therapy for lacerations include suture repair with non-absorbable sutures and still remains the "gold standard" for repair and cosmetic outcome. In recent years, there have been numerous studies investigating alternative therapies to standard suture repair. Studies have shown non-inferiority of both absorbable sutures, topical adhesives, and adhesive strips in simple lacerations in both the adult and pediatric population (3,4,5,6). Studies in the biology of wound healing have shown that the three stages of healing, inflammation, epithelialization, and maturation, occur regardless of whether wounds were closed or left open (7,8). A recent study by Quinn, et al, in the general population showed no significant difference in cosmetic appearance and patient satisfaction of suture repair or conservative management (non-repair) in lacerations (9). There have also been investigations that challenge the past standards of care in pre-repair wound management. It has been observed that there was a decreased infection rate in suture-less laceration repairs, when compared to traditional suturing (10). The use of povidone-iodine as irrigation medium has been shown to delay wound healing and reduce wound strength (11). Running water has been shown to have equivalent infection rates as high-pressure irrigation with sterile saline (12). Another study found no increased infection rate when comparing sterile versus non-sterile technique in the repair procedure (13, 14). When you consider the time, cost, and pain involved in traditional suture repair procedures, a method decreasing all three of these factors without any increase in infection rates or decrease in patient satisfaction seems to be beneficial for both patients and the Emergency Departments that serve them. This earlier referred study by Quinn serves as the starting point for the current proposed investigation. This study found non-inferiority of suture versus conservative repair of simple hand lacerations, in both cosmetic outcomes and infection rates.

Please save frequently

b) **Describe any animal experimentation and findings leading to the formulation of the study, if**

there is no supporting human data.

n/a

2. Purpose of the study

a) **Provide a brief lay summary of the project in <200 words. The lay summary should be readily understandable to the general public.**

The purpose of this study is to compare outcomes of 2 repair methods in simple (<2cm) hand and feet lacerations in the pediatric population (2-17 yrs). Our hypothesis is that there is no statistical difference in cosmetic outcomes between suture repair and non-repair of these injuries. This study has been performed in the adult population, but has not yet been done in children. We would like to be the first to show that conservative repair can be done in our pediatric population. The suture group will have their injuries repaired with non-absorbable sutures (nylon) which remain the gold standard in cosmetic repair of hands and feet. The conservative group will have identical cleaning and preparation of the wound, but the laceration will be covered with antibiotic ointment and sterile gauze without repair. Secondary outcome measure include patient satisfaction, infection rates, pain during repair, time of initial ED visit stay, and cost of supplies used in repair. Our patients will return in 7-10 and 14 days and in 3 months for evaluation. Wounds and scars will be evaluated at both 7-10 and 14 days and 3-4 months by both the researchers and the parents or care givers. A satisfaction survey will be administered to the parent or guardian. At 3-4 months, digital photographs of the healing lacerations will be graded for appearance by clinicians blinded to the repair method. The initial visit will be billed to their insurance and the follow-up visits will be free (non-registered).

Page numbers from a sponsor's protocol/grant may be referenced in 2b and 2c.

b) **List your research objectives (specific aims & hypotheses of the study).**

Our primary hypothesis is that there is no difference in cosmetic outcomes between suture repair and conservative treatment of simple, superfical (<2cm) hand and feet lacerations in the pediatric population. Secondary measures will be infection rates, pain scores, time to return to normal activity, time of initial ED visit, and cost of supplies used in repair. Our aim is to show that conservative repair saves time, money and reduces patient pain compared to traditional suture repair, while having no decrease in cosmetic satisfaction or infection rates.

Please save frequently

c) **Describe the study design (e.g., single/double blind, parallel, crossover, control, experimental, observational, etc.). If the study is investigator-initiated, a timeline for individual subject recruitment, follow-up, and analysis for the study is required. Also, indicate if the subjects will be randomized.**

We will use a prospective clinical trial with computer generated randomization to test our hypothesis. Patients will be recruited by a qualified pediatric emergency physician. Once consent is obtained from the parent(s)/legal guardians, patient data will be collected. The patient will have their hand or foot laceration(s) treated in the emergency department at that time by an attending physician, PEM fellow, or senior resident. The patient will then follow-up in 10-14 days for a wound check and satisfaction survey, and then again at 3-4 months for repeat survey and photograph of the healed wound. Our timeline for recruitment is approximately 15-18 months, 12-15m for recruitment, plus 3 months for additional follow-up visits. Analysis of the data should take an additional month.

d) If subjects will be given placebo, please justify placebo use. *?HELP?*

There will be no placebos used in this study.

3. Study Procedures

a) N Is this project a multicenter study (i.e., same project is conducted elsewhere by a different investigator) OR does this study involve conduct of research at multiple sites?

Is SLU acting as a coordinating center for other sites OR is the SLU PI a direct recipient of a federal grant for this research? If yes, complete and attach the Supplemental Application for Coordinating Center Activities.

Will the SLU site be participating in all parts/procedures/arms of the study?

If No, explain what SLU will NOT participate in:

Please save frequently

Page numbers from a sponsor's protocol/grant may be referenced in 3b, 3c, and 3d.

b) **Describe all the procedures, from screening through end-of-study, that the human subject must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care. Specify which procedures are for research and which are standard of care. Please note: The box below is for text only. If you would like to add tables, charts, etc., attach those files in the Attachment section (#16).**

Once a patient is deemed eligible, based on a review of his or her medical record, he/she will be approached by one of the pediatric emergency physicians to participate in the study. English-speaking parents or legal guardians will be asked to sign the consent form on behalf of the minor. Emancipated patients will be asked to sign for their own consent. A computer generated randomized allocations schedule will be determined upon opening of the sealed enrollment packets containing the pre-assigned repair method. Once consent has been obtained, initial demographic and injury data will be collected (see Data Collection Sheet, Appendix A). Patients will be ineligible for study enrollment if the digits' ligaments, bone or vascular supply is compromised by the injury or if the attending physician determines the depth of the wound is too deep, often greater than 0.5cm for healing by secondary intention.

The wound will be prepared by the usual and standard ED protocol. Lidocaine-epinephrine-tetracaine (LET) gel will be applied to the wound on presentation. The wound will be irrigated under tap water for 1-2 minutes and direct pressure applied to dry the wound. For patients in the suture repair group, the wound will have local infiltration with 1% lidocaine with epinephrine. Sutures used will be 5-0 nylon. Bacitracin ointment and sterile gauze will then be used to cover and dress the wound. In the conservative group, no local anesthesia will be used after irrigation. Bacitracin ointment and sterile gauze will be used to cover and dress the wound. Standardized wound care instructions will be given to patients prior to discharge (see Wound Care Instructions, Appendix B).

Patients will be asked to follow-up in the Pediatric Emergency Department in 10-14 days. The patients will have a reminder phone call on day 6-8 for their follow-up visit and arrange for an appointment time. The wounds will be evaluated for complications that were defined a priori as follows: "wound infection" was one that required systemic antibiotics as determined by the treating attending physician; and "wound dehiscence" as a wound that required the placement

of additional sutures or tissue adhesives. Children in the suture repair group will have their sutures removed. Parents will fill out a follow-up survey at this visit (see Initial Follow-up Survey).

Follow up data will be obtained from the parent or care giver for all subjects in the form of a questionnaire, patient with healing laceration will return with the parent or guardian for inspection of the wound with possible suture removal at 10-14 days then a re-evaluation of the healing wound with digital pictures taken at 3-4 months post ED enrollment for both treatment groups.

Patients will be asked to follow-up in the Pediatric Emergency Department in 12-16 weeks from the initial presentation. The patient will have a reminder phone call in week 11 for this visit and arrangement with time. The parent will fill out a second survey (see Final Follow-up Survey). Photographs of the wound will be taken, using a standardized protocol with a dedicated digital camera, and then printed by a pre-assigned printer. These photographs will be loaded to a computer to prevent alterations.

The photographs will be rated by 3 pediatric emergency physicians on the research team blinded to the treatment assignments. Independent evaluations will enable us to assess inter-observer reliability. The previously validated Visual Analogue Scale (VAS) will be used to assess the cosmetic outcome. The frequently used scale is a 100mm continuous line that is marked on the right end with "best scar" and on the left with "worst scar". The observer will be asked to mark on the line where they believe the scar "best fits". If the patient does not appear for their follow-up visit, a phone call will be made to the parent or guardian, who will be asked to report their satisfaction of the wound on a scale of 1 to 10, with 1 being "very unsatisfied" and 10 being "very satisfied".

c) **If the proposed study is a clinical trial where a drug, vaccine, device or other treatment is compared to a placebo group or comparison treatment group, what are the guidelines or endpoints by which early decisions regarding efficacy or lack of efficacy can be made? For example, it may be reasonable to stop enrollment on a study when efficacy has already been clearly demonstrated, to avoid unnecessary enrollments of additional subjects. Alternatively, it may be reasonable to stop enrollment when it is clear that efficacy will never be demonstrated, given the statistical power of the study as designed. Describe the guidelines that are in place to assist in making these determinations, if relevant to the proposed study.**

On an ongoing basis, we will evaluate potential complications and if we identify serious complications related to the study group, we will consider study termination.

d) **Describe how data analysis will be performed (statistical tests, methods of evaluating data) and indicate the smallest group/unit for which separate reporting will occur. For studies involving a questionnaire, if data and reliability information are available, please describe or provide references. For full board, unfunded studies describe sample size determination and power analysis. If none, please justify.**

Differences between groups will be analyzed using the Student's t-test for independent samples. Proportions will be compared using chi-square and the z-test for independent proportions. A significance level of 0.05 will be used in all analysis. Since this is an equivalence trial, a non-inferiority average difference of 15mm with the cosmesis VAS scale will be considered clinically equivalent. Previous studies have determined that the minimal clinically important differences between two groups ranged from 10 to 15mm (4,15,16).
A sample size of 18 patients per group will be needed to provide a power of 90% with 0.05 alpha error to detect a 15mm difference in the VAS. A patient attrition rate of 40% is expected and with this considered, a total of 50 patients will be enrolled in order to power the study this will include the 20 patients already enrolled in the previous study (#23300).

Please save frequently

e) State if deception (including incomplete disclosure of study purpose/procedures) will be used. If so, describe the nature of the deception and provide a rationale for its use. Also, describe debriefing procedures or justify a waiver of the requirement to debrief. NOTE: for studies using deception, an alteration of consent must be justified in the Informed Consent section of the protocol (#13) and the debriefing script/statement must be uploaded in the Attachments section (#16). See IRB Deception Guidelines.

f) Is there an accepted standard of care and/or standard practice at SLU for the condition/disease/situation being studied? This information will assist in comparing the risk/benefit ratio of study procedures relevant to usual care that would be received outside of the research context. *?HELP?* Y

If yes, please describe the standard of care and standard practice at SLU for the condition/disease/situation being studied.

The accepted standard of care for lacerations is suture repair. Recently, the type of sutures (absorbable versus non-absorbable) has been found to have equal efficacy. Studies have also shown comparable efficacy of topical adhesives and adhesive strips to close lacerations, but this is not yet accepted standard of care in most emergency departments. Although recent studies, including one at St. Louis University have shown non-inferiority of absorbable sutures when compared to non-absorbable, it has not yet become global standard of care.

g) Does this study involve any diagnostic imaging, labwork or genetic testing that could result in clinical discovery (diagnoses, genetic mutations, etc.)? Note that this could include discovery that is expected (related to the research) or incidental (not related to research aims, but possible, like a mass/shadow found in imaging despite not looking for it). N

If yes, please describe and include whether there are plans to share findings with study participants.

h) Is this study subject to the NIH Genomic Data Sharing Policy? N

The NIH GDS policy applies to all NIH-funded research that generates large-scale human genomic data as well as the use of these data for subsequent research and includes: genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomics, epigenomic and gene expression data, irrespective of NIH funding mechanism. Click here for more specific examples.

*** Radioisotopes or Radiation Machines ***

You have not selected the Radioisotopes option in the General Checklist. If you would like to add Radioisotopes information, please select the option to enable this section.

4. Radioisotopes or Radiation Machines

In this section, investigators must enter all radiation usage associated with the protocol.

Important: Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-233", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). In these cases, submission to the RSO/RSC should occur first, even before submission to IRB. For more information on how to submit for radiation safety review, see RSC instructions or contact the Radiation Safety Officer at 977-6895.

(1) It is the responsibility of the PI to assure the accuracy and completeness of the data submitted in this section, consistent with guidelines provided below. (2) For projects requiring radiation procedures, please refer to this guidance.

a) **If applicable, list and quantify the radiographic diagnostic and therapeutic procedures associated with this protocol by clicking "Add" and adding to Table 1 below. (Includes X-ray, fluoroscopy, CT, radioactive materials, nuclear medicine, PET-CT, radiation oncology, accelerator, Cyber Knife procedures, etc.)**

b) **Total estimated research radiation dose * :**

* Calculate from the table above by adding the Effective Dose Subtotals for all procedures.

NOTE: Informed Consent Radiation Exposure Risk Statement- The applicant must insert the appropriate Informed Consent Radiation Exposure Risk Statement template language into the SLU IRB Informed Consent, inclusive of applying the total estimated research radiation dose specified in item b) from the table above, as instructed in the SLU IRB Informed Consent Template. Contact the IRB Office at 977-7744 or irb@slu.edu with any questions.

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* * * Devices * * *

5. Devices

a) Please list in the space below all investigational devices to be used on subjects during this study.

b) Please list in the space below all FDA approved devices to be used on subjects during this study.

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

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* * * Drugs, Reagents, Chemicals, or Biologic Products * * *

6. Drugs, Reagents, Chemicals, Biologic Products, or Dietary Supplements, Vitamins, and Other Food Agents

Pilot	Phase I	Phase II
Phase III	Phase IV	X Not Phased

List placebo if it is considered a drug (contains more than inactive ingredients). For example, normal saline is considered a drug that should be listed, whereas placebo tablets are usually inert ingredients that do not need to be listed.

b) Please list in the space below all investigational drugs, reagents or chemicals to be administered to subjects during this study. Attach all applicable Investigator Brochures in section #16 (Attachments).

c) Please list in the space below all FDA approved drugs, reagents, chemicals to be administered to subjects during this study. Attach all applicable package inserts in section #16 (Attachments).

d) Please list in the space below all dietary supplements, vitamins, minerals, or foods to be administered to subjects during this study.

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* * * Other Levels Of Review * * *

7. Other Levels Of Review

1. University Radiation Safety

Protocols that involve non-standard of care radioactive materials (which includes the terms "radioisotopes", "radionuclides", "radiopharmaceuticals", and "nuclear medicine studies", e.g., "PET", "MUGA", "Zevalin", and/or specific radionuclides such as "F-18", "Tc-99m", "Th-201", "I-131", "Ra-223", "Y-90", etc.) will receive review by the Radiation Safety Officer (RSO) and/or Radiation Safety Committee (RSC). For information on how to submit for radiation safety review, see RSC <a href=https://www.slu.edu/research/faculty-resources/research-integrity-safety/documents/irb-protocols-requiring-rsc-review-instructions-for-coordinators.pdf target=_blank > instructions or contact the Radiation Safety Officer at 977-6895.

X **Not Applicable**

Yes, study involves radioactive materials (per instructions, submit to RSC before IRB)

2. Institutional Biosafety

Experiments involving the deliberate transfer of Recombinant or Synthetic Nucleic Acid Molecules (e.g.,

Gene Transfer), or DNA or RNA derived from Recombinant or Synthetic Nucleic Acid Molecules, or Microorganisms containing Recombinant or Synthetic Nucleic Acid Molecules and/or infectious agents (including select agents and toxins as defined by CDC and/or Animal and Plant Health Inspection Service (APHIS)) into one or more human research participants must be reviewed by the SLU Biological Safety Officer. Most of these protocols also require review and approval by the SLU Institutional Biosafety Committee (IBC). Please contact the SLU Biological Safety Officer at 977-6888 for more information.

X **Not Applicable**

Yes, study requires Institutional Biosafety review

3. Pharmacy, Therapeutics, Nutrition, and Transfusion (PTNT) Committee

Saint Louis University Hospital requires that all research involving the administration of medications within the hospital (including outpatient areas such as the Emergency Department, Outpatient Center, Saint Louis University Hospital-South Campus, etc.) be reviewed and approved by the Pharmacy, Therapeutics, Nutrition, and Transfusion (PTNT) Committee and that study drugs are received, stored, prepared, and dispensed by the Hospital's Department of Pharmacy Services. Please contact the Investigational Drug Services Clinical Pharmacist at 268-7156 or SLUH-IDS@ssmhealth.com for more information.

X **Not Applicable**

Yes, study requires PTNT review

4. Saint Louis University Hospital

All research involving Saint Louis University Hospital, including the Emergency Department, inpatient or outpatient services (including outpatient surgery at ABI and the infusion center at DOB) and medical record access, requires approval from the Saint Louis University Hospital Research Review Committee prior to study initiation. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. Documents should be submitted as soon as possible, or at the latest, concurrently with IRB submission. Please contact the Research Compliance Office at 577-8113 or sluh-research@ssmhealth.com of the SLU Clinical Trials Office (CTO) at 977-6335 or clinical-trials-office@health.slu.edu for more information.

X **Not Applicable**

Yes, study requires Saint Louis University Hospital review

5. SSMSL

All research involving SSMSL locations (including Cardinal Glennon), including inpatient or outpatient services and medical record access, requires approval from the SSM STL or SSM Cardinal Glennon Research Business Review (RBR) prior to study initiation. This process is designed to facilitate compliance with state and federal regulations as they pertain to research in hospitals and clinical research billing. While researchers can begin to complete the SSM RBR form at any time, the form should not be submitted until the IRB and the CTO have approved the study. Please contact the SSMSL Office at 989-2058 or Marcy.Young@ssmhealth.com for more information.

Not Applicable

X Yes, study requires RBR review

6.   Does this project require registration on ClinicalTrials.gov, and/or is this project subject to the NIH GCP Training Requirement? (Select "Yes" if either apply) Y

Registration may be required if any of the following apply: 1) The project meets the FDAAA definition of an "Applicable Clinical Trial", which requires registration on ClinicalTrials.gov. 2) As of January 1, 2017, a new NIH policy mandated biomedical and behavioral "Clinical Trials" to be registered on ClinicalTrials.gov. In addition, NIH policies require personnel on NIH "Clinical Trials" to take GCP training every three years. 3) Registering may be required for Journal Publication (ICMJE). Please review relevant definitions here. Contact the CTO at clinical-trials-office@slu.edu with questions about registering on ClinicalTrials.gov and refer to the training page of the IRB website for information on NIH GCP Training requirements.

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* * * Subject Population * * *

8. Subject Population - In the space below, please detail the participants that you are requesting to recruit (include description of each group requested)

a) Expected age range of subjects. (For example ≥ 18 yrs to 90 yrs).

2 -17 years

b) Number of evaluable subjects to be accrued at SLU or SLU site (this includes all sites under the direction of the SLU PI). 50

Exceeding the number listed here is a protocol violation. Prior IRB approval is required if additional participants are to be accrued. If applicable, this number should be consistent with your power analysis described in 3d.

c) Number of evaluable subjects to be accrued study wide. *?HELP?* 50

d) If including vulnerable populations (minors, pregnant women and fetuses, neonates, non-English speaking, economically or educationally disadvantaged, prisoners, adults temporarily or permanently unable to consent for themselves): 1) provide the rationale for the importance of including this population in the research, and 2) specify the measures being taken to minimize risks to potentially vulnerable subjects. Click on hyperlinks to access SLU Guidelines containing additional considerations and strategies for mitigating risks.

It has been shown that suture and conservative repair have equivalent cosmetic outcomes in the adult population. There has not been a similar study in the pediatric population. If this study in children has similar results and simple hand and feet lacerations do not require suture repair, we would be able to avoid painful, lengthy local infiltration and suture repair in these subjects. In some children, it is required to sedate them for repair, and this comes with additional risks with sedation and anesthesia. Avoiding these risks and pain would be advantageous for children and their caregivers. We used the minimum age of 2

years, due to the frequency of these injuries in small children and toddlers. The patient's weight or BMI will not effect their eligibility.

e) **If women, minorities, or minors are not included, a clear compelling rationale must be provided unless not applicable. Examples for not including minors: disease does not occur in children; drug or device would interfere with normal growth and development; etc. If federally funded reference appropriate section of the sponsors protocol/grant. *?HELP?***

n/a

f) **If any specifically targeted subjects are students, employees, or laboratory personnel, specify the measures being taken to minimize the risks and the chance of harm to these potentially vulnerable subjects. See SLU Guidelines for additional considerations and strategies for mitigating risks.**

g) **Describe (labeled a-c): a) who you are recruiting for this study (e.g., your patients/students/colleagues, those in existing database or registry, the general public), and b) how you are recruiting (flyers, advertisements, direct call/mailing, membership networks, in-person recruitment in clinic, classroom, public locations, etc.). For secondary data analysis or specimen studies, state how you have access to materials. Importantly: do not contact participants prior to obtaining IRB approval for your study.**

c) Also indicate whether or not you plan to obtain personal/private information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective subjects prior to obtaining informed consent and how (obtained by communicating with prospective subjects or obtained by accessing records or stored biospecimens). Note: if you are accessing medical records other than those of your own patients or those in your immediate department, you will need to submit a <a href= https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/prep_to_research_form.doc target=_blank>HIPAA Preparatory to Research form and submit to the SLU Privacy Officer PRIOR to accessing records.

Please refer to the <a href=https://www.slu.edu/research/faculty-resources/research-integrity-safety/institutional-review-board-irb/irb_assets/guidelines_subject_recruitment.doc target=_blank>SLU IRB Recruitment Guidelines when designing recruitment strategies and upload recruitment materials to the Attachments page for IRB review. You are expected to obtain permission for individuals/organizations that assist with recruitment, and whenever possible, those assisting should share your materials with potential participants on your behalf rather than providing you with private contact information.

We will not be soliciting study participants via news releases or public service announcements asking for volunteers. The primary and sub-investigators in the emergency department at Cardinal Glennon Children's Medical Center will be responsible for recruiting and obtaining consents. The parent(s)/ legal guardian(s) will be given ample time to make their decision. We will give parents/guardians 30 minutes to make their decision to participate, as the topical LET solution takes 30 to 40 minutes to take effect, thus, this wait will not impact outcomes or delay treatment. The parent(s)/ legal guardian(s) may change their mind about being included in the study or they may pull out of the study at any point in time. Parent(s)/ legal guardian(s) will be informed that their child will still need to have their laceration repaired regardless of their participation in the study.

* * * Subject Population * * *

8. Subject Population (continued)

Page numbers from a sponsor's protocol/grant may be referenced in 8h.

h) **Inclusion and Exclusion Criteria.**

Identify inclusion criteria.

Any English-speaking child, 2 to 17 years of age that presents to the emergency department at Cardinal Glennon Children's Medical Center with a hand or foot laceration less than or equal to 2 cm is eligible for the study.

Identify exclusion criteria.

Patients will be excluded if their laceration is greater than 2 cm, have irregular borders or are, deeper than 0.5.cm. Wounds that are the result of a mammalian bite, are more than minimally contaminated on visual inspection, are more than 8 hours old, or are associated with an open fracture, involve a partial amputation, involve a puncture wound, or involve the nailbed or a fingernail avulsion will be excluded. Patients with confirmed or suspected retained foreign bodies in the wound would also be excluded. Pt will also be excluded if hemostasis could not be attained after 15 minutes of pressure. Patients with complex lacerations who need plastic surgery or other sub-specialty repair will be excluded. Complex lacerations include: associated or suspected neurovascular, tendon, ligament, or bone injury, need for deep/multi-layer sutures. Patients with known or suspected immunodeficiency, bleeding or clotting disorders, pregnancy, diabetes, renal dysfunction, or allergic reaction to local anesthesia are also excluded. We will also exclude patients with a history of anticoagulant or chronic steroid use in the last year. Chronic steroid use is defined by use of steroids (PO, IV, IM, or topical) for more than 14 consecutive days, for more than 3 separate courses per year. Foster children will also be excluded, due to complications regarding custody, consent, and follow-up issues. In the case of injuries caused by broken glass, the patient will first receive a radiograph of the hand in order to r/o any radio-opaque foreign bodies, as this is standard of care for any suspected retained foreign body. In the case of injuries caused by knifes or other stabbing instruments, the Emergency Room Physician will use their clinical judgement as to whether the injury is a superficial knife wound versus a puncture or "complex" wound (as defined above) and determine if the patient is eligible according to the full exclusion criteria. Lastly, patients with allergies to LET solution would be excluded from the study.

i) **Compensation. Explain the amount and schedule of compensation, if any, that will be paid for participation in the study. Include provisions for prorating payment.**

Each patient who appears for and completes their follow-up visit will receive two (2) $25 pre-loaded gift cards, one at each visit.

j) **Describe who will cover study related costs. Explain any costs that will be charged to the subject.**

The initial Emergency Department visit will be covered by the patient's insurance as treatment for their laceration is standard of care. The patients will not be charged for their follow up visits as these two follow-ups are study-related. The two follow-up visits will not require registration or billing. The gift cards ($25 for each of two follow-up visits) will be paid for by the Department of Pediatrics. The first follow-up visit for suture removal and wound check is considered standard of care. The second follow-up visit for photography and survey is not considered standard of care for lacerations, as no treatment or procedure is being provided at this encounter. The antibiotic ointment will be provided to the patient at no charge at the initial visit.

k) **Estimate the probable duration of the entire study including data analysis and publication. This estimate should include the total time each subject is to be involved and the duration the data about the subject is to be collected. If the study is Investigator-initiated, a timeline for individual subject recruitment, follow-up, total time for subject accrual, and data analysis for the study is required.**

Each subject will be involved in the study for a period of 3-4 months, starting at the initial enrollment and ending at the completion of the 3-4 month follow-up visit. Our estimated length of time for enrollment is 15 months, with an additional 3 months to complete follow up and a month for data analysis, for a total study length of 18 months.

length of 18 months.

*** Risks ***

9. Risks

There is no research that can be considered totally risk free (e.g., a potential risk of breach of confidentiality). Therefore, when describing the risk, the lowest level of risk is "no more than minimal risk".

Page numbers from a sponsor's protocol/grant may be referenced in 9.1, 9.2, 9.3, and 9.4.

1. Use of investigational devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that subjects may experience while in the study.

2. Use of investigational drugs. Please include the clinical AEs associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with placebos or washout periods that subjects may experience while in the study.

3. Use of FDA approved drugs, reagents, chemicals, or biologic products. Please include the clinical AEs associated with each of the drugs with an indication of frequency, severity and reversibility. This information can often be found in the package insert provided by the manufacturer. NOTE: Include any likely adverse effects associated with placebos or washout periods that subjects may experience while in the study.

4. Use of FDA approved devices. Please include the clinical adverse events (AEs) associated with each of the devices with an indication of frequency, severity and reversibility. This information can often be found in the Investigator(s) brochure. NOTE: Include any likely adverse effects associated with procedures that subjects may experience while in the study.

5. Describe any risks related to performing study procedures. Please include all investigational, non-investigational, and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).

Risks related to laceration repair include pain during repair, bleeding, infection, wound dehiscence, suture abscess, scar and/or keloid formation. Risks related to conservative treatment of lacerations include bleeding, infection, poor wound closure, and scarring. Patients may also have allergic reactions to the LET solution, suture material, antibiotic ointment, gauze, or adhesive tape. There is

also a risk of unrecognized damage to deeper tissues and structures in either group.

Additional risks include the wound not healing, the wound dehiscing, and the wound becoming infected.

6. **Describe any risks related to the use of radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy).**

7. **Describe why this investigational compound/drug/device/procedure's risks/benefits are potentially better than standard of care or other common alternatives. Any standard treatment that is being withheld must be disclosed and the information must be included in the consent form. *?HELP?***

The alternatives to conservative laceration care are: suturing, using steri-strips, or wound adhesives (dermabond). Standard of care is suture repair. The non-suture alternatives involve less pain, and have been shown to be non-inferior in cosmetic result. Risks of conservative repair as discussed in this protocol are wound dehiscence, infection, and scar/keloid formation.

8. **Describe any psychological, social, or legal risks the subject may experience. *?HELP?***

There is a minimal risk of loss of confidentiality, although all measures will be taken to keep patient information confidential including the use of assigned numbers instead of PHI and the keeping of PHI in locked offices only accessible to the PI.

Page numbers from a sponsor's protocol/grant may be referenced in 9.9 and 9.10.

9. **Special Precautions. Describe the planned procedures for protecting against or minimizing potential risks. If appropriate, include the standards for termination of the participation of the individual subject. Discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.**

On a constant basis, we will evaluate the data for incidence of serious AEs, or other risks that may be occurring. At any time, an individual subject can withdraw from the study.

10. **Reproductive Risks.**

a. **Please list the pregnancy category of any drugs or N/A.**

N/A

b. **Please describe any reproductive risk associated with any part of the research study. Include any data**

from other studies (animal or human).

N/A

11. **Data Safety Monitoring**

Federal regulations require that when appropriate, the research protocol makes adequate provisions for monitoring the data to ensure the safety of participants. Monitoring should be commensurate with risks and with the size and complexity of the research, and could range from no plan needed to an independent data safety monitoring board. Please refer to SLU Guidelines for Data and Safety Monitoring as you complete the questions below.

a. Is there a Data Monitoring Committee (DMC) or Board (DSMB)? N/A

If yes, please provide the following information (labeled a-g): a) the composition of the board (degrees/qualifications of members), b) whether the board is independent from the sponsor and research team or not, c) frequency of meetings and issuance of reports to sites, d) assurance that the board is reviewing aggregate safety data and making recommendations regarding study continuance, e) provisions for ad hoc meetings if needed, f) who is reviewing SAEs in real time (MD or DO), and g) stopping/halting rules (if any exist).
A DSM charter can be referenced for all items except for "f) who is reviewing SAEs in real time."

If no, please justify why not.

b. Is there a Data Safety Monitoring Plan (DSMP)? Y

Note, if all relevant plan information is included in DSMB question above, select 'Yes' and state "see above" in the answer box.

If yes, provide details (labeled a-e) including: a) what types of data or events are captured and how are they documented, b) who is monitoring data, their independence/affiliation with the research and their degrees/qualifications, c) frequency of aggregate data review, d) who is reviewing SAEs in real time (MD or DO), and e) stopping/halting rules (if any exist).

On an ongoing basis, we will evaluate potential complications and if we identify serious complications related to the study group, we will consider study termination. If at any point, a member of the research team judges a patient's clinical status to put him at risk for serious complications, they can terminate the patient's participation in the trial.

If no, please justify why not.

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

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12. In case of international research (research outside of the U.S. or research on international populations (non-U.S.)), describe qualifications/preparations that enable you to evaluate cultural appropriateness and estimate/minimize risks to subjects. Include whether research is sensitive given cultural norms.

a. State any local laws/regulations governing Human Subjects Research in the country(ies) you will conduct the research and attach any relevant approvals. If none, state N/A.

b. Will there be language barriers and if so, how will they be addressed?

Note: If materials are to be distributed to subjects in their native language, please follow SLU's Guidance For Studies Involving Non-English Speaking Subjects.

         NOTE: Export control laws include the transfer of technical information and data, as well as information
         and technology to foreign nationals. If this study has international components, contact the SLU Export
         Control Officer for direction on whether export control policies apply.

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* * * Benefits/Alternatives, Procedures to Maintain Confidentiality and Privacy * * *

10. Benefits/Alternatives

a) Benefits. Describe the potential benefit(s) to be gained by the subjects and how the results of the study may benefit future subjects and/or society in general. Indicate if there is no direct benefit to the participants.

There are potential benefits related to this study. In the conservative repair, the patients benefit from less pain during treatment, as well as shorter time spent in the Emergency Department. In the patient population, decreasing pain also will decrease emotional trauma experienced during the stay. The potential benefit to society of conservative repair of minor hand lacerations is lower cost of supplies and medications for the hospital. Lower length of stay in Emergency Rooms and lower pain suffered during these repairs. In addition, some sutures need to be removed in a follow-up appointment. This appointment would not be necessary with conservative repair, negating the need for missed school or work. These benefits have either been found, or theorized to exist based on adult studies, but have not been studied in the pediatric population. The patient might not receive any benefit, direct or indirect, as result of this study.

b) Alternatives. Describe any alternative treatments and procedures available to the subjects should they choose not to participate in the study. If no such alternatives exist, please state that the alternative is nonparticipation. For some studies, such as record reviews, a description of alternatives would not be applicable.

Other ways lacerations can be treated include: letting it heal by itself, by application of steri-strips or adhesive glues. The method of repair is clinician-dependent, although most lacerations are repaired in some form due to concerns over cosmetic result and patient/parent satisfaction. Participation in this study is completely voluntary. Should the family and/or patient care not to participate, care will be rendered as per the normal standard of care. This standard of care could be either suture or conservative repair based

per the normal standard of care. This standard of care could be either suture or conservative repair based on the clinical judgement of the Emergency Room Physician.

11. Procedures to Maintain Confidentiality and Privacy

Federal regulations require that research materials be kept for a minimum of three (3) years and HIPAA documents be kept for a minimum of six (6) years after the closure of the study. For FDA-regulated or sponsored projects, the PI may be required to keep the data and documents for a longer time period.

Confidentiality

To determine whether adequate provisions for confidentiality of data are in place, the IRB must ensure that research materials are stored in appropriate locations throughout the study (during collection, transport/transmission, analysis and long term storage). Research information must be protected using appropriate safeguards based on identifiability of the data and risk associated with the study (See SLU IRB Confidentiality Guidelines).

For the questions below, please use the following definitions:

Anonymous/De-identified: data contain no identifiers, including code numbers that investigators can link to individual identities;

Coded: data in which (1) identifying information, such as name or social security number, has been replaced with a number, letter, symbol, or combination thereof (i.e., the code), and (2) a key to decipher the code exists enabling linkage of data to identifying information (e.g., a master list), and (3) the key (master list) is kept separately from coded data; AND/OR

Identifiable: data that includes personal identifiers (e.g., name, social security number), such that information could be readily connected to respective individuals.

a) **Electronic (Computer) Data**

Click "Add" to enter data security information for each type of electronic data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data. See the SLU ITS Sensitive Data Guide for acceptable data security methods.

Not Applicable, No Electronic (Computer) Data

Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

Electronic Data

Type of Data	Storage Location	Data Transmission Outside of SLU	Supplemental information related to above items can be entered here or leave blank:
Coded	SLU ITS network storage (T: drive (shared drive), U: drive (personal drive))	SLU Email account with an encrypted file attachment	

b) Hardcopy (Paper) Data

Click "Add" to enter information for each type of hardcopy (paper) data that will be created in the study: anonymous/de-identified, coded, and/or identifiable (see definitions above).

To properly address this question, there should only be one listing of each type of data in the table. Depending on your project, you could have up to three types of data.

Not Applicable, No Hardcopy (Paper) Data

Study IRB-approved Prior to New Question (Question N/A- Grandfathered)

Hardcopy Data

Type of Data	Storage Location	Transported Data Security	Supplemental information related to above items can be entered here or leave blank:
Coded	SLU Locked Room/Office	SLU Email account with an encrypted file attachment	

c) If a master list is used in this study (linking study codes to subject identifiers), explain: a) how and where you will secure the master list, b) how long it will be kept/when it will be destroyed, and c) provide a sample of the code.

All subject's data in this study will be kept confidential. The subjects' identifying name will be linked to a code number, which will be used on all study documents and data collection sheets. The list linking the identifier to the code number will be kept secure by being locked in a private office and cabinet. We will take all reasonable steps to protect each patient's identity. All patient identifier information will be disposed of following completion of the study.

d) If data or specimens are being shared outside of the research team, indicate who will receive the material, specifically what they will receive (data or specimens), and if an agreement has been signed to cover the transfer. Note: unless covered under a Clinical Trial or other agreement, the transfer of data or specimens to an external entity will require an agreement. For the transfer of materials (specimens), a Materials Transfer Agreement (MTA) is used; for the transfer of data, a Data Use or Data Transfer Agreement is

Transfer Agreement (MTA) is used; for the transfer of data, a Data Use or Data Transfer Agreement is used. Please contact the Research Innovation Group at 314-925-3027 for assistance.

n/a

e) If samples or data will be provided to SLU from an outside source, indicate whether you will have access to identifiers, and if so, how identifiable information is protected. Note: unless covered under another agreement (e.g., Clinical Trial Agreement or subcontract), the transfer of data or specimens from an external entity to SLU may require an agreement. For the transfer of materials (specimens), a Materials Transfer Agreement (MTA) may be required; for the transfer of data, a Data Use or Data Transfer Agreement may be required. Please contact the Research Innovation Group at 314-925-3027 for assistance.

n/a

f) If data will be collected via e-mail or the Internet, how will anonymity or confidentiality be affected? Describe how data will be recorded (i.e., will internet protocol (IP) addresses and/or e-mail addresses be removed from data?).

g) If you will be audio/video recording or photographing subjects, provide a rationale as voiceprints and images of faces/unique body markings are considered identifiers. Describe confidentiality procedures, including any restricted access to images and/or the final disposition of the recordings/photos (destruction, archiving, etc.).

Photographs of the repaired wound will be taken at the 3-month follow up visit. These photographs are necessary to grade the repaired laceration's appearance. The patient's face or other personal information will not be visible in the photograph. Only the repaired laceration will be photographed. The photographs will be kept on a digital disk and identified with the patient's code number. The photographs will then viewed on a computer by the reviewing pediatric emergency medicine physicians. The photographs will be deleted at the completion of the data analysis portion of the study.

h) Describe any study-specific (non standard of care) information or documentation that will be put in the participants' medical records for this research (e.g., study visit notes, lab results, etc.). If none, state "not applicable". NOTE: documentation of research in Epic should be done in accordance with the SLUCare Epic Research Charting Policy and Clinical Workflow: Documenting Research Encounters in Epic.

not applicable

i) Are there any information security requirements identified in the project's RFP/Award Notice/Contract? This could include data security, technical safeguards, security controls, NIST, FISMA, CFR, etc. N

If yes, SLU ITS approval is required. Contact InfoSecurityTeam@slu.edu to start the approval process.

Privacy

Privacy refers to persons having control over the sharing of oneself with others.

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j) Please indicate how participant privacy will be protected in this study (select all that apply):

X Discussion of health related and/or personal information in a private room/area

X Research interactions/interventions are conducted in a private room/area

X Use of drapes or other privacy measures

X Collection of sensitive/identifiable information is limited to the minimum necessary to achieve the aims of the research

X Access to study information is limited to the minimum amount of persons necessary to achieve the aims of the research (e.g., access restricted to research team members only)

X Consideration of parental inclusion/absence for studies involving minors

Other (please explain):

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* * * Potential Conflict of Interest * * *

12. Potential Conflict of Interest

Indicate whether you, your spouse or dependent children, have, or anticipate having, any income from or financial interest in a sponsor, device or drug manufacturer of this protocol, or a company that owns/licenses the technology being studied. Please remember that you are responding for you and any other investigator participating in the study. Financial Interest includes but is not limited to: consulting; speaking or other fees; honoraria; gifts; licensing revenues; equity interests (including stock, stock options, warrants, partnership and other equitable ownership interests). For questions regarding Conflict of Interest consult the Conflict of Interest in Research Policy.

Check one of the following (please remember that you are responding for yourself, your spouse, dependent children and any investigator, investigator's spouse and dependent children participating in the study):

1) X No equity interest and/or Financial Interest less than or equal to $5K
2) Any equity interest and/or Financial Interest exceeding $5K but not exceeding $25K in the past year or expected in the current year
3) Financial Interest exceeding $25K in the past year or expected in the current year

Check all those that apply:

Consulting
Speaking Fees or Honoraria

Gifts

Licensing agreement or royalty income

Equity interests, (including stock, stock options, warrants, partnership or equitable ownership interests), or serving on a scientific advisory board or board of directors

Other fees/compensation

If you have marked #2 or #3, please contact coi@slu.edu to initiate review of this study and provide the following information:

1. A Conflict of Interest Management Plan.
   - has been approved for all investigators for this study
   - is pending
   - has not been initiated

2. Describe who has, and briefly explain, the conflict of interest and indicate specific amounts for each subcategory checked:

Note to Investigator(s) Reporting a Potential Conflict of Interest

Investigator(s) must have:

1. Current, up-to-date Conflict of Interest Disclosure Form on file with the SLU Conflict of Interest in Research Committee (COIRC) that describes any financial relationship indicated above.

   - This information must be disclosed on the SLU confidential Conflict of Interest Disclosure Form and reviewed by the COIRC before accruing research subjects in this study. If your current Disclosure Form does not contain this information, you are required to submit an updated Disclosure Form to the COIRC.

2. You may not begin your study until your disclosure form has been reviewed and any required management plan has been approved by the COIRC for this study. To initiate COIRC review of your study, please contact coi@slu.edu.

* * * Informed Consent * * *

13. Informed Consent

Federal regulations require that informed consent be obtained from individuals prior to their participation in research unless the IRB grants a waiver of consent. Answer the questions, below, then click Add to provide the necessary consent documents and information regarding subject consent. Multiple consents/waivers may be added, but they must be uploaded one at a time.

NOTE: You may refer to the SLU IRB Guidance for Obtaining Informed Consent for considerations regarding the consent/assent process.

State N/A if not applicable.

1) **How is consent being obtained? When and where will the discussion take place? If the study involves a Non-English Speaking participant/population, please include details about plans for translated consent materials and interpreters to be used (see SLU Guidelines for Involving Non-English Speaking Subjects for more details).**

Informed consent will be obtained by the principal investigator and all members of the research team, as identified in the Research Team section of the IRB proposal. The parental consent document will be provided to the parent(s) or legal guardian(s) in person. Risks, benefits, and alternatives will be discussed. The consent document will be discussed in the patient's room in the emergency department. The parent(s) or legal guardian(s) must give consent before their child can participate in the research study. All efforts will be made to obtain assent, via a child assent from patients 6-18 years of age. If a child does not give assent, they will not be enrolled in the study. Patients that turn 18 during the follow-up period will be consented at the time of their follow up visit. Patients and parents will be provided up to 30 minutes to decide on participation in the study, so not to delay repair of the laceration. The child's laceration can be repaired even if participation in the study is declined.

2) **If the study involves adults unable to consent for themselves (whether diminished capacity to consent is temporary, permanent, progressive or fluctuating), please address the following: a) how is capacity to provide consent being assessed (initially and throughout study, if applicable); b) if unable to provide consent, how is LAR being determined (See SLU LAR Guidelines); c) if unable to provide consent, will assent be obtained and if not, why not?; d) if unable to provide assent, will dissent be honored and if not, why not? Note: participants initially unable to provide consent for themselves are expected to be given an opportunity to provide consent once capacity is gained. See SLU Guidelines for Adults Unable to Provide Consent for additional detail.**

n/a

Note: Any assent documents which will be used per the Adults Unable to Provide Consent guidance, should be appropriately named and uploaded using the Add button and the Consent drop down menu selection.

Informed Consent

Title	Consent Type	Attached Date
Approved_CR2018_26912 CONSENT FORM (CR 2017)	Consent	06/13/2018

* * * Assent * * *

14. Assent

Complete this section if your study includes minors. The Assent Form Templates (For children and For adolescents) provide guidelines for writing the assent document.

1. **Will minors be asked to give assent, then consent once they reach adulthood? If not, please justify. If not capable to provide assent initially, please address whether assent will be obtained as the minor gains capacity. Note: children who reach the age of adulthood during participation should be given the opportunity to provide consent as parent/guardian consent no longer applies. If obtaining consent would be impracticable (e.g., this is a registry with data/specimen obtained long ago), a waiver of consent should be added for IRB review. See SLU Guidelines for Research Involving Minors for additional detail.**

   Yes

2. **If minors are asked to assent and do not wish to participate, will they still be accrued in the study? If yes, justify.**

   No

3. **How will the minor's ability to give assent be assessed? (Consider the age and maturity of the minors as well as their physical or mental condition). If capacity is fluctuating, please explain how capacity will be assessed throughout the study.**

   For minors that can give assent (ages, 6-17), the member of the research team obtaining consent for the study will explain in simple terms how their cut needs to be fixed. We will explain they if they give their permission, we will fix their cut one of two ways and have them tell us how they felt about it afterwards. The research team member will use their clinical judgement to decide whether assent was properly given and the patient understands the study, to the best of their ability based on their age and maturity level.

Note: For studies that require a discussion about reproductive risks, note that the conversation with the minor should take place separately from the parents. Also, if a minor will reach adulthood (18 in Missouri) during the course of the study, they will need to be asked to consent as an adult at that time to continue in the study.

Assent Documents

Title	Upload assent document	Attached Date
Approved_CR2018_Conservative versus Sut...	Approved_CR2018_26912 marked child assent	06/13/2018
Approved_CR2018_Conservative versus Sut...	Approved_CR2018_26912 marked adolescent assent	06/13/2018

* * * HIPAA * * *

15. HIPAA

Studies that access, receive or collect protected health information (PHI) are subject to HIPAA regulations. PHI is health information with one or more personal identifiers. For more information refer to the SLU IRB HIPAA Guidance.

1. **Will health information be accessed, received or collected?**

   No health information. HIPAA does not apply.

   X Yes (continue to question 2).

2. **Which personal identifiers will be received or collected/recorded?**

   No identifiers. I certify that no identifiers from the list below will be received or collected and linked to health information. (Skip remainder of page).

   Limited identifiers will be received or collected/recorded (study will likely require a data use agreement). Select Data Use Agreement- INTERNAL or Data Use Agreement- EXTERNAL as appropriate, below.

   City/State/Zip codes

   Person-specific dates (e.g., date of birth, dates of service, admission/discharge dates, etc.)

   Age (if subjects are 90+ years)

   At least one direct identifier will be received or collected/recorded.

   X Names

   Social Security numbers

   X Telephone numbers

   X Linkable code or any other unique identifying number (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

   All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000

   X All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and 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 or older

   Fax numbers

   Electronic mail addresses

   X Medical record numbers

   Health plan beneficiary numbers

   Account numbers

   Certificate/license numbers

   Vehicle identifiers and serial numbers, including license plate numbers

   Device identifiers and serial numbers

   Web Universal Resource Locations (URLs)

   Internet Protocol (IP) address numbers

   Biometric identifiers, including finger and voice prints

   Full face photographic images and any comparable images

If you are receiving or collecting/recording health information and at least one personal identifier, please continue to complete the sections, below.

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

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3. **Sources of Protected Health Information:**
   - X Hospital/medical records for in or out patients
   - X Physician/clinic records
   - Laboratory, pathology and/or radiology results
   - Biological samples
   - X Interviews or questionnaires/health histories
   - Mental health records
   - Data previously collected for research purposes
   - Billing records
   - Other

   Please describe:

4. **If data will be shared outside the research team and the study involves PHI indicate how the research team will share the information.**

   X Not applicable (continue to question 5).

   Only linkable code that can link data to the identity of the subject. A code access agreement or business associate agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below.

   Limited identifiers: Zip codes, dates of birth, or other dates only. The study qualifies as a Limited Data Set. A data use agreement may be needed when data are shared with other non-SLU entities. If necessary, the agreement can be added and uploaded in item #5, below, using DUA-external option.

   With unlimited identifiers. The consent document and HIPAA Authorization form must describe how the information will be disclosed.

5. **HIPAA Documentation is required for this study. Use the table below to add HIPAA Documents for your study.**

HIPAA Documents

HIPAA Documents	Title	Attached Date
HIPAA Authorization	Approved_26912 marked HIPAA	08/18/2016

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* * * Attachments * * *

16. Attachments

In this section, please upload additional documents associated with your protocol. Failure to attach files associated with the protocol may result in the protocol being returned to you.

associated with the protocol may result in the protocol being returned to you.

Possible documents for this protocol could include:

- Bibliography
- Cooperating Institution's IRB Approval
- Data Collection Sheet
- Debriefing Script
- Device Information/Documentation
- Grant Proposal/Sub-Contract
- Human Subjects Training Certificate/Proof of Training
- Information Sheet/Brochure
- Interview/Focus Group Questions
- Investigator's Brochure
- Letter of Agreement/Cooperation
- IND Application Letter
- Package Insert
- Patient Diary Form
- Questionnaire/Survey
- Recruitment Material (e.g., flyers, ads, e-mail text)
- Safety Information (DSM Information)
- Scientific/PPC Review or Department Chair Review
- Sponsor's Protocol
- Sponsor's Protocol Amendment
- Study Design Chart/Table
- Other files associated with the protocol (most standard formats accepted: pdf, jpg, tiff, mp3, wmv, etc.)

To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.

Document Type	Document Name	Attached Date	Submitted Date
Bibliography	References	02/16/2016	06/02/2016
Other	Approved_Initial Visit Sheets	08/18/2016	08/18/2016
Other	Approved_Wound Care Instructions.docx	08/18/2016	08/18/2016
Questionnaire/Survey	Approved_First Follow Up Survey	08/18/2016	08/18/2016
Questionnaire/Survey	Approved_Second Follow Up Survey	08/18/2016	08/18/2016
Committee Approvals	Approval Letter.Nakanishi SLU #26912	11/11/2016	04/21/2017

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

Human Subjects Training Certificate/Proof of Training	citiCompletionReport6748429.neel	11/02/2017	11/03/2017
Other	Tredway IRB 26912 - July 2019	07/24/2019	07/29/2019

* * * PI Obligations * * *

PI Obligations

By clicking the box below you indicate that you accept responsibility for and will follow the ethical guidelines set forth by the Belmont Report, Declaration of Helsinki, the Nuremberg Code, and the Ethical Principles of the American Psychological Association (if applicable) for the research described. It also indicates that you have the requisite funding, credentials, training, and any necessary hospital privileges, if needed, to carry out all procedures and treatments involved in the protocol.

Clicking the box also affirms that the activities involving human subjects will not begin without prior review and approval by the Institutional Review Board, and that all activities will be performed in accordance with state and federal regulations and Saint Louis University's assurance with the Department of Health and Human Services. The PI assures that if members of the SLU research team access protected health information (PHI) from a covered entity in order to seek consent/authorization for research or to conduct research, such access is necessary for the research, is solely for that purpose, and the information will not be removed from the covered entity without IRB authorization or approved waiver. PI further assures that the SLU research team will comply with the terms of a Data Use Agreement to PHI (if any).

1) Have you completed the annual Conflict of Interest in Research Disclosure Form? Y

You can only select N/A if you are not currently listed on any externally funded research projects nor listed on any proposals for externally funded research support.

NOTE: An annual disclosure must be completed by all faculty, staff and students involved in the design, conduct or reporting of externally funded research applications and awards.

2) Have your financial interests changed significantly since you completed the annual disclosure form? N

The PRINCIPAL INVESTIGATOR certifies that he/she has read the University's Conflict of Interest Research Policy and has checked the appropriate box in the 'Potential Conflict of Interest' section of the application. In addition, the PRINCIPAL INVESTIGATOR certifies that, to the best of his/her knowledge, no person working on this project at SLU has a conflict of interest or if a conflict of interest does exist, that an appropriate management

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plan is in place.

According to the Saint Louis University Conflict of Interest in Research Policy, as PI, it is your responsibility to inform co-investigators, staff, or students involved in the design, conduct, or reporting of externally sponsored research of their requirement to complete a Conflict of Interest in Research Disclosure Form.

X **I accept this responsibility.**

X **The Principal Investigator has read and agrees to the above certifications and will abide by the above obligations.**

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* * * Event History * * *

Event History

Date	Status	View Attachments	Letters
09/30/2019	CONTINUING REVIEW 3 FORM WITHDRAWN		
07/30/2019	CONTINUING REVIEW 3 FORM REVIEWER(S) ASSIGNED		
07/29/2019	CONTINUING REVIEW 3 FORM SUBMITTED (CYCLE 1)	Y	
07/29/2019	CONTINUING REVIEW 3 FORM TABLED		
07/08/2019	CONTINUING REVIEW 3 FORM TABLED		
06/21/2019	CONTINUING REVIEW 3 FORM REVIEWER(S) ASSIGNED		
06/21/2019	PROTOCOL EXPIRED		
06/20/2019	CONTINUING REVIEW 3 FORM PANEL MANAGER REVIEW		
06/09/2019	CONTINUING REVIEW 3 FORM SUBMITTED	Y	
06/05/2019	CONTINUING REVIEW 3 FORM CREATED		
06/13/2018	CONTINUING REVIEW 2 FORM APPROVED	Y	Y
05/25/2018	CONTINUING REVIEW 2 FORM REVIEWER(S) ASSIGNED		

05/25/2018	CONTINUING REVIEW 2 FORM PANEL MANAGER REVIEW		
05/07/2018	CONTINUING REVIEW 2 FORM PANEL REASSIGNED		
04/25/2018	CONTINUING REVIEW 2 FORM SUBMITTED	Y	
04/22/2018	CONTINUING REVIEW 2 FORM CREATED		
11/06/2017	AMENDMENT 1 FORM APPROVED	Y	Y
11/04/2017	AMENDMENT 1 FORM REVIEWER(S) ASSIGNED		
11/04/2017	AMENDMENT 1 FORM PANEL REASSIGNED		
11/03/2017	AMENDMENT 1 FORM SUBMITTED	Y	
10/18/2017	AMENDMENT 1 FORM CREATED		
09/25/2017	REPORT 1 FORM APPROVED	Y	Y
08/25/2017	REPORT 1 FORM REVIEWER(S) ASSIGNED		
08/25/2017	REPORT 1 FORM PANEL MANAGER REVIEW		
08/02/2017	REPORT 1 FORM SUBMITTED	Y	
08/02/2017	REPORT 1 FORM CREATED		
06/15/2017	CONTINUING REVIEW 1 FORM APPROVED	Y	Y
06/13/2017	CONTINUING REVIEW 1 FORM SUBMITTED (CYCLE 1)	Y	
05/26/2017	CONTINUING REVIEW 1 FORM REVIEWER(S) ASSIGNED		
05/26/2017	CONTINUING REVIEW 1 FORM PANEL MANAGER REVIEW		
05/04/2017	CONTINUING REVIEW 1 FORM PANEL REASSIGNED		
04/21/2017	CONTINUING REVIEW 1 FORM SUBMITTED	Y	

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

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04/21/2017	CONTINUING REVIEW 1 FORM CREATED		
08/18/2016	NEW FORM APPROVED	Y	Y
08/17/2016	NEW FORM REVIEWER(S) ASSIGNED		
08/14/2016	NEW FORM SUBMITTED (CYCLE 3)	Y	
07/29/2016	NEW FORM SUBMITTED (CYCLE 2)	Y	
07/12/2016	NEW FORM SUBMITTED (CYCLE 1)	Y	
06/22/2016	NEW FORM CONTINGENT		
06/10/2016	NEW FORM REVIEWER(S) ASSIGNED		
06/07/2016	NEW FORM PANEL MANAGER REVIEW		
06/03/2016	NEW FORM PANEL ASSIGNED		
06/02/2016	NEW FORM SUBMITTED	Y	
06/02/2016	NEW FORM PREREVIEWED		
06/01/2016	NEW FORM PREAPPROVAL		
02/16/2016	NEW FORM PROTOCOL CLONED (26780)		

*** Comments ***

Protocol Title: Conservative versus Suture Repair of Hand and Feet Lacerations in Children

Comment Title	Section Name	Comment/Response	Response Necessary
RENEWAL : 06/09/2019			
Cycle : 1			
1	Continuing Review	At the Full Board Meeting on July 2, 2019, the Board deferred this continuing review submission because, as written, the reviewers were unable to make the necessary determinations required for the continuation of IRB approval of the research. The comments that follow outline the modifications and clarifications the reviewers have requested prior to reconsideration of the protocol continuation at a future meeting. Please note, during the lapse in approval, all research activities including but not limited to recruitment, advertisement, enrollment, interventions, interactions, data collection, and data analysis must stop. If you feel that harm to participants will result from stopping research activities, please immediately contact the IRB at irb@slu.edu. You will need to provide specific justification for IRB consideration to allow study procedures to continue for the brief time that IRB approval has lapsed. will respond accordingly	Y
2	Continuing Review	It is the Board's understanding that Dr. Nakanishi is no longer at the University. Please revise the protocol to list a new PI. In addition, please attach the department chair approval of this PI change in section 16 of the protocol. A letter signed by the new Department chair for Pediatrics, Dr Teckman has been placed under sect #16. Dr Tredway will now be PI going forward.	Y

4	Continuing Review	Question 17 of the Continuing Review Form describes an amendment to the protocol that has not yet been submitted for review/approval. Please remove this information from Question 17 of the Continuing Review Form, and describe these requested change in questions 19-24 of the Continuing Review Form. In addition, please be sure to incorporate the changes throughout the protocol and consent documents, as applicable. There is very limited information in question 17 regarding the proposed changes. Please be sure to describe the crowd-sourcing data considerations as it pertains to outcomes, consent changes, validity related to this type of wound repair. Please also describe how experimental design and primary/secondary outcomes for this study can incorporate the Amazon Mechanical Turk. In addition, question 17 states the incorporation of mTurk is necessary in order to salvage this study. If these changes are not made, please describe how the study plans to accrue more subjects and obtain adequate follow-up data. Done	Y
5	Continuing Review	Please provide an explanation as they why follow-up data was able to obtained for the first 18 subjects, but not for the last 9 subjects. Uncertain as to why we could not get patients to return for a follow up 4 month visit, gift cards were still valid. It is this reason that we are changing the data analysis	Y
3	Continuing Review	Question 14 of the Continuing Review Form states there is no Data Safety Monitoring Plan for this study. However, section 9-11b of the protocol includes a plan for Data Safety Monitoring. Please revise the response to this question. Since no further patient enrollment will take place and only the method of data analysis will change there is no further reason to have a DSM plan going forward	Y
Additional Response by			