A Prospective Randomized Study Comparing Suture Anchor and Soft Tissue Pectoralis Major Tendon Techniques for Biceps Tenodesis

NCT03529162

Study Protocol and
Statistical Analysis Plan

Date of Submission
3/5/2019

Protocol Title:	A Prospective Randomized Study Comparing Suture Anchor and Soft Tissue Pectoralis Major Tendon Techniques for Biceps Tenodesis
Protocol Status:	APPROVED
Date Submitted:	03/05/2019
Approval Period:	03/19/2019-03/18/2020
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?

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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:**	03/20/2018
3.	**Approval date of previous continuing review:**	
4.	**Total number of participants/records/specimens you are approved to enroll.**	80
5.	**Total number of subjects that have given consent (verbal or written) to date.**	3
6.	**Total number of subjects that failed screening (if not applicable, state N/A).**	1
7.	**Total number of participants accrued since the beginning of the project.**	2
8.	**For multi-center studies, number of subjects approved for accrual study-wide (SLU site plus all other sites).**	N/A
9.	**For multi-center studies, number of subjects enrolled study-wide (SLU site plus other sites).**	N/A

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

One patient screen fail - intra-op assessment found patient to be ineligible for study procedure.

11. **Description and number of:**

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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.**

We started recruiting patients for this study. Three patients consented to participate, two have not had their surgeries yet.

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

No

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

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

No adverse events or serious adverse events related to the surgical procedure to report.

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: Y

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

If yes, please explain:

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

If yes, please explain:

The Mitek Super Quickanchor being utilized in this study is an FDA approved device.

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

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?** N

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?** N

If yes, please explain:

Have current subjects been notified? Please explain:

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

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.**

The patients have not had their surgeries yet, and therefore there are no outcome measures

17. **Have there been any significant amendments or revisions to the protocol during the past approval period? (Significant amendments include changes in study design or risk level including those that resulted in a change in consent).** N

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.

Addition of study personnel to study.

21. **Provide justification/explanation for the proposed changes.**

Jacob Dodd will provide additional support in collecting and maintaining date for the study. Dr. Otto will contribute cases to help study reach target enrollment.

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

If no, please justify why not.

The addition of study personal does not affect their participation.

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

23. **Does the SLU IRB Protocol need to be modified?** Y

24. **Are consent documents modified?** N

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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
Informed Consent (13)
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
Kim, Christopher	MD	Instructor
Email	**Phone**	**Fax**
christopher.kim@health.slu.edu	314 256-3850	
Department Name		
Orthopaedic Surgery		
Human Subjects Training Completed?		Y

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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?***

Designed and published a level 1 prospective randomized controlled trial comparing two techniques of ACL reconstruction. Dr. Kim was involved in all aspects of the study, including designing methodology, pt recruitment, data analysis, manuscript write-up, etc.

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.	X	Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed)	6b.	X	Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices
7.	X	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
christopherkim	11-03-2016	CITI Biomedical Research Basic Training

Administrative Contact

Name of Administrative Contact	Degree	Title
Dawson, Sarah	RN	Research Nurse
Hill, Brian	MD	Housestaff Resident
Bell, Matthew	BS	Student

Key Personnel (Research Team)

Name of Key Personnel (Research Team)	Degree	Title	Department Name
Kaar, Scott	MD	Associate Professor	Orthopaedic Surgery
Dodd, Jacob	BS	Student	Student Affairs-Medical School
Otto, Randall	MD	Faculty/Staff	Orthopaedic Surgery

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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
Place, Howard	MD	Professor

Email	Phone	Fax
howard.place@health.slu.edu	(314) 577-8850	

Department Name
Orthopaedic Surgery

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

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
place	12-12-2003	CITI/University of Miami Training
place	04-24-2001	Protecting Study Volunteers in Research
place	02-13-2013	SLU Boot Camp Training

Research Team Roles

Name(s), Degree	Department	Experience	Duties
Kim, Christopher, MD	Orthopaedic Surgery	Designed and published a level 1 prospective randomized controlled trial	Recruitment, Obtains consent, Determine Subject Eligibility for

		comparing two techniques of ACL reconstruction. Dr. Kim was involved in all aspects of the study, including designing methodology, pt recruitment, data analysis, manuscript write-up, etc.	Accrual, Subject Physical Examinations, Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed), Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Review Adverse Events, Treat and Classify Adverse Events
Hill, Brian, MD	Graduate Medical Education	Brian has been a sub-PI on many previous ortho protocols.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis, Review Adverse Events
Bell, Matthew, BS	Student Affairs-Medical School	Matthew has participated in both clinical and basic science research in the fields of immunology, rheumatology, and infectious disease at UCSF medical center as well as Washington Hospital Center in D.C. He will be mentored by senior research team members.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed), Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis, Review Adverse Events
Kaar, Scott, MD	Orthopaedic Surgery	Dr. Kaar has authored and been a PI on numerous publications in the areas of shoulder injuries and sports medicine. Specifically, he has conducted research in	Recruitment, Obtains consent, Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection,

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		has conducted research in shoulder kinematics, instability, knee biomechanics, and hip preservation.	Specimen Collection, Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed), Receive, Store, Manipulate or Account for Study Drugs, Biologics or Devices , Report Data (CRFs, e-CRFs, Spreadsheets), Review Adverse Events
Dodd, Jacob, BS	Student Affairs-Medical School	Jacob has limited research experience and will work with Dr. Kim and research team to ensure quality data collection. Research team will be in regular communication throughout the study.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Data Analysis, Review Adverse Events
Otto, Randall, MD	Orthopaedic Surgery	Dr. Otto has extensive research experience in orthopaedic surgery, including research during residency at SLU and recently as a community surgeon. Research include industry sponsored clinical trials and outcome studies.	Recruitment, Obtains consent, Determine Subject Eligibility for Accrual, Subject Physical Examinations , Follow-up Visits including physical assessments, Perform study procedures or Specimen Collection, Administer and/or Dispense Study Drugs, Biologics or Devices (must be licensed), Subject Randomization or Registry, Collection of Subject Data, Report Data (CRFs, e-CRFs, Spreadsheets), Review Adverse Events, Treat and Classify Adverse Events

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* * * Subject Population * * *

Subject Population(s) Checklist

Select All That Apply :

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X Adults
Cognitively Impaired Subjects
Employees (specifically targeted)
Fetuses
Minors (under 18)
Neonates
Non English Speaking Subjects
Pregnant Women
Prisoners
Students (specifically targeted)
Terminally Ill Subjects
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
X SSM STL (DePaul Hospital, St. Mary's Health Center, St. Joseph (St. Charles, Wentzville, Lake Saint Louis), St. Clare)
Cardinal Glennon Children's Medical Center
X 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

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Deception/Incomplete Disclosure
Dietary Supplements, Vitamins, and Other Food Agents
X 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?*
X Medical Records
Photography, Video, or Voice-Recording Subjects
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)
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

X **NONE**

NOTE: Applicable grant application, contract or subcontract, investigator's brochure, and sponsor's

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protocol (for all industry sponsored clinical trials) must be attached. You will be prompted for these in section #16 (Attachments).

*** * * 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.

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

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

Title

A Prospective Randomized Study Comparing Suture Anchor and Soft Tissue Pectoralis Major Tendon Techniques for Biceps Tenodesis

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?***

A rotator cuff tear is the most common shoulder injury that requires surgical intervention. Frequently, rotator cuff tears are accompanied by many other pathological lesions. Most often rotator cuff tears are accompanied by superior labrum-biceps complex (SLBC) lesions (3,9) which include superior labrum anterior to posterior (SLAP) lesions, partial tears of the long head of the biceps tendon (LHBT), subluxations and complete ruptures of the LHBT, and biceps pulley lesions (1,6). When a LHBT partial tear, pulley lesion, or subluxation/dislocation of the LHBT is observed, debridement alone could result in persistent pain even after a successful rotator cuff repair procedure (6). In this setting, tenotomy (biceps tendon transection) or tenodesis (surgical fixation of the biceps tendon to the humerus) can provide prolonged relief (9,10,12).

Although biceps tenotomy can effectively relieve pain, biceps tenodesis may be preferred in select patients because it preserves the normal tension-length relationship of the LHBT, maintains elbow flexion and supination strength and results in less cramping pain and "Popeye" deformities compared with tenotomy (14). Several methods can be used for performing biceps tenodesis in patients presenting with rotator cuff tears, such as suprapectoral or subpectoral techniques, but superiority of a technique has yet to be reported (2). In open subpectoral techniques, interference screw (IS) and suture anchor (SA) fixation to the humerus are two popular techniques. Previous studies have indicated that though the IS technique is simple and requires a relatively short operative time, it is associated with tenodesis failure in patients with poor tendon quality and osteoporosis at the site of the screw insertion (5). The SA technique has also been shown to result in good clinical outcomes, improvement in restoration of elbow flexion and supination strength, as well as in shoulder functional scores (8,11). However, the

SA technique is expensive and can require a lengthier operative time. An alternative method is to tie the LHBT around the tendon of the pectoralis major (PMT) and utilize sutures to secure the construct (2,16). This procedure does not require hardware, and is extremely cost-effective, and can potentially reduce surgical time. There are no studies comparing the outcomes of the PMT with other methods for tenodesis.

Please save frequently

b) **Describe any animal experimentation and findings leading to the formulation of the study, if there is no supporting human data.**

Not applicable.

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.**

Long head of biceps tendon rupture is a common complication of rotator cuff shoulder surgeries. When the tendon ruptures it gives a malformation similar to a "popeye" arm. We are evaluating and comparing two different procedures that fix the long head of the biceps tendon to prevent this "popeye" deformity.

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).**

Therefore, the aim of this study is to compare the clinical and anatomic outcomes of the suture anchor (SA) and pectoralis major (PMT) fixation techniques for biceps tenodesis performed with arthroscopic rotator cuff repair. We hypothesize that the two techniques will not differ significantly with respect to postoperative outcome measures and integrity of tenodesis.

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.**

This study will be a prospective randomized control trial. Patients will be randomized using sealed envelopes created through a computer randomization system into one of two groups: the SA and PMT groups. The study will recruit 80 eligible patients for up to a two year period. Patients will undergo the same standard rehabilitation for rotator cuff repair and biceps tenodesis. Patients will be followed for 1 year with functional assessments at 3, 6, and 12 months. Patients will not be blinded to their treatment allocation.

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

Not applicable.

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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).**

Patients will be screened for eligibility in the trial during a routine preoperative assessment.
Randomization will occur at the time of the surgery.
Postoperative rehabilitation will be done in accordance with standard of care.
Follow up visits will be performed at 3, 6, and 12 months postoperatively for thorough physical examination including range of motion (ROM) using a goniometer along with functional assessments including visual analog scale (VAS) for pain, the quick Disabilities of the Arm, Shoulder and Hand (DASH), a single assessment numerical evaluation (SANE), the American Shoulder and Elbow Society (ASES) score and long head of the biceps (LHB) score. The SANE score, and VAS are currently standard of care. The ASES, DASH and LHB score will be collected for research purposes only.

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.**

This study will compare two approved standard techniques of biceps tenodesis that are accepted standard of care and practiced by many orthopaedic surgeons.

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.**

Postoperative long head of the biceps (LHB) score will be utilized as the primary outcome of this study. The LHB score is a composite endpoint that (maximum 100 points) evaluates 'biceps pain and muscle cramps', 'cosmesis', and 'flexion strength at the elbow'. In a prior study, the LHB score following the suture anchor technique was 91.8. Assuming an effect size of 0.76 (e.g., a clinically meaningful difference of 9 points with a standard deviation of 12 points) and drop out rate of 30%, 40 patients in each group will provide 81% statistical power with alpha=0.05 to detect a clinically meaningful difference between the two groups (14). Statistical analysis will be performed with SPSS software. Mean distances, standard deviations, range and 95% confidence intervals will be calculated. Interobserver reliability and intraobserver reproducibility will be calculated for all measured distances.

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.

Both procedures being evaluated are used as standard of care for different surgeons at SLU.

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).** Y

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

Diagnositic evaluation includes MRI but these are standard of care with patients presenting with rotator cuff tears. This will be performed before patient screening occurs. All diagnostic imaging will be shared with patients.

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

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mechanism. Click here for more specific examples.

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* * * 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.

FDA Approved Devices

Device Name	Manufacturer	Provide IDE #. Documentation of IDE # required unless imprinted on sponsor protocol (attach in section #16).
Super Quickanchor	DePuy Mitek	

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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.

Please read the IND Statements.

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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 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@ssmsluh.com for more information.

X **Not Applicable**

Yes, study requires PTNT review

4. Saint Louis University Hospital

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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.

Not Applicable

X **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).

18 years to 90 yrs

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b) **Number of evaluable subjects to be accrued at SLU or SLU site (this includes all sites under the direction of the SLU PI).** 80

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?*** 80

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.**

We are not enrolling vulnerable populations in this study.

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?***

This is not a disease in minors and in general, this is an elective procedure that would not be performed in pregnant women.

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

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participants on your behalf rather than providing you with private contact information.

Subjects will be identified from patients who are referred to Dr. Kim and Dr. Kaar for shoulder rotator cuff repair surgeries.

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* * * 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.

Eligibility criteria include:
1.Age 18 to 90 years
2.Able to provide written informed consent
3.Has: (a) partial- or full-thickness rotator cuff tear verified by preoperative magnetic resonance imaging (MRI) and arthroscopy; (b) concomitant biceps lesions (LHBT partial tear>50%, SLAP type II lesion, pulley lesion, or subluxation/dislocation of LHBT) that were diagnosed arthroscopically with concomitant symptoms; and (c) arthroscopic rotator cuff repair.

Identify exclusion criteria.

Exclusion criteria include:
1.Any medical illness that adversely impacts the patient's ability to complete the study procedures
2.Isolated glenohumeral pathological conditions
3.Any prior surgery on the same shoulder
4.Complete rupture of the LHBT assessed by MRI or at time of procedure
5.Incomplete repair of the rotator cuff

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.

There will be no compensation for participation in the study.

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

The procedures and surgeries are standard of care and any expenses related to surgeries will be charged to the patient or their current insurance. Patients would have one of these surgeries regardless because they are standard of care. The patients will not incur additional charges as a result of participation in the study.

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.

We plan to begin recruiting patients and initiate data collection in April 2018. We estimate patient recruitment to continue for two years until April of 2020. Thus, because all of our participants will be followed-up postoperatively for 1 year, data collection will continue until July 2021. Data will be gathered at their routine clinic visits as part of their routine postoperative assessments, which will be at 2 weeks, 6

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their routine clinic visits as part of their routine postoperative assessments, which will be at 2 weeks, 6 weeks, 12 weeks, 6 months, and 12 months postoperatively. Gathering data specific to the study will take approximately 10 minutes each visit. We expect our data analysis to be completed in July of 2021 as well and our manuscript preparation to be completed in August 2021. Finally, we estimate our manuscript submission to the American Journal of Sports Medicine will occur in August 2021.

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* * * 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.**

   There are no risks specific to the Mitek Super Quckanchor. It is used widely in orthopaedic surgery for various indications that require a suture anchor. Potential risks associated with any suture anchor may include suture breakage, anchor pull-out, humerus fracture during anchor insertion, and suture knot irritation.

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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).**

The biceps tenodesis procedure is part of the surgical procedure, and its risk and benefits are discussed as part of the surgical informed consent. Both techniques are widely used, and so the risks are similar. In the suture anchor technique, it is possible for the anchor to “pull out” of the bone, resulting in failure of the repair and the biceps tendon falling down the arm of the patient. IIn the pectoralis major technique (PMT), there is a possibility that the sutures break, causing the tendon to again fall down the patient's arm. There are additional risks including pain, swelling, infection, reduced shoulder mobility, bruising, and contusion. All these procedures will be performed in accordance with standard of care.

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?***

Both of the techniques being evaluated are standard of care. Our hypothesis is that there is no difference in the benefits of these two techniques. Standard of care will not be withheld from patients.

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

Every effort will be made to protect the research study data. There is, however, always the possibility of a breach of confidentiality.

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.**

This is an outcome study that evaluates patients after routine surgery, thus there will be no ongoing intervention that would need to be interrupted.

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).

Not applicable.

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

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.

This study is evaluating the outcomes of two standard of care procedures for biceps tendon repair.

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).

This is a randomized open-label controlled study of two standard-of-care interventions differing in their approach to anchoring the long head of the biceps being conducted at a single center. Because it is a

approach to anchoring the long head of the biceps being conducted at a single center. Because it is a single site study, the PI (Dr. Kim) will be aware of all the patients and cases throughout the entirety of the study. Adverse events and serious adverse events related to the surgical procedure will be collected in real time. Aggregate safety data by treatment arm will be reviewed by the surgeons (Drs. Kim and Kaar) every six months to assess for potential safety signals. The IRB will be notified if any differences in risk associated with either procedure are observed during that safety review.

The adverse events would include the same adverse events in any open subpectoral biceps tenodesis, including risks of infection, poor wound healing, nerve or blood vessel injury, and failure of the tenodesis. Failure of the tenodesis can be due to failure of the suture anchor (anchor pull-out or suture breakage), failure of the suture fixation to the pectoralis major, tearing of the biceps tendon at its attachment, or tearing of the portion of the pectoralis major tendon that is holding the biceps tendon.

If no, please justify why not.

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.

* * * 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.**

We do not believe there will be a direct benefit to the study participants. If there is no difference in the clinical and anatomic outcomes between the PMT fixation technique and the SA method, adoption of the PMT fixation technique could lead to lower health care costs and shorter operative times.

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.**

Alternative procedures to the Pectoralis Major Tendon (PMT) technique include utilizing a suture anchor or screw for tenodesis. Participants can choose not to participate.

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 managed device (computer, tablet, etc.) with encryption	Not Applicable, I will not be sending/sharing electronic data outside of SLU	

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 Cabinet; SLU Locked Room/Office	Personnel Supervision	The master randomization list with the identifying information will be kept in a locked cabinet in an office. The coded patient assessments will be kept in a study binder in a locked office. These assessments include the ASES, VAS, DASH, SANE, and LHB scores which will all be completed by the study personnel.

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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.**

a) The data will all be coded and the master list with the identifying information will be kept locked in a cabinet in a locked room.
b) It will be destroyed once the data is cleaned and analyzed or after the publication of the study.
c) Each patient screened will be assigned a unique four-digit code will progress in ascending order beginning with 0001. The master file that relates the patients to their assigned code will be kept in a locked cabinet in a locked room.

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 used. Please contact the Research Innovation Group at 314-925-3027 for assistance.**

The individual data will not be shared outside of the research team.

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.**

There will be no provided data to SLU from an outside source in this study.

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.).**

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.**

The technique used will be stored in the subject's medical record.

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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.

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

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)

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.

Protocol Title: A Prospective Randomized Study Comparing Suture Anchor and Soft Tissue Pectoralis Major Tendon Techniques for Biceps Tenodesis

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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

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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.

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* * * 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 two surgeons performing the procedure, Dr. Scott Kaar and Dr. Christopher Kim as well as the resident Brian Hill and Matthew Bell who is a study administrative contact. This will be done in the clinic preoperatively.

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.**

Not applicable.

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_CR2019_Consent Form updated	Consent	03/29/2019

Protocol Title: A Prospective Randomized Study Comparing Suture Anchor and Soft Tissue Pectoralis Major Tendon Techniques for Biceps Tenodesis

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* * * Assent * * *

14. Assent

Complete this section if your study includes minors. The Assent Form Template provides guidelines for writing assent documents.

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.

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

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.

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.

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* * * 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 visit the IRB HIPAA page or 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?

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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)

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

X Names

Social Security numbers

X Telephone numbers

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)

X 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.

3. Sources of Protected Health Information:

X Hospital/medical records for in or out patients

X Physician/clinic records

X 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_Version 2	06/05/2018

*** * * 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.

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	Biceps_TenodesisRCT_Bibiography	02/06/2018	02/22/2018
Device Information/Documentation	Suture Anchor 501k and Device Manual	02/06/2018	02/22/2018
Other	BicepsTenodesisProtocolFinal	02/06/2018	02/22/2018
Human Subjects Training Certificate/Proof of Training	CITICompletionReport	02/12/2018	02/22/2018
Human Subjects Training Certificate/Proof of Training	citiCompletionReport6586522	02/23/2018	02/28/2018
Committee Approvals	29091_SSM RBR Approval	06/14/2018	07/31/2018
Questionnaire/Survey	Approved_ASES Form	08/17/2018	08/17/2018
Questionnaire/Survey	Approved_DASH Form	08/17/2018	08/17/2018

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Questionnaire/Survey	Approved_LHB Form	08/17/2018	08/17/2018
Human Subjects Training Certificate/Proof of Training	R. Otto_citiCompletionReport_Biomedical Research	03/04/2019	03/05/2019
Human Subjects Training Certificate/Proof of Training	R Otto_citiCompletionReport_GCP	03/04/2019	03/05/2019
Human Subjects Training Certificate/Proof of Training	R.Otto_citiCompletionReport_fCOI	03/04/2019	03/05/2019

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* * * 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

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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 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
03/29/2019	CONTINUING REVIEW 1 FORM APPROVED	Y	Y
03/20/2019	PROTOCOL EXPIRED		
03/08/2019	CONTINUING REVIEW 1 FORM REVIEWER(S) ASSIGNED		
03/08/2019	CONTINUING REVIEW 1 FORM PANEL MANAGER REVIEW		
03/08/2019	CONTINUING REVIEW 1 FORM PANEL REASSIGNED		
03/05/2019	CONTINUING REVIEW 1 FORM SUBMITTED	Y	
02/18/2019	CONTINUING REVIEW 1 FORM CREATED		
08/17/2018	AMENDMENT 1 FORM APPROVED	Y	Y
08/16/2018	AMENDMENT 1 FORM REVIEWER(S) ASSIGNED		
08/08/2018	AMENDMENT 1 FORM SUBMITTED (CYCLE 1)	Y	

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08/08/2018	AMENDMENT 1 FORM PANEL MANAGER REVIEW		
08/08/2018	AMENDMENT 1 FORM PANEL REASSIGNED		
07/31/2018	AMENDMENT 1 FORM SUBMITTED	Y	
07/31/2018	AMENDMENT 1 FORM CREATED		
06/05/2018	NEW FORM APPROVED	Y	Y
06/03/2018	NEW FORM REVIEWER(S) ASSIGNED		
05/24/2018	NEW FORM SUBMITTED (CYCLE 2)	Y	
05/07/2018	NEW FORM REVIEWER(S) ASSIGNED		
04/11/2018	NEW FORM SUBMITTED (CYCLE 1)	Y	
03/20/2018	NEW FORM CONTINGENT		
03/09/2018	NEW FORM REVIEWER(S) ASSIGNED		
03/09/2018	NEW FORM PANEL MANAGER REVIEW		
02/28/2018	NEW FORM PANEL ASSIGNED		
02/28/2018	NEW FORM RESUBMITTED	Y	
02/23/2018	NEW FORM RETURNED		
02/22/2018	NEW FORM SUBMITTED	Y	
02/22/2018	NEW FORM PREREVIEWED		
02/14/2018	NEW FORM PREAPPROVAL		
01/31/2018	NEW FORM CREATED		