Official Title of the Study

**Clinical Registry Assessment of the Missouri Osteochondral Allograft Preservation System - MOPS**

NCT Number

**NCT02503228**

Date of the Document:

**07/14/2015**

# IRB #2003053 HS

## Repository/Database Application #206420

Submission date: **07/14/2015**
Submitted by: **Rucinski, Kylee Jenae**

## 1. Investigators

1. Project title (do not use all capitals)

   *Provide the full title of the project.*

   Missouri Orthopaedic Institute Regenerative Orthopaedics and Joint Preservation Registry

2. Study Staff (students, fellows & residents must have a faculty member as a co-investigator)

| Role | Investigator | Department | CITI IRB Training | Consent personnel role | Primary contact | Truman VA Hospital personnel |
|---|---|---|---|---|---|---|
| Principal Investigator | Cook, James L | Orthopaedic Surgery | 10/28/2019 | Authorized to Obtain Consent | ☐ | ☐ |
| Co-Investigator | Stannard, James Patrick | Orthopaedic Surgery | 05/03/2020 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Coordinator | Cunningham, Suzin Marie | Orthopaedic Surgery | 01/22/2019 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Coordinator | Durante, Elizabeth Cole | Orthopaedic Surgery | 02/26/2020 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Coordinator | Rizzo Esposito, Ennio Antonio | Resident Orthopedics | 04/18/2019 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Coordinator | Suzzarini, Maria Luisa | Orthopaedic Surgery | 07/12/2019 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Staff | Blecha, Kyle M | ATC Program | 11/26/2019 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Staff | Clawson, Stacee Wise | Orthopaedic Surgery | 04/30/2019 | Authorized to Obtain Consent | ☑ | ☐ |
| Research Staff | Clemons, Bryce Asher | Orthopaedic Surgery | 11/30/2019 | Participate in the Process | ☐ | ☐ |
| Research Staff | Friedman, Steven C | Orthopaedic Surgery | 04/12/2020 | Non-Consenting Personnel | ☐ | ☐ |
| Research Staff | Humpherys, Joseph | Resident Orthopedics | 08/03/2018 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Staff | Jones, Vicki Lynn | Orthopaedic Surgery | 05/23/2019 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Staff | Leary, Emily Vanessa | Orthopaedic Surgery | 05/28/2020 | Non-Consenting Personnel | ☐ | ☐ |
| Research Staff | Livesay, Lauren Nicole | Orthopaedic Surgery | 05/01/2018 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Staff | Love, Jessica Windsor | Orthopaedic Surgery | 03/10/2020 | Non-Consenting Personnel | ☐ | ☐ |
| Research Staff | Mozingo, Nathan | Orthopaedic Surgery | 03/21/2020 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Staff | Oladeji, Lasunkanmi O | Resident Orthopedics | 03/16/2019 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Staff | Pashuck, Troy Daniel | Resident Orthopedics | 04/27/2018 | Authorized to Obtain Consent | ☐ | ☐ |

| Role | Investigator | Department | CITI IRB Training | Consent personnel role | Primary contact | Truman VA Hospital personnel |
|---|---|---|---|---|---|---|
| Research Staff | Rucinski, Kylee Jenae | MOI Joint Preservation Center | 05/02/2018 | Authorized to Obtain Consent | ☑ | ☐ |
| Research Staff | Schreiner, Anna Janine | Orthopaedic Surgery | 11/02/2019 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Staff | Si, Zhengye | Orthopaedic Surgery | 09/07/2018 | Non-Consenting Personnel | ☐ | ☐ |
| Research Staff | White, Branden Perry | Orthopaedic Surgery | 06/17/2019 | Non-Consenting Personnel | ☐ | ☐ |
| Research Staff | Williams, Jonathan Chase | Orthopaedic Surgery | 04/02/2019 | Non-Consenting Personnel | ☐ | ☐ |
| Research Staff | Wilson, Nichole Suzanne | Orthopaedic Surgery | 01/07/2020 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Staff | Wissman, Robert David | Radiology | 10/11/2019 | Non-Consenting Personnel | ☐ | ☐ |
| Research Staff | Worley, John Robert | Resident Orthopedics | 05/04/2020 | Authorized to Obtain Consent | ☐ | ☐ |
| Research Staff | Zelasko, Eric R | Orthopaedic Surgery | 06/13/2019 | Non-Consenting Personnel | ☐ | ☐ |
| Research Staff | Zitsch, Bradford Paul | Dean - Medical Education | 06/07/2019 | Non-Consenting Personnel | ☐ | ☐ |

## 3. Contact Information

### Principal investigator

**Cook, James L**

| | |
|---|---|
| Job title | PROFESSOR |
| Department | Orthopaedic Surgery |
| Division | Medicine |
| Business unit | University of MO-Columbia |

### Primary contact

**Clawson, Stacee Wise**

| | |
|---|---|
| Job title | DIR I RESEARCH OPS AND PLNG |
| Department | Orthopaedic Surgery |
| Division | Medicine |
| Business unit | University of MO-Columbia |

| Rucinski, Kylee Jenae | |
|---|---|
| Job title | SPVSR, REV MGMT |
| Department | MOI Joint Preservation Center |
| Division | Mo Orthopaedic Institue |
| Business unit | Hospital |

4. Conflicts of Interest

   A. Describe any Conflicts of Interest with this study.

   *Example: Financial, Personal, Institutional, or Other, for any study team member. If none please indicate N/A.*

   N/A

   B. Do all study team members have a current, up-to-date MU Conflict of Interest Disclosure on file with the Office of Research?

   *for more information click the link to the COI website http://research.missouri.edu/complia/coi_new2.htm*

   ● Yes ○ No

   C. Has it been updated to include the conflict with this study?

   ○ Yes ○ No ● N/A

5. Will the team include external investigators not affiliated with the University of Missouri-Columbia?

   ○ Yes ● No

6. If yes, identify the investigator(s) and their institution and describe their role in the study.

   *Specify if the external investigator(s) will interact or intervene with the participants in the study or have access to their private identifiable information. Also, clarify whether they will obtain informed consent from participants.*

## 2. Funding Information

1. How is this project funded? *

**No Cost**

● None (There is no cost associated with this project.)

**Internal Funding**

○ Internal Grant (ex. Research council, etc)
○ Personal funds
○ Departmental Funding

**External Funding**

○ HHS funded (The Department of Health and Human Services)
○ Industry Sponsor (ex. Pharmaceutical company, device company, etc) * IRB fees apply
○ External Grant (ex. Federal funding, foundation funding)

○ In-kind (donation of equipment or services)

2. Sponsor or Funding Source Information

3. If this study is sponsored please provide the MU Sponsored Program Grant Proposal Number (OSPA)

*If you receive funding after IRB approval, please update this information using the Identification Form.*

## 3. Protocol Information

1. Protocol Information

*All applications must submit a protocol in addition to the grant application with the application materials. The information provided below will be reflected in your approval letter.*

**A.** Protocol Number

*Please upload a copy of the protocol under document storage. This link is located at the end of the application on the page for submission.*

**B.** Protocol Version Number

**C.** Protocol Version Date

2. Informed Consent

*The information provided below will be reflected in your approval letter.*

**A.** Informed Consent Version Number

*Leave blank unless you have a sponsor provided version number in the footer of your consent.*

**B.** Informed Consent Version Date

*Leave blank unless you have a sponsor provided version date in the footer of your consent.*

## 4. Location of Research

1. Is this a multi-center study?

*A multi-site study is defined as a research study being conducted at multiple sites. Studies being conducted at more than one MU facility are not considered multi-site.*

○ Yes ● No

2. If this is a multi-center study, is MU functioning as the lead site?

○ Yes ○ No ● N/A

3. Does another institution(s)/organization(s) IRB want to Rely on MU IRB Approval?

*If yes, a subform will automatically generate for your completion at the end of the application.*

○ Yes ● No

# 5. Project Information

1. List all committees (other than the MU HS IRB) that have and/or will review this project.

   ☐ VA Research and Development

   ☐ Institutional Biosafety

   ☐ Other

   A. If other, please list:

2. What is the purpose of creating this repository (or database)?

   This project will be used to capture data from previous and future patients of the Regenerative Orthopaedics and Joint Preservation Center in order to catalog them into a database. This data will be collected and analyzed in order to provide outcome measures and ongoing tracking of the Joint Preservation Center's patient population. Analyzing this data will allow staff to identify trends in patient populations over time.

3. Describe the subject's participation:

   *What will be expected of the participants?*

   The registry will be a database that contains information about past and present patients of the Center for Regenerative Orthopaedics and Joint Preservation at the Missouri Orthopaedic Institute. The potential subjects will be asked to give their consent to be a part of the registry, and the retrospective patients will be asked to give consent to provide further information if further data capture is needed from them.

   1. Name
   2. MRN
   3. DOB
   4. Gender
   5. Age
   6. Race
   7. Height
   8. Weight
   9. BMI
   10. Preop activity level
   10. Insurance Carrier
   11. Dx
   12. Mechanism of Injury
   13. Preop imaging – XR, CT, MRI, scope
   14. Tobacco Use
   15. Diabetes
   16. City/State/Country
   17. Affected Joint
   18. Injury type (i.e. meniscus, ACL, etc.)
   19. Surgical Procedure Performed
   20. Non-Operative Procedures Performed and Date (PRP, etc)
   21. Contact Phone Number
   22. Secondary Phone Number
   23. Email
   24. Surgical Side
   25. Location of treatment

26. DOS
27. Surgeon
28. Patient reported outcomes

**4.** Provide a project summary for non-medical and community members on the IRB.

*The IRB includes members without a scientific or medical background. Using lay language, provide a brief, but thorough, summary of the project.*

The Center for Regenerative Orthopaedics is seeking to create a registry that will track patient data in order to identify trends among patient populations. It is the hope of the CRO that this database will allow doctors to provide better outcomes for patients by identifying techniques and procedures that have positives outcomes for similar patients. This institutional registry will allow surgeons to assess the outcomes of regenerative orthopaedic patients, to evaluate the effectiveness of quality improvement initiatives on short and long term outcomes, and to engage new technologies while providing timely identification of success and failures.

**5.** Procedures/Tests/Surveys

*Please Note: List all tests and surveys that will be performed during the study. These tests should include tests done for medical purposes ONLY IF the data will be collected for the research.*

**Procedures/Tests/Survey #1**
**PROMIS v.1.1 - Global**

**1.** Name of test/procedure

PROMIS v.1.1 - Global

**2.** Brief description

Standard of care survey given to patients at follow-ups to check their overall health.

**3.** Relationship

● Routine care where the information/data will be collected for the research study

○ Research Only

**4.** Indicate the study visit(s) at which this will occur

Initial visit and every follow-up after.

**5.** Where will this test take place?

In person via OBERD, or emailed through OBERD.

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**Procedures/Tests/Survey #2**
**Tegner Activity Level Scale**

**1.** Name of test/procedure

Tegner Activity Level Scale

**2.** Brief description

Measures the change of abilities in surgery patients before and after surgery.

**3.** Relationship

● Routine care where the information/data will be collected for the research study

○ Research Only

**4.** Indicate the study visit(s) at which this will occur

Each follow-up.

5. Where will this test take place?

   Either in person using OBERD, or by email using OBERD.

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**Procedures/Tests/Survey #3**
**IKDC Form**

1. Name of test/procedure

   IKDC Form

2. Brief description

   International Knee form that documents the ability of the patient.

3. Relationship

   ● Routine care where the information/data will be collected for the research study
   ○ Research Only

4. Indicate the study visit(s) at which this will occur

   Pre-op and follow-ups.

5. Where will this test take place?

   Electronically through OBERD or via OBERD through email.

6. Subject Participation

   A. How long is the subject actively participating in the research?

   Throughout the treatment of their injury.

7. Visit Information

   A. Number of total visits:

   all standard of care visits

   B. Frequency of visits:

   standard of care

   C. Length of visits:

   N/A

8. Inclusion criteria:

   Alll patient of the center will be considered for inclusion. Patients must have the ability to understand the consent form and to provide consent for participation in the registry.

9. Exclusion criteria:

   1) Patients who are unable to provide informed consent due to inability to understand written or spoken English language or secondary consent through an interpreter

10. Review requested

    Expedited

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# 6. Subject Recruitment

1. Explain how you will have access to a population that will allow recruitment of the required number of subjects in the proposed recruitment time.

*(For example, will you be going to a particular location, are they potential patients in the clinic, etc.)*

Any patient of the Regenerative Orthopaedics and Joint Preservation Center makes up this population. They will be patients that organically decide to come to the Center, as well as patients referred there. Retrospective patients will be called by the number they provided at time of their initial consultation, or will be approached at a follow-up visit to collect additional outcome data if needed.

**2.** Target accrual

**A.** For all MU sites, how many people do you expect to complete the study?

*You may indicate undetermined or unknown.*

The goal is to enroll any willing subjects with no max on possible completions of the study.

**B.** How many people will be enrolled (sign the consent) to reach the number listed in the previous question?

*For some studies this number may be the same, for other studies there may be a high rate of screen failures.*

Any patient that meets the criteria and decides to participate will be enrolled, with no max on enrollments.

**C.** If this is a multi-center trial, what is the study wide target accrual?

N/A

**3.** What methods will be used to identify and recruit subjects?

***Check all that apply.*** *Please note, if you are recruiting with a flyer, you may need a waiver of documentation of consent if you are screening subjects before they sign a consent.*

- ☐ Flyers
- ☐ Advertisements
- ☐ Letters
- ☑ Patients of the PI/Co-I
- ☐ other

**A.** If other, please explain.

**4.** What methods will be used to avoid inadvertent coercion in the recruitment process?

Patients will be advised that participation in the registry is not required as part of their medical treatment, and that they may refuse to participate without any change to their treatment.

# 7. Consent Process

Repository Banking Consent Template

This section should only be completed for studies using Written Consent or Waiver of Documentation (Signature). Please click the link above to access the CONSENT TEMPLATE.

**1.** Describe the consent process.

*Describe in detail how the consent process will be presented to the subject, how subject comprehension of the study is determined, where and when consent is performed, and how questions from the subject are answered.*

Prospectively: All patients of the Center for Regenerative Orthopaedics and Joint Preservation, who meet entry criteria, will be offered the opportunity to participate. They will be advised that participation is voluntary. They will either be given a hard copy of the consent/HIPAA document to read and sign, or they will read an electronic version of the consent/HIPAA document on an iPad, and give their consent by clicking a button on an iPad in OBERD. This is a button that states they consent to the research study (please see uploaded example) but is not a signature. Research staff will be aware that a patient chose to participate in the study by routinely looking at OBERD generated reports that states which patients have chosen to enroll.

Retrospectively: data will be collected on patients who meet our study criteria. We will be asking for permission to waive the HIPAA authorization and consent for the retrospective subjects for all previously collected data. We will also be reaching out to retrospective patients via phone if further data collection is necessary. The retrospective subjects who are contacted by phone will be asked to consent via waiver of documentation of consent/phone screening script and we may utilize OBERD for retrospective patients if they desire to fill out the surveys by email.

2. How long will participants be given between the time they are approached to participate and signing the consent for participation.

   *The regulations require investigators to seek consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate minimizing the possibility of coercion or undue influence.*

   Patients will be given as long as possible to consider before being asked to consent. If the patients are comfortable with the Registry and are willing to consent at the time of their first clinic appointment, this would be acceptable.

   Patients will be allowed to provide consent either before their surgery date or after they return for postoperative follow-up.

3. Please indicate how the language level of the consent matched to the comprehension level of your prospective participants?

   *Note: The regulations require the information be understandable to the subject or the representative so please consider the subject population and type of study.*

   The consent form will be written to be comprehended by an 8th grade reading level and will be confirmed through appropriate personnel.

4. What measures will be taken to ensure the prospective participant/representative understands the consent?

   Patients will be given time and will be allowed to ask questions before consideration of consent.

5. Informed Consent

   A. Who will be approached for informed consent?

      *Mark all that apply:*

      - [x] Subject
      - [ ] Subjectŝ parent or legal guardian
      - [ ] Other

   B. If other, please explain.

**6.** Subject Privacy

*Note: Privacy refers to a person, not the confidentiality of their data.*

**A.** If subjects have an expectation of privacy, please describe your plan to protect their privacy during and after the course of the data collection?

Data Security Data will be maintained in a file on a secured computer with password protection.

Data maintained in the MU/MOI institutional repository will be kept on secured servers. If the data is transferred to external agencies with associated PHI, appropriate encryption processes will be utilized to ensure that the data is not subject to discovery in the process of transmission.

No highly sensitive patient information (e.g. Hepatitis, HIV, other communicable disease states) will be included in the registry data obtained from patients. Information regarding causative organisms (e.g. MRSA, Staph, Strep, etc) may be included in the data set, but will not be transmitted outside the data set (infection status only will be identified externally).

**B.** What are the consequences to subjects if a loss of privacy were to occur (e.g. risks to reputation, insurability, embarrassment, other social risks)?

Consequences from a loss of privacy will be minimized by the types of data that will be obtained.

The expected likelihood of inadvertent disclosure of data is expected to be minimal.

**7.** Describe the methods for identifying data/samples for which consent has been withdrawn or will ensure no future use.

*Indicate if there is a point where withdrawal would not be possible.*

Patients may elect to withdraw from the registry on written request.

# 8. Confidentiality and Security

**1.** Confidentiality

*Confidentiality concerns data, specifically the researchers plan to handle, manage, and disseminate the participant's identifiable private information.*

*PLEASE INDICATE ALL IDENTIFIERS THAT MAY BE INCLUDED IN THE RESEARCH RECORDS FOR THE STUDY. CHECK ALL THAT APPLY.*

- [x] Names
- [x] Dates
- [ ] Postal Address
- [x] Phone Numbers
- [ ] Fax Numbers
- [x] Email Addresses
- [ ] Social Security Number
- [x] Medical Record Numbers
- [ ] Health Plan Numbers
- [ ] Account Numbers
- [ ] License or Certificate Numbers

- ☐ Vehicle ID Numbers
- ☑ Device Identifiers or Serial Numbers
- ☐ Web URLs
- ☐ IP Address Numbers
- ☐ Biometric Identifiers
- ☐ Facial Photos or Images
- ☐ Any Other Unique Identifier
- ☐ None of the 18 Identifiers Listed Above

**2.** Data Security

**A.** Will any web applications be utilized for such purposes as recruiting subjects or processing data?

● Yes ○ No

**B.** Will you be utilizing REDCap (Research Electronic Data Capture)?

● Yes ○ No

**C.** List all web applications that will be used.

OBERD utilizes web-based technology to allow patients to access the PROMs remotely.

Patient information (e-mail, phone/text) will be provided at their discretion, if they wish to use electronic means for communication/notification of survey availability.

**D.** Describe the security features for the web application(s).

Standard, CFR Title 21 Part 11 complaint encryption.

**3.** Will the data be collected and stored as:

- ☐ Hard Copy
- ☐ Electronic (Hard Drive - best practice is to encrypt the PC)
- ☐ Electronic Portable (mobile) device (For VA the device must be encrypted and is FIPS-140-2 validated)
- ☑ Hard Copy and Electronic

**4.** Check the appropriate box below:

- ☐ Data are coded; data key is destroyed at the end of the study
- ☐ Data are coded; data key is kept separately and securely
- ☐ Data are kept in locked file cabinet
- ☑ Electronic data are protected with a password
- ☑ Electronic data are encrypted
- ☐ Data are kept in locked office or suite
- ☑ Data are stored on a secure MU network
- ☐ Data are stored on a secure VA network

**A.** If data are coded and the data key will be destroyed, please provide the anticipated date of destruction:

**5.** If you plan to disclose any of the identifiers listed above as part of the study process, check all that apply:

- [x] No identifying information will be disclosed.
- [ ] The subject's medical record
- [ ] The study sponsor
- [ ] Foreign Country or Countries
- [ ] The US Food & Drug Administration (FDA)
- [ ] Other

**A.** If other, please specify.

**6.** How will the data be stored while the repository (or database) is active?

Data will be stored on a secured server. The partnering database (OBERD) obtains data through the MU electronic portal. Registry data that combines OBERD data with Hospital coding data, and OR obtained patient implant and operative details will be electronically entered into the registry. If the registry is maintained exclusively within the University, this will be utilizing REDCAP. If the MU-MOI export data into OBERD, the registry may be maintained with OBERD.

**7.** How will the data be stored/discarded after the study is completed?

The data will be maintained indefinitely

- [x] **Check this box to confirm you will retain all research records for a period of seven years following the completion of the study, in accordance with MU Policy.**

**8.** Certificates of Confidentiality

*For more information on Certificates of Confidentiality, please go to http://grants.nih.gov/grants/policy/coc/*

**A.** Will this research collect any information that may require a Certificate of Confidentiality?

*Certificates of Confidentiality are issued to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.*

○ Yes ● No

**B.** If YES, has a Certificate of Confidentiality been applied for?

○ Yes ○ No

# 9. Risks and Benefits

**1.** Pregnancy

**A.** Please indicate if any specimen collection may affect (known/unknown) an unborn child.

N/A

B. If applicable, how will pregnancy be determined:

- [ ] Verbal confirmation
- [ ] Serum
- [ ] Urine

2. If participants with reproductive potential are involved, what contraceptive measures will be taken for both females and males during the active phase of the study?

   N/A

3. Indicate risks associated with specimen (or other data) collection.

   *For example, bruising due to blood draw.*

   N/A

4. What procedures will be used to prevent and/or minimize any potential risks and discomfort?

   N/A

5. What are the potential direct benefits to the subject?

   *If there are no direct benefits, state none.*

   The subject may not personally benefit from having their information entered into the database, but they will be contributing to medical knowledge.

6. What are the potential benefits to the community and/or society?

   The subject will be contributing to medical knowledge, specifically the knowledge related to joint health and regenerative orthopaedics.

7. Are there any other options for participants?

   Patient can choose not to participate in the study.

8. Describe the data and safety monitoring plan developed to ensure the safety of participants as well as validity and integrity of research data.

   *This needs to include, when something needs to be reported, the frequency of the monitoring, such as points in time or after a specific number of participants are enrolled; who will conduct the monitoring, such as a data monitoring committee, data and safety monitoring board, medical monitor, investigator, independent physician, the specific data to be monitored; procedures for analysis and interpretation of the data; actions to be taken upon specific events or end points; and procedures for communication from the data monitor to this site.*

   All data collection is considered standard of care and is used to monitor patient safety as a part of standard care.

9. Describe the mechanism for releasing specimens (or other data) for future research.

   *This includes identifiable information and de-identified information shared with internal and/or external investigators. (An additional requirement for external investigators would be implementing a Data Use Agreement.)*

   N/A

## 10. Blood/Fluid/Tissue Samples

This section is ONLY for repositories collecting blood, fluid, or tissue. SKIP THIS SECTION FOR DATABASE ONLY STUDIES.

1. Select the items that are included as part of your study:

   ☐ Collection of blood, fluid, or tissue

   ☐

Infectious and zoonotic agents (viruses, bacteria, etc.), biological toxins, or recombinant DNA or synthetic DNA products

**2.** Blood, Fluid, or Tissue

**A.** Describe the blood draw process.

N/A

**B.** Specify the amount of blood drawn each time.

N/A

**C.** How many times will blood be drawn?

N/A

**D.** Where will the blood collection take place?

N/A

**E.** If someone other than a phlebotomist or nurse is drawing the blood, please specify who will draw the blood and any training or certifications the person may have.

N/A

**F.** Please list all other tissue, fluid, or body samples that will be obtained for this study.

N/A

**G.** Are the samples being collected by a non-invasive technique?

○ Yes ● No

**H.** Please describe the collection process for all other tissues.

N/A

**I.** Are the blood draws and/or collection of fluid/tissue samples being done in an environmental health and safety (EHS) approved space?

N/A

**3.** Access/Storage

**A.** Who will have access to the samples?

*Please indicate if investigators not listed on this application will have access to the samples, and if so, what information will be associated with the samples.*

N/A

**B.** Please describe where and how long the samples will be kept.

N/A

# 11. Sub-forms

**1.** Select the items that are included as part of your study.

*For items marked, a sub-form will be generated for your completion at the end of this application.*

☐ VA participants, VA resources, and/or time of VA personnel

☑

Requesting a waiver of documentation of consent (no signature) - (Some studies may have a waiver of documentation and written consent.)

- [x] Requesting a waiver of consent or an alteration of the required elements of consent
- [ ] Children (under 18)
- [ ] Non-English speaking subjects
- [ ] Participants with impaired decision-making capacities (Some subjects maybe temporarily incompetent due to circumstances or medication. Please checkt this box if the subject population for this study meet these criteria)
- [ ] Pregnant women or fetuses (Check for studies that will enroll pregnant women and there is a potential for the research to cause harm to the pregnant woman or the unborn fetus. Do not check this box for survey research.)
- [ ] Non-viable neonates or neonates of uncertain viability
- [ ] Prisoners
- [ ] Costs and/or Compensation (Select this box for subject payments/compensation and costs associated with the research (including subject costs).
- [x] Access to Health Information (HIPAA)

**2.** The research is sponsored and/or supported by:

- [ ] US Department of Education
- [ ] Department of Energy
- [ ] Department of Defense
- [ ] Department of Justice
- [ ] Environmental Protection Agency

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# HIPAA Subform

## 1. HIPAA

**1.** HIPAA regulations apply to this research if you select any item listed below.

*Check all that apply.*

- [x] Data are derived from a medical record
- [ ] Data are added to the hospital or clinical medical record
- [x] Data are created or collected as part of health care
- [ ] Data are used to make health care decisions
- [x] The research is being conducted in a covered entity or at a location where there is patient billing

**2.** If data are derived from a medical record, please identify the source here.

Cerner/EMR; Hospital Coding/Database; Intra-op Entry (OBERD/REDCAP)

**3.** If HIPAA regulations apply, select the form that will be used.

- [x] HIPAA Authorization
- [x] Waiver of Authorization
- [ ] Preparatory to Research
- [ ] Limited Data Set
- [ ] Data Use Agreement

4. For VA research, you must use the:

- [ ] VA Authorization (if data/specimens are to be removed from the VA, it must be reflected in the Authorization)
- [ ] VA Waiver of Authorization
- [ ] VA Preparatory to Research

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# Waiving Documentation of Consent Subform

## 1. Waiving Documentation of Consent

1. If you are conducting research with more than one subject population, then this form will need to be completed for each population. Please specify the subject population for this form:

   Prospective Patients

2. Your project must fall under one of the following two criteria for waiving documentation of consent.

   *Check the criteria that applies to your study.*

   - [x] The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
   - [ ] The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. [The study cannot be FDA regulated]

3. Justify how your project meets the criteria for a waiver of documentation.

   This is a high volume of patients and allowing them to use OBERD for an electronic consent results in a lower wait times.

   Instruction: A copy of the consent must be uploaded with your Application for IRB review.

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# Waiver or Alteration of Consent Subform

## 1. Waiver or Alteration of Informed Consent

1. If you are conducting research with more than one subject population, then this form will need to be completed for each population. Please specify the subject population for this form:

   Retrospective Subjects

**2.** Please select the option that you are requesting.

- [x] A waiver of consent is being requested.
- [ ] Partial waiver (alteration) of consent is being requested.

**3.** Criteria for Waiving or Altering Consent

*Provide study specific justification for each of the following:*

**A.** The research involves no more than minimal risk to participants.

It is strictly a retrospective, chart review, so there will be no change/alteration in patient treatment or outcome. There will be no identifiable information correlated to the patient information, so there will be no risk of any possible release of information or HIPAA violation. The information we will be looking for is already in the medical record.

**B.** The waiver or alteration will not adversely affect the rights and welfare of the participants.

Our site will not release any of this protected information to anyone outside the study team. The site will destroy the information if the subject does not sign consent and enroll in the study.

**C.** The research could not practicably be carried out without the waiver or alteration.

Participants have already had the surgical procedure performed and are no longer being routinely seen in clinic.

We will be calling them for all future data collection in order to consent them, but for previous data we are asking for a waiver of consent.

**D.** Whenever appropriate, the subjects will be provided with additional pertinent information after participation (debriefing).

N/A

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