MICRO Study: Detecting Bacterial Infections Related to Orthopaedic Surgical Implants

Approval Date: 23 Jul 2018

Protocol Date: 12 Jul 2018

NCT03132246

Date: Monday, March 16, 2020 2:12:24 PM Print Close

Introduction Page

1 * Abbreviated Title:
Microbiology Study

2 * Full Title:
Early Determination of Biofilm Formation on Orthopaedic Devices

3

* Select Type of Submission:

- [x] **IRB Application**
- [ ] Humanitarian Use Device (for FDA approved Indication & non-research purposes ONLY)
- [ ] Emergency Use
- [ ] Unsure if this proposal requires IRB review (Not Human Subject Research)

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:

ID: VIEW4DF8709A33C00
Name: v2_Introduction Page

Research Team Information

1 * Principal Investigator - Who is the PI for this study (person must have faculty status)? ***Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***
Robert V. O'Toole

1.1 * Does the Principal Investigator have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

2 Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:
Robert V. O'Toole

2.1 Does the Point of Contact have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

3 Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:

Name	Edit Submission	cc on Email	Research Role	Has SFI?
Aaron Johnson	yes	yes	Research Team Member	no
Michael Schloss	no	no	Research Team Member	no
Jason W Nascone	no	no	Sub-Investigator	no
Katherine Ordonio	yes	yes	Research Team Member	no
Dimitrius Marinos	yes	yes	Research Team Member	no
W. Andrew Eglseder Jr	no	no	Sub-Investigator	no

Name	Edit Submission	cc on Email	Research Role	Has SFI?
Raymond Pensy	no	no	Sub-Investigator	no
Christopher LeBrun	no	no	Sub-Investigator	no
Victoria Longo	no	no	Research Team Member	no
Dominique Gelmann	no	no	Research Team Member	no
Gerard Slobogean	yes	no	Sub-Investigator	no
Mitchell Baker	yes	yes	Research Team Member	no
Max Hamaker	yes	yes	Research Team Member	no
Haley Demyanovich	yes	no	Research Team Member	no
Jonathan Hurst	no	no	Research Team Member	no
Marcus F Sciadini	no	no	Sub-Investigator	no
Stephan Olaya	no	no	Research Team Member	no
Theodore Manson	no	no	Sub-Investigator	no
Andrew N. Pollak	no	no	Sub-Investigator	no
Mark Shirtliff	yes	yes	Sub-Investigator	no
Syed Zaidi	no	yes	Research Team Member	no
Manjari Joshi	no	no	Sub-Investigator	no
Zachary Kim	no	no	Research Team Member	no
Joshua Rudnicki	yes	yes	Research Team Member	no
Zachary Hannan	no	yes	Research Team Member	no
Andrea Howe	yes	yes	Research Team Member	no
Yasmin Degani	yes	yes	Study Coordinator	no
Daniel Connelly	yes	yes	Research Team Member	no
Alexandra Mulliken	yes	yes	Research Team Member	no

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

Resources

If this study is a collaborative UM/VA study, please clarify which resources are being used at each institution.

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
PI will be involved in consenting and ongoing monitoring of data. Most of the sample collection and analysis will be conducted by other trained staff members and in the laboratory of Sub-Investigator (Dr. Shirtliff).

2 * Describe the facilities where research procedures are conducted:
Shock Trauma Outpatient Clinic
Lab of Dr. Mark Shirtliff (University of Maryland Dental School)

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
Available through the outpatient clinic staff members. Patients will be referred to outside providers if needed.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
Patients will be given informed consent by a member of the research staff. They will then be allowed to ask any questions to the staff regarding the project prior to signing the consent document. They will be given a copy of the consent form as well.

ID: VIEW4DF83CB976400
Name: v2_Resources

Sites Where Research Activities Will Be Conducted

1 * Is this study a:

☐ **Multi-Site**

☐ Single Site

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?
☐ Yes ☐ **No**

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?
☐ Yes ☐ **No**

3.1 Attach the applicable regulatory documents here (i.e., IRB Authorization Agreement (IAA), FWA, local ethics approval, other IRB approvals, etc.). Final UM approval will be contingent upon final execution of all required regulatory approvals:

Name	Created	Modified Date

There are no items to display

4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)
☐ **Yes** ☐ No

5 Is VA the Coordinating Center for this study? (Applicable for Collaborative studies between the VA, UM and other sites. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project)
☐ Yes ☐ **No**

6 * Institution(s) where the research activities will be performed:

- ☑ **University of Maryland, The Founding Campus**
- ☐ VAMHCS
- ☐ University of Maryland, Upper Chesapeake Kaufman Cancer Center
- ☐ UMB School of Medicine
- ☐ Marlene and Stewart Greenebaum Cancer Center
- ☐ University Physicians Inc.
- ☑ **Shock Trauma Center**
- ☐ General Clinical Research Center (GCRC)
- ☐ Maryland Psychiatric Research Center (MPRC)
- ☐ Johns Hopkins
- ☐ International Sites
- ☐ UMB Dental Clinics
- ☐ Center for Vaccine Development
- ☐ Community Mental Health Centers
- ☑ **Private Practice in the State of Maryland**
- ☐ Institute of Human Virology (IHV) Clinical Research Unit
- ☐ Joslin Center
- ☐ UMB Student Classrooms
- ☐ National Institute of Drug Abuse (NIDA)
- ☐ National Study Center for Trauma and EMS
- ☐ Univ of MD Cardiology Physicians at Westminster
- ☐ Nursing Homes in Maryland
- ☐ University of Maryland Biotechnology Institute
- ☐ Department of Health and Mental Hygiene (DHMH)

- [ ] Mount Washington Pediatric Hospital
- [ ] Capitol Region PG Hospital
- [ ] Maryland Proton Treatment Center
- [x] **Other Sites**
- [ ] University of Maryland Medical System (Select below)

ID: VIEW4DF870DF2C000
Name: v2_Sites Where Research Activities Will Be Conducted

UM Coordinating Center

You indicated that UM is the Coordinating Center for this multi-site study.

2.1 *Describe the processes to ensure communication among sites.
Things to consider including in the communication plan:

- all sites have the most current version of the protocol, consent document, etc.
- all required approvals have been obtained at each site (including approval by the site's IRB of record).
- all modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.
- all engaged participating sites will safeguard data as required by local information security policies.
- all local site investigators conduct the study appropriately.
- all non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

This is not a true multi-center study. We are, however, coordinating the data collection efforts between the clinic staff and the laboratory of analysis.

2.2 *Describe the method for communicating to engaged participating sites including:

- reportable new information.
- problems.
- interim results.
- the closure of a study.

This is not a true multi-center study. We are, however, coordinating the data collection efforts between the clinic staff and the laboratory of analysis.

ID: VIEW4DF737D4C2800
Name: v2_UM Coordinating Center

Other Sites Where Research Activities Will Be Conducted

You selected "Other Sites," "Private Practice," "Community Mental Health Centers," and/or "Nursing Homes in Maryland" as a site where research will be conducted.

3.1 * Specify the name of the site(s):
University of Maryland Medicine at Timonium and University of Maryland Orthopaedics at Camden Yards

3.2 * Contact Person(s) for Other Site:
Ted Manson- Timonium Micheal Suit-Camden

3.3 * Phone (if no phone available, input "none"):
(410) 683-2120/ None

3.4 * Email Address (if no email available, input "none"):
none/ None

ID: VIEW4DF8712DB5800
Name: v2_Other Sites Where Research Activities Will Be Conducted

Funding Information

1 * Indicate who is funding the study:

- [ ] Federal
- [ ] Industry
- [x] **Department / Division / Internal**
- [ ] Foundation

- [ ] Private
- [ ] State Agency

2 * What portion of the research is being funded? (Choose all that apply)

- [ ] Drug
- [ ] Device
- [ ] Staff
- [ ] Participant Compensation
- [ ] Procedures
- [x] **Other**

3 Please discuss any additional information regarding funding below:

ID: VIEW4DF85DF452400
Name: v2_Funding Information

Research Protocol

1 * Do you have a research protocol to upload?

- [ ] Yes
- [x] **No, I do not have a research protocol and will use the CICERO application to enter my study information**

2 If Yes, upload the research protocol:

Name	Created	Modified Date

There are no items to display

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

* Choose One:

- [x] **Minimal - The probability & magnitude of harm/discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.**
- [ ] Greater Than Minimal - Does not meet the definition of Minimal Risk.

ID: VIEW4E02805225800
Name: v2_Risk Level

Type of Research

1 * Indicate **ALL** of the types of research procedures involved in this study (Choose all that apply):

- [ ] Use of unapproved drug(s)/biologic(s) or approved drug(s)/biologic(s) whose use is specified in the protocol.
- [ ] Evaluation of food(s) or dietary supplement(s) to diagnose, cure, treat, or mitigate a disease or condition.
- [ ] Use of device(s) whose use is specified in the protocol
- [ ] Psychological/Behavioral/Educational Method or Procedure (i.e., survey, questionnaires, interviews, focus groups, educational tests).

- [x] **Sample (Specimen) Collection and/or Analysis (including genetic analysis).**
- [x] **Data Collection or Record Review (i.e., chart review, datasets, secondary data analysis).**
- [ ] None of the above.

2 * Is this study a clinical trial OR will this study be registered at ClinicalTrials.gov?
A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

☐ **Yes** ☐ No

ID: VIEW4E0280569E000
Name: v2_Type of Research

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.

Surgical site infection in the orthopaedic surgery population is a significant public health issue. Wound infections result in both increased length of hospital stay and total cost of care.
Surgical site infection (SSI) is the most common preventable adverse outcome after a major operation. The economic costs to the US healthcare system are enormous estimated to be in excess of $1.8 billion per year. For patients who develop an SSI, the cost may be even higher with length of stay and risk of death doubled. Thus the benefits of any intervention decreasing the risk of SSI are very tangible.
A biofilm is a layer of bacteria that adheres to a surface; in Orthopaedics, this often means adherence to implanted metal after fracture surgery. The test that has been designed by one of the investigators on the study has been shown in an animal model to detect the formation of a biofilm up to 1 month prior to clinical detection. Having a blood assay such as this would allow earlier antiobiotics and potentially prevent the need for further surgeries to remove metal implants and clean out the biofilm.

ID: VIEW4E02805CF7000
Name: v2_Lay Summary

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:

To determine if a new assay to detect early biofilm colonization can be validated in acute postoperative wound infections in orthopaedic trauma patients who have sustained high energy open/closed lower extremity fractures. This would potentially help decrease the amount of surgical interventions needed for infections as it could allow for early intervention and antiobiotics.

2 * Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:

A prospective trial conducted at Shock Trauma of patients between 18 years of age and older who have sustained a fracture with metal implanted. We will be collecting between 1-3 routine blood draws for the purpose of laboratory analysis to assess biofilm growth. Patients may be infected or non-infected at the time of blood draw; they will be selected at random for purposes of this study. All patients will be followed as standard of care by their treating physician for all their follow up visits.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:

Surgical site infection in the orthopaedic surgery population is a significant public health issue. Wound infections result in both increased length of hospital stay and total cost of care. Specifically, a biofilm assay would help identify early infection in patients and potentially reduce the need for re-operations for infections as it would allow early antiobiotic delivery to the affected areas. Our bacteria of focus would be Methicillin-resistant Staphylococcus aureus (MRSA), as this is is one of the most predominant organisms in orthopaedic surgical site infections, but can be included to other pathogens causing surgical site infections.

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:

Surgical site infection in the orthopaedic surgery population is a significant public health issue. Wound infections result in both increased length of hospital stay and total cost of care. Specifically, a biofilm assay would help identify early infection in patients and potentially reduce the need for re-operations for infections as it would allow early antiobiotic delivery to the affected areas. Our bacteria of focus would be Methicillin-resistant Staphylococcus aureus (MRSA), as this is is one of the most predominant organisms in orthopaedic surgical site infections, but can be included to other pathogens causing surgical site infections.

ID: VIEW4E02805EA0C00
Name: v2_Justification, Objective, & Research Design

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***

One of the co-investigators, Dr. Shirtliff, recently published an article using a murine model to assess its immune response to a biofilm formation on a prosthetic implant similar to what would be used as orthopaedic hardware. This paper demonstrates a Th1 response during early biofilm formation, with Th2 and Tregs responding later, representing the formation of a chronic biofilm.

2 If available, upload your applicable literature search:

Name	Created	Modified Date
Murine Response to a Chronic Staphylococcus aureus Biofilm Infection.pdf	9/26/2013 6:03 PM	9/26/2013 6:03 PM

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:
Patients will be identified at random in the orthopaedic trauma clinic and current admitted patients who have been diagnosed with an infection. Once eligibility has been confirmed, the informed consent process will be completed by the Research Coordinator and the attending surgeon. Patients will be approached about potential participation in the study as soon as is feasible following determination of eligibility.
Once consented into the study, baseline data regarding participant characteristics, injury characteristics, fracture classification and medical history/co-morbidities will be collected. Characteristics about hospital course and treatment received will also be collected (i.e. blood culture results, antibiotic usage, etc).
At each follow up visit, participants will undergo a clinical evaluation by the treating surgeon as part of standard of care following any surgical procedure and will be interviewed by the research coordinator. Blood draws will be taken at the initial and each subsequent visit and will be analyzed in the laboratory of one of the investigators in the study. If the patient is currently infected currently, or become infected at any point in the future, additional blood draws may be taken, at a maximum of 10 draws, over the period of two years from the clinical diagnosis of infection. The amount of blood that is drawn will not exceed 50 ml or 3 ml per kg in a 8 week period, and collection may not occur more frequently that 2 times per week.
Finally, we would prospectively correlate the laboratory findings with clinical findings by searching the patients' medical records to find outcomes such as a biofilm formation.

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):
As part of the routine standard of care for any patient readmitted to the hospital for suspected surgical site infection cultures are obtained and sent for laboratory analysis to confirm bacterial colonization. As this is an assay to identify earlier a surgical site infection, this would be done earlier than any current testing.

3 * Describe the duration of an individual participant's participation in the study:
Following index clinic blood draws, patients will be followed during their regularly scheduled visits with their surgeon to assess wound healing.

4 * Describe the amount of time it will take to complete the entire study:
The study will last 1-2 years in total.

5 * Describe any additional participant requirements:
There are no additional requirements.

ID: VIEW4E0280585B400
Name: v2_Study Procedures

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:
In order to validate the designed test, we hypothesize needing a large study to determine if it is effective in a human model. Additionally, we will follow out the patients to determine if some become infected (the primary outcome of the study that we are trying to ultimately be able to predict. We anticipate 1000-1200 patients enrolled in this study.

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:
We will describe the population in terms of general descriptive statistics for age, injury, surgery and outcome. We will use t-testing and other statistical analysis as appropriate.

ID: VIEW4E02806052800
Name: v2_Sample Size and Data Analysis

Sharing of Results

1 * Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:
Results will not be shared with anyone but the study team. This data will be blinded from any treating surgeons and will not be used to affect patient care.

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

Sample Collection/Analysis

You indicated on the "Type of Research" page that your study involves a sample (specimen) collection and/or analysis.

1 * What type of samples will be involved in this study? (Check all that apply)

- [x] **Prospective (will be collected)**
- [ ] Existing (previously collected at the time of initial IRB submission)

2 * Will genetic analysis/testing be done on any of the samples?

- [ ] Yes
- [ ] **No**

3 * Will this study involve banking of samples (storing for future research use)?

- [ ] **Yes**
- [ ] No

4 * What is the purpose of the sample collection and/or analysis?

The purpose of the sample collection is to culture and determine bacterial colonization or immune response as a proxy for biofilm formation.

5 * Is there the possibility that cell lines will be developed with any of the samples?

- [ ] Yes
- [ ] **No**

6 * Will the samples be released to anyone not listed as an investigator on the protocol?

- [ ] Yes
- [ ] **No**

6.1 If Yes, give name(s) and affiliation(s):

7 * Will the sample material be sold or given to any third parties?

- [ ] Yes
- [ ] **No**

7.1 If Yes, give name(s) and address(es):

ID: VIEW4E0E1A4B80000
Name: v2_Sample Collection/Analysis

Prospective Samples

You indicated that the study involves collection of prospective samples (specimens).

1 * What type of sample will be collected? (Check all that apply)

- [x] **Blood**
- [ ] Bone Marrow Aspirate/Biopsy
- [ ] Cerebrospinal Fluid
- [ ] Saliva
- [ ] Skin
- [ ] Sputum
- [ ] Stool
- [ ] Tissue
- [ ] Tumor
- [ ] Urine
- [ ] Other

1.1 If Other, specify:

2 For blood draws, specify the amount drawn, in teaspoons, at each visit and across the course of the subject's entire participation time:

Blood draws are routinely taken throughout a patient's follow-up to monitor their health. We plan to take up to three blood draws, with the use of an indwelling catheter when available, to culture for research purposes during their hospitalization for diagnosed surgical site infection.
Patients will be identified at random in the orthopaedic trauma clinic and current admitted patients who have been diagnosed with an infection. Once eligibility has been confirmed, the informed consent process will be completed by the Research Coordinator and the attending surgeon. Patients will be approached about potential participation in the study as soon as is feasible following determination of eligibility.
Once consented into the study, baseline data regarding participant characteristics, injury characteristics, fracture classification and medical history/co-morbidities will be collected. Characteristics about hospital course and treatment received will also be collected (i.e. blood culture results, antibiotic usage, etc).
At each follow up visit, participants will undergo a clinical evaluation by the treating surgeon as part of standard of care following any surgical procedure and will be interviewed by the research coordinator. Blood draws will be taken at the initial and each subsequent visit and will be analyzed in the laboratory of one of the investigators in the study. If the patient is currently infected currently, or become infected at any point in the future, additional blood draws may be taken, at a maximum of 10 draws, over the period of two years from the clinical diagnosis of infection. The amount of blood that is drawn will not exceed 50 ml or 3 ml per kg in a 8 week period, and collection may not occur more frequently that 2 times per week.
Finally, we would prospectively correlate the laboratory findings with clinical findings by searching the patients' medical records to find outcomes such as a biofilm formation.

3 * What type of samples will be collected? (Check all that apply)

- ☐ Leftover samples that were obtained for clinical purposes (no additional research procedures required)
- ☐ Samples obtained specifically for research purposes-additional taken during a clinical procedure
- ☐ Commercial (for profit) samples
- ☑ **Samples obtained specifically for research purposes-obtained via a separate collection procedure done solely for the purposes of the study**
- ☐ Other

3.1 If Other, specify:

4 * How are these samples labeled? For example, do they contain name, initials, dates, Social Security number, medical record number, or other unique code?

Unique code for each patient such that the samples will be blinded from obvious patient identifiers.

5 * Will sample(s) be made available to the research subject (or his/her medical doctor) for other testing?

☐ Yes ☐ **No**

6 * If a participant withdraws from the study, will that participant have the option to get the remaining portion of their sample(s) back?

☐ Yes ☐ **No**

7 * If the participant withdraws, explain how their sample(s) will be handled (For example, will sample(s) be destroyed, anonymized, etc.):

Samples will be held anonymously if the patient withdraws until analysis is complete.

8 * Will the samples be destroyed after the study is over?

☐ Yes ☐ **No**

8.1 If No, describe how the samples will be stored, where they will be stored, and for how long.

The samples will be stored in a freezer at Dr. Shirtliff's lab until deemed no longer useful.

ID: VIEW4E0E257D60C00
Name: v2_Prospective Samples

Sample Banking

You indicated that the study involves banking of samples (storing for future research use).

1 * Where will the sample(s) be banked? (If this study involves the VA, please state the name of the registry/repository and the CICERO protocol number is was approved under.)

Dr. Shirtliff's lab at the Dental school in a freezer.

2 * Does the banking institution have an approved policy for the distribution of samples?

☐ Yes ☐ **No**

3 How long will the sample(s) be kept?

Until deemed no longer useful for testing.

4 * Will sample(s) be made available to the research subject (or his/her medical doctor) for other testing?
☐ Yes ☐ **No**

5 * If a participant withdraws from the study, will that participant have the option to get the remaining portion of their sample(s) back?
☐ Yes ☐ **No**

6 * If the participant withdraws, explain how their sample(s) will be handled (For example, will sample(s) be destroyed, anonymized, etc.):
Samples will be held anonymously if the patient withdraws until analysis is complete.

7 * If the participant withdraws, explain how the data obtained from their sample(s) will be handled (e.g., will it be deleted?) ***(Please note that data for FDA regulated research cannot be deleted):***
The data will be held anonymously if the patient withdraws until analysis is complete.

ID: VIEW4E0E7E82B5800
Name: v2_Sample Banking

Data Collection/Record Review

You indicated on the "Type of Research" page that your study involves data collection or record review (i.e., chart review, not self-report).

1 * What type of data will be collected/analyzed in this study? (Check all that apply)
☐ Retrospective/Secondary Analysis (data has already been collected at the time of initial IRB submission)
☑ **Prospective (data is not yet in existence and/or collected)**

2 * Will this study involve adding data to a registry or database for future use?
☐ Yes ☐ **No**

3 * Will the data be released to anyone not listed as an investigator on the protocol?
☐ Yes ☐ **No**

3.1 If Yes, give name(s) & affiliation(s):

ID: VIEW4E0E25A8CA400
Name: v2_Data Collection / Record Review

Prospective Data

You indicated that the study involves the collection of prospective data.

1 * Where is the data being collected from? (Check all that apply)
☑ **Medical records**
☐ Medical images
☐ Commercial (for profit) entity
☐ Publicly available records
☐ Schools
☑ **Other**

1.1 If Other, please specify:
Blood tests as collected in lab and outlined above

2 * What data fields will you have access to/collect for the study? For example, name, initials, date of birth, Social Security number, income, demographic information, family units, housing, etc.
name, MRN, DOB, demographic information - available data

We will only need name and MRN for purposes of this study. This information will be destroyed after initial data analysis phase.

You can also upload a copy of the data fields/variables to be collected for the study:

Name	Created	Modified Date

There are no items to display

ID: VIEW4E0E25B643800
Name: v2_Prospective Data

Clinical Trial Registration

You indicated on the "Type of Research" page that your study is a clinical trial.

1 * Does the UM Clinical Trials Registry policy require registration of this trial?
☐ Yes ☐ **No**

2 * Has this trial been registered?
☐ **Yes** ☐ No

ID: VIEW4E093BF078C00
Name: v2_Clinical Trial Registration

Clinical Trial Registration Information

You indicated that this clinical trial has been registered.

1 * Was this trial registered at www.clinicaltrials.gov?
☐ **Yes** ☐ No

2 If no, was this trial registered on a site other than clinicaltrials.gov?
☐ Yes ☐ No

2.1 If Yes, specify the name of the other site:

2.2 Provide justification for registering this trial on this site:

3 * Registration Number
NCT03132246

ID: VIEW4E093BF1D0800
Name: v2_Clinical Trial Registration Information

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
5000

2 * How many participants (or specimens, or charts) will be enrolled/used for this study? ***A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.***

Local - the number being enrolled at this site:
1200

Worldwide - the number being enrolled total at all sites (including local enrollment):
1200

3 * Gender:
☑ **Male**
☑ **Female**

4 * Age(s):
☐ 0 to 27 days (newborn infants)
☐ 28 days to 12 months (Infant)
☐ 13 months to 23 months (Toddler)

- [ ] 2 to 5 years (Preschool)
- [ ] 6 to 11 years (Child)
- [ ] 12 to 17 (Adolescents)
- [x] **18 years and older (Adult)**
- [ ] 89 years and older

5 * Race/Ethnicity:

- [x] **All Races Included**
- [ ] American Indian or Alaskan Native
- [ ] Asian/Other Asian
- [ ] Asian/Vietnamese
- [ ] Black or African American
- [ ] Hispanic or Latino
- [ ] Mixed Race or Ethnicity
- [ ] Native Hawaiian or Pacific Islander
- [ ] White or Caucasian

6

* Language(s):

- [x] **English**
- [ ] Chinese
- [ ] French
- [ ] Italian
- [ ] Japanese
- [ ] Korean
- [ ] Local Dialect
- [ ] Spanish
- [ ] Vietnamese
- [ ] Other

6.1 Specify Other:

7

* Are you excluding a specific population, sub-group, or class?

- [ ] Yes
- [ ] **No**

7.1

If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:

ID: VIEW4E0E519C1D000
Name: v2_Participant Selection

Vulnerable Populations

1 * Will you be targeting ANY of the following Vulnerable Populations for enrollment? (Select all that apply)

- [ ] Employees or Lab Personnel
- [ ] Children (Minors)
- [ ] Cognitively Impaired/ Impaired Decision Making Capacity

- [ ] Pregnant Women/Fetuses
- [ ] Wards of the State
- [ ] Students
- [ ] Prisoners
- [ ] Nonviable Neonates or Neonates of Uncertain Viability
- [ ] Economically/Educationally Disadvantaged
- [x] **None of the above**

Only select populations which you will be targeting for enrollment. Do not include populations that may be enrolled incidentally. Enrollment of a vulnerable population is considered to be "targeted" if the study team will be aware that a subject is from a vulnerable group as a result of interaction with the subject or collection of specific information about the subject, and the research team does not wish to exclude them. "Incidental" enrollment is limited to situations where a study team is unaware that a subject is from a vulnerable group.

ID: VIEW4E0E519917800
Name: v2_Vulnerable Populations

Eligibility

1 * Do you have an existing Eligibility checklist(s) for this study?
☐ Yes ☐ **No**

1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE**. The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date

There are no items to display

1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Previous fracture fixation with an implant (intramedullary nail, plate, screws), or joint revisions, or periprosthetic fracture, or admitted from orthopaedic trauma clinic due to infection, or inpatient with a known infection.
View	2	Age 18 and older
View	3	English speaking

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Patients with planned follow-up at another medical center
View	2	Patient lives outside of the hospital catchment area

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00055743_7 v10-6-2015-1444148031816(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them: (If this study involves the VA please list all sites at which recruitment will take place.):
All orthopaedic patients over age 18 attending a follow-up visit with an attending orthopaedic traumatologist will be eligible. Patients over the age of 18 admitted directly from the orthopaedic trauma clinic will be eligible. Current patients over the age of 18 that have been diagnosed with an infection. Once eligibility is confirmed the research coordinator and/or the attending surgeon with initiate the research consent conversation.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):
All patients will be assured that their care is standard and will not be affected by their choice to paricipate. In addition, the outcome of the study will not be revealed to the patient nor their doctor, therefore participation in the study is completely voluntary.

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)

- ☐ PI
- ☑ **Study Staff**
- ☐ Third Party

3.1 If you are using a third party, specify Third Party Recruiters:

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E0BCAA0A6C00
Name: v2_Recruitment

Advertising

1 * Will you be using advertisements to recruit potential participants?

☐ Yes ☐ **No**

ID: VIEW4E0BCCF811000
Name: v2_Advertising

Research Related Risks

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/seriousness of the risk, and the provisions for minimizing the risk:

1. Blood draw - risk of further bleeding and site infection. Minimal risk. Unlikely that the patient will experience complications as it will be drawn in concordance with other laboratory requirements by either a nurse or lab technician. If no other laboratory requirements on the day of the visit, will still draw one vial per visit.
Safety issues related to this are only concerns related to patient privacy.

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the potential direct benefit(s) to participants:

While there are no direct benefits to patients participating in the study, participation may help determine the best treatment for surgical site infections in the future.

2 * Describe the importance of the knowledge expected to result from the study:

The purpose of this study is to attempt to determine the appropriate analysis technique for the proper identification of wound bioburden in order to effectively diagnose and treat deep surgical site infections.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:

The breach of confidentiality is minimal. The benefits of properly identifying the bacterial colony of traumatic wounds and specifically treating them to reduce infection and other complications associated with traumatic injuries will have a much more profound and positive effect.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.

Participation is voluntary; the alternative is not to participate.

ID: VIEW4E1B5251B0400
Name: v2_Potential Benefits and Alternatives

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

1 * Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:

Patients will be withdrawn if the study is ended early, if the PI decides it is no longer in the subject's best interest, or for other reasons.

2 * Describe procedures for orderly termination:

If there were to be any issues which would force closure of the study all participants would be notified immediately. None of the protocol affects their care so the overall effect would be minimal.

3 * Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from

procedures with continued data collection:
Patient data already collected will be maintained for analysis with the remainder of the research pool. Identifiers will be eliminated in accordance with the other data.

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

1 * Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***
It is the Investigator's responsibility to conduct the protocol under the current version of Declaration of Helsinki, Good Clinical Practice, and rules of local IRBs. The investigator must ensure that the patient's anonymity be maintained in their data submission. Patients will be identified only by identification code but not by their name, SSN, or hospital medical record number. The investigator will maintain a separate confidential enrollment log which matches identifying codes with the patients' names and addresses (i.e., available only to local clinic staff). All study material will be maintained in strict confidence.
All study forms, reports, and other records that are part of the study data collection materials will be identified by coded number to maintain patient confidentialiy. All paper records will be kept in locked file cabinets. All electronic records of study data will be identified by coded number. Consent procedures and forms, and the communication, transmission and storage of patient daata will comply with individual site IRB requirements for compliance with The Health Insurance Portability and Accountability Act (HIPAA).

2 * Describe the location where potential participants will receive research information and detail the specific actions the study team will take to ensure adequate privacy areas:
Potential participants could receive information in the orthopaedic trauma clinic, where there are private rooms. Current inpatients who are eligible will be approached in their private hospital rooms.

3 * Describe potential environmental stressors that may be associated with the research:
The primary stressor would be the requirement of an additional blood draw at a visit that may not have otherwise had any blood drawn for the visit. No other stressors noted.

4 * Will this study have a site based in the European Union?
☐ Yes ☐ No

5 * Will the study have planned recruitment or data collection from participants while they are located in the European Union?
☐ Yes ☐ No

Access link below for information about the EU General Data Protection Regulations to assist in answering these questions.
https://www.umaryland.edu/oac/general-data-protection-regulation/

ID: VIEW4E1B525B87C00
Name: v2_Privacy of Participants

Confidentiality of Data

1 * Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?
■ **Yes**
☐ No, the data will be stored de-identified/anonymous (stripped of all identifiers, no way to identify individual participants)

2 * Where will research data be kept (address electronic and paper data as applicable)? (If this is a VA study please list specific sites that data will be kept.)
All study forms, reports, and other records that are part of the study data collection materials will be identified by coded number to maintain patient confidentialiy. All paper records will be kept in locked file cabinets. All electronic records of study data will be identified by coded number. Consent procedures and forms, and the communication, transmission and storage of patient data will comply with individual site IRB requirements for compliance with The Health Insurance Portability and Accountability Act (HIPAA).

3 * How will such data be secured?
All data will be password protected and locked in an office to which there is limited access.

4 * Who will have access to research data?
Approved research staff and PI

5 * Will study data or test results be recorded in the participant's medical records?
☐ Yes ☐ **No**

6 * Will any data be destroyed? ***(Please note that data for FDA regulated research and VA research cannot be deleted)***
☐ Yes ☐ **No**

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

7 Do you plan to obtain a Certificate of Confidentiality?
☐ Yes ☐ **No**

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date
There are no items to display		

8 * Discuss any other potential confidentiality issues related to this study:
N/A

ID: VIEW4E1B5265E0400
Name: v2_Confidentiality of Data

Monitoring Plan Selection

1 * Type of data safety monitoring plan for the study:
☐ Will use/defer to the external sponsor's Data Safety Monitoring Plan
☐ Data Safety Monitoring by a Committee
☑ **Data Safety Monitoring by an Individual**
☐ There is no data safety monitoring plan in place

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

Monitoring Plan - Individual

You indicated that the monitoring will be done by an Individual.

1 * Identify the individual who will be performing the safety monitoring:
Robert V. O'Toole, MD

2 * Describe this individual's role in relation to the protocol:
Principal investigator

3 * What data will be reviewed?
☑ **Adverse Events**
☑ **Enrollment Numbers**
☑ **Patient Charts/Clinical Summaries**
☑ **Laboratory Tests**
☐ Medical Compliance
☐ Procedure Reports
☐ Raw Data
☑ **Outcomes (Primary, Secondary)**
☐ Preliminary Analyses
☐ Other

3.1 If Other, specify:

4 * What will be the frequency of the review?

- [ ] Annually
- [ ] Bi-Annually
- [x] **Other**

4.1 If Other, specify:
On an as-needed basis.

5 * Safety monitoring results will be reported to:

- [x] **IRB**
- [ ] GCRC
- [ ] Sponsor
- [ ] Other

5.1 If Other, specify:

ID: VIEW4E1B026A2A400
Name: v2_Monitoring Plan - Individual

Research-Related Costs

1 * Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?

- [ ] No
- [x] **Yes**

1.1 If Yes, check all that apply:

- [x] **Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)**
- [x] **Investigational or Study Device**
- [ ] Investigational or Study Drug
- [ ] Investigational Procedure(s)

1.2 If No, who is responsible for payment?

2 * Who is responsible for the uncovered research-related costs?

- [ ] Participant
- [ ] Sponsor
- [ ] UM
- [ ] Other
- [x] **There will be no uncovered research-related costs**

2.1 If Other, specify:

3 If the participant is responsible for any research-related costs, identify and estimate the dollar amount:

ID: VIEW4E1B5D9641800
Name: v2_Research Related Costs

Compensation for Research-Related Injury

1 * Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?

☐ Yes ☐ **No**

1.1 If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:

Name	Created	Modified Date
There are no items to display		

1.2 If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?

☐ Yes ☐ **No**

1.2.1 If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:

1.2.2

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research?

☐ Yes ☐ **No**

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

HIPAA (Health Insurance Portability and Accountability Act)

1 * HIPAA applies to the University of Maryland School of Medicine, the University of Maryland School of Dentistry and the VA. Are you affiliated with, or will be accessing data from, any of these places? ☐ **Yes** ☐ No

2 If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA? ☐ **Yes** ☐ No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

Protected Health Information (PHI)

You indicated that HIPAA applies and the study will view, access, share, collect, use, or analyze health information that is individually identifiable.

1 * Which PHI elements will be used or disclosed in this study? (Check all that apply)

- ☑ **Name**
- ☐ Address (if more specific than Zip Code)
- ☑ **Dates**
- ☐ Ages over age 89
- ☑ **Telephone numbers**
- ☐ Fax numbers
- ☐ Email addresses
- ☐ Social Security numbers
- ☑ **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 locators (URLs)
- [ ] Internet protocol (IP) address numbers
- [ ] Biometric identifiers, including fingerprints and voiceprints
- [ ] Full-face photographic images and any comparable images
- [ ] Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification
- [ ] None

2 * Why is the PHI necessary for this research?
If SSNs are going to be used, describe the specific use and type of SSN to be used (real, scrambled, last 4 digits).
Used to correspond name and MRN to specific code to file. Patient records will be accessed to determine clinical correlation to biofilm assay.

3 * What is the source(s) of the PHI?
Medical record.

4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).
PHI will not be used but for purposes of our study.

5 * How will permission to allow the use/disclosure of the individual's protected health information (PHI) be obtained? (Choose all that apply:)

- [x] **Obtain written authorization** ***(upload authorization form at the end of the application under "Consent and HIPAA Authorization Forms")***
- [x] **Requesting waiver/alteration of authorization (includes waiver of authorization for recruitment only)**
- [ ] Qualifies as a limited data set (LDS)

5.1 If you are using a limited data set (LDS), please attach the Data Use Agreement (DUA):

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E1B0A24AA400
Name: v2_Protected Health Information

Waiver/Alteration of Authorization

You indicated that a waiver/alteration of authorization is requested.

1 * Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:
Data stored in password-protected file on password-protected computer. Research subjects will be assigned a unique study ID to further reduce the chances for the release of PHI.

2 * Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:
Research subjects will be assigned a unique study ID to reduce the chances for the release of PHI.

3 * Describe the plan to destroy the PHI collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain PHI, provide a justification:
PHI collected for this study will be eliminated after initial data analysis.

4 * Why could the research not practicably be done without access to and use of this PHI?
We will need to have access to the patient's name and MRN prior to recruitment in order to determine their eligibility for the study. We would not be able to enroll without this. Phone numbers are necessary to follow up with patients that will not come back in to the clinic for a standard visit. A HIPAA waiver is being sought for these purposes.

5 * Why could the research not practicably be done without the waiver or alteration?
We will need to have access to the patient's name and MRN prior to recruitment in order to determine their eligibility for the study. Phone numbers are necessary to follow up with patients that will not come back in to the clinic for a standard visit. A HIPAA waiver is being sought for these purposes.

6 * Will the subjects' PHI be disclosed to (or shared with) any individuals or entities outside of UM?
- [ ] Yes
- [ ] **No**

6.1 If Yes, describe the individuals or entities outside of UM to whom PHI will be disclosed.

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)

- ☐ Not applicable (study may qualify as exempt)
- ☐ Request to Waive Consent/Parental Permission (Consent is not being obtained)
- ☐ Request to Alter Consent (Some Elements of Consent Waived)
- ☐ Request to Waive Documentation of Consent (Verbal/Oral Consent)
- ☑ **Written Consent Form**
- ☐ Electronic Consent

2 * Describe the Informed Consent process in detail:

To encourage a high level of participation from eligible patients, the attending surgeon will be involved in the consent conversation. The conversation will be initiated by the research coordinator and/or the surgeon together. Patients will be informed of the study and intended use of blood samples obtained and any relevant data that will be collected or analyzed in conjunction with the study. Patients and their families will be provided with copies of the consent form describing the study, the risks and benefits of participation and what will be expected of them if they choose to participate.

Any participant who is enrolled in the study via consent of a Legally Authorized Representative will be re-evaluated during follow-up and will then sign the consent form if they are determined competent.

3 Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

* ☐ **Yes** ☐ No

4 * Describe who will obtain Informed Consent:

The conversation will be initiated by the research coordinator and/or the treating surgeon.

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. *(Answer "N/A" if not obtaining consent from LARs)*

LAR will be confirmed by providing ID. These will be used in the case of minors, however we are not specifically targeting this group for enrollment.

6 * Describe the setting for consent:

All interaction will occur in private patient areas where curtains can be drawn or doors closed in the orthopaedic trauma clinic.

7 * Describe the provisions for assessing participant understanding:

The research staff will endeavor to answer all questions posed by the patient and his/her family to ensure their understanding of the protocol. A limited number of questions will be asked of all patients after they are introduced to the study and have reviewed the consent form.

The Research Coordinator will ask the questions and determine the appropriateness of the responses. If the Research Coordinator is at all unsure about the patient's ability to consent s/he will consult with the study site PI.

The choice of LAR will follow standard procedures. The following with be approached in this order of priority:
• Legal guardian
• Proxy (health care agent) named in an advance directive or durable power of attorney for health care;
• Family member or other surrogate identified by the state law on health care decisions.

Recognizing that consent is an ongoing process, the study team will encourage the participants to ask additional questions that may arise during the course of their participation in the study.

8 * Describe the consideration for ongoing consent:

At all intervals where data is collected, participants will be reminded of their participation in the study and the events that are to occur at that interval. They will be asked if they wish to proceed.

Consent and HIPAA Authorization Forms - Draft

1 Upload all of your Consent Forms for approval. Use only Microsoft Word.

Name	Created	Modified Date
Modified consent 7.2018 clean.docx	7/12/2018 2:01 PM	7/12/2018 2:01 PM
Microbiology Consent 4.28.2016.doc	4/28/2016 9:25 AM	5/25/2018 3:13 PM
Microbiology Consent 5.25.2018.doc	5/25/2018 3:14 PM	5/25/2018 3:14 PM
Microbiology Consent 10.15.2015.doc	10/14/2015 9:13 AM	11/11/2015 2:01 PM
Modified consent 6.2018 with track changes.docx	6/25/2018 5:11 PM	6/25/2018 5:11 PM

IMPORTANT NOTE: the above list of consent forms (if any) are DRAFT versions. Under no circumstances should copies of these be distributed to patients/study subjects. If/when this research submission is approved by the IRB, approved consent forms will be available for download and use from the "Documents" tab of the Submission's workspace (click Exit and then look for the Documents tab - approved submissions only)

1A Archived Consent Forms:

Name	Created	Modified Date
There are no items to display		

2 Upload any HIPAA authorization forms here:

HIPAA.doc	10/14/2013 1:03 PM	11/11/2015 1:59 PM

Please refer to HRPO's website for specific instructions for preparing informed consent documents and to access current templates: http://hrpo.umaryland.edu/researchers/consents.html

ID: VIEW4E1C7712D3000
Name: v2_Consent Forms - Draft

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

Orthopedics

If this information is incorrect, please notify the HRPO office.

2

RSC Review Criteria - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation? ☐ Yes ☐ **No**

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer? ☐ **Yes** ☐ No
-OR-
Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

4 **Cancer Center Criteria** - Answer the following to determine if review by the Cancer Center (Hematology-Oncology) may be required.

* Does the protocol involve in any way studies related to the prevention, treatment, diagnosis, or imaging of neoplastic diseases? ☐ Yes ☐ **No**

5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity? ☐ Yes ☐ **No**

6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)? ☐ Yes ☐ **No**

* 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)? ☐ Yes ☐ **No**

* 6.3 - Will the research be conducted on VA property, including space leased to and used by VA? ☐ Yes ☐ **No**

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

ID: VIEW4E1AF91AB2400
Name: v2_Organization Review Requirements (other than IRB)

Institutional Biosafety Committee Review Required

1 **NOTE**: based on your answers to questions on a previous page (see below) review by the Institutional Biosafety Committee (IBC) is required. This will involve extra steps on your (study team) part. Clicking the Continue button will result in the system creating a blank IBC Submission form for you. You will be required to fill out and submit this IBC form before you will be able to submit the Protocol form. The IBC Submission workspace and form can be reached by clicking the appropriate button on the left hand side of the Protocol submission's workspace (web page) after exiting the Protocol form.

2 **Question** - answered on IBC RSC review requirements page:

3.1 Does the research involve human gene transfer? - OR - Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.
3.2 Does the research involve: a) the exposure of human subjects to pathogenic microorganisms, or b) the potential exposure of UMB research staff to infectious materials through the sampling or processing of materials from patients with known infectious disease or from environmental surfaces?
3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard? **Yes**

If the answer to this question is wrong, an IBC submission is not required, use the Jump To menu or your browser's <

3 * **Confirm** - you have read the above information and understand that in addition to the IRB Protocol form, you will fill out and submit the IBC Submission form :

☐ **Yes** ☐ No

ID: VIEW4E1AF91ED4C00
Name: v2_Institutional Biosafety Committee Review Required

Summary of Required Reviews (other than IRB)

1 **Additional Committee Reviews** - Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission		
IBC: Microbiology Study (HP-00055743)	Workspace	SmartForm

2 **Required Department and Specialty Reviews** - Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study

team are required.

Name of Organization	Review Status
Orthopedics	Complete
SOM Program in Trauma	Complete

ID: VIEW4E1C8D9AE4000
Name: v2_Summary of Required Reviews (other than IRB)

Additional Documents

1 Upload all additional documents here:

Name	Created	Modified Date
Enrollment Interview Form	9/22/2014 3:41 PM	9/18/2015 1:25 PM
Diagnosis of Infection Form	9/22/2014 3:42 PM	9/22/2014 3:42 PM
Follow-Up Form	9/22/2014 3:41 PM	9/22/2014 3:41 PM

ID: VIEW4E0962513A000
Name: v2_Additional Documents

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	Review Status
Orthopedics	Complete
SOM Program in Trauma	Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission		
IBC: Microbiology Study (HP-00055743)	Workspace	SmartForm

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation
By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- If Required, obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

ID: VIEW4E1B10C500000
Name: v2_Final Page of Application

Add a Team Member

1 * Select Team Member:
Aaron Johnson

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
☐ **Yes** ☐ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
☐ **Yes** ☐ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Has vast knowledge and experience conducting research at the local study site.

Add a Team Member

1 * Select Team Member:
Michael Schloss

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
This team member has extensive knowledge of the local study sites, culture and society.

Add a Team Member

1 * Select Team Member:
Jason W Nascone

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a

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☐ Yes ☐ **No**

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5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Shock Trauma attending Orthopaedic surgeon with extensive research experience

Add a Team Member

1 * Select Team Member:
Katherine Ordonio

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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☐ **Yes** ☐ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Has vast knowledge and experience conducting research at the local study site.

Add a Team Member

1 * Select Team Member:
Dimitrius Marinos

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all

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☐ **Yes** ☐ No

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☐ **Yes** ☐ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Researcher has been sufficiently trained on the study and has observed enrollment process

Add a Team Member

1 * Select Team Member:
W. Andrew Eglseder Jr

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Shock Trauma attending Orthopaedic surgeon with extensive research experience

Add a Team Member

1 * Select Team Member:
Raymond Pensy

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Shock Trauma attending Orthopaedic surgeon with extensive research experience

Add a Team Member

1 * Select Team Member:
Christopher LeBrun

2 Research Role:
Sub-Investigator

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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Shock Trauma attending Orthopaedic surgeon with extensive research experience

Add a Team Member

1 * Select Team Member:
Victoria Longo

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Extensive experience conducting research and good knowledge of the local study sites, culture, and society.

Add a Team Member

1 * Select Team Member:
Dominique Gelmann

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Extensive experience conducting research and good knowledge of the local study sites, culture, and society.

Add a Team Member

1 * Select Team Member:
Gerard Slobogean

2 Research Role:
Sub-Investigator

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☐ Yes ☐ **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Gerard Slobogean has vast experience and knowledge conducting research at the local study site.

Add a Team Member

1 * Select Team Member:
Mitchell Baker

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Has vast knowledge and experience conducting research at the local study site.

Add a Team Member

1 * Select Team Member:
Max Hamaker

2 Research Role:
Research Team Member

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6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Has vast knowledge and experience conducting research at the local study site.

Add a Team Member

1 * Select Team Member:
Haley Demyanovich

2 Research Role:
Research Team Member

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5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Extensive experience conducting research and good knowledge of the local study sites, culture, and society.

Add a Team Member

1 * Select Team Member:
Jonathan Hurst

2 Research Role:
Research Team Member

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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Extensive experience conducting research and good knowledge of the local study sites, culture, and society.

Add a Team Member

1 * Select Team Member:
Marcus F Sciadini

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Shock Trauma attending Orthopaedic surgeon with extensive research experience

Add a Team Member

1 * Select Team Member:
Stephan Olaya

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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☐ Yes ☐ **No**

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Extensive experience conducting research and good knowledge of the local study sites, culture, and society.

Add a Team Member

1 * Select Team Member:
Theodore Manson

2 Research Role:
Sub-Investigator

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Shock Trauma attending Orthopaedic surgeon with extensive research experience

Add a Team Member

1 * Select Team Member:
Andrew N. Pollak

2 Research Role:
Sub-Investigator

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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Shock Trauma attending Orthopaedic surgeon with extensive research experience

Add a Team Member

1 * Select Team Member:
Mark Shirtliff

2 Research Role:
Sub-Investigator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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☐ **Yes** ☐ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Dr. Shirtliff is part of the team who designed the biofilm assay in an animal model.

Add a Team Member

1 * Select Team Member:
Syed Zaidi

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study

sites, culture, and society:
This team member has extensive knowledge of the local study sites, culture and society.

Add a Team Member

1 * Select Team Member:
Manjari Joshi

2 Research Role:
Sub-Investigator

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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Has vast knowledge and experience conducting research at the local study site.

Add a Team Member

1 * Select Team Member:
Zachary Kim

2 Research Role:
Research Team Member

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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Extensive experience conducting research and good knowledge of the local study sites, culture, and society.

Add a Team Member

1 * Select Team Member:
Joshua Rudnicki

2 Research Role:
Research Team Member

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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Experienced in conducting research and has good knowledge of local study sites, culture, and society.

Add a Team Member

1 * Select Team Member:
Zachary Hannan

2 Research Role:
Research Team Member

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☐ **Yes** ☐ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
This team member has extensive knowledge of the local study sites, culture and society.

Add a Team Member

1 * Select Team Member:
Andrea Howe

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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☐ **Yes** ☐ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
University of Maryland Shock Trauma Orthopedics research staff currently working with multiple IRB approved studies

Add a Team Member

1 * Select Team Member:
Yasmin Degani

2 Research Role:
Study Coordinator

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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☐ **Yes** ☐ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Years of experience as a research specialist working on a multitude of clinical trials, is current with local CITI, HIPAA, and GCP.

Add a Team Member

1 * Select Team Member:
Daniel Connelly

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
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☐ Yes ☐ **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
Experienced in conducting research and has good knowledge of local study sites, culture, and society.

Add a Team Member

1 * Select Team Member:
Alexandra Mulliken

2 Research Role:
Research Team Member

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This team member has extensive knowledge of the local study sites, culture and society.