ASES Shoulder PJI Multicenter Research Group

Dear Investigator(s):

Thank you for your interest in participating and contributing to the ASES Shoulder Periprosthetic Joint Infection (PJI) Multicenter Research Group. A central IRB at the University of Washington (coordinating site) has been approved, and a REDCap database for multi-institutional contribution is in place. The workflow for this database is included at the end of this document.

Two important aspects of this multicenter database are to make certain 1) we establish a high bar for data integrity, and 2) surgeons are as consistent as possible in their evaluation of revision shoulder arthroplasty patients. This will allow us to answer many important questions formulated at the International Consensus Meeting in 2018 and ensure that we have good quality data to tackle these questions as a group again in a few years.

To confirm that participating groups understand the requirements and level of involvement with this multicenter database, **we are asking participating surgeon(s) and appropriate research personnel to participate in two virtual site initiation meetings**. The first meeting would be to outline the objectives of the database, outline involvement of the surgeons and protocols that must be followed, and answer questions on logistics with data entry and follow-up. Participating surgeons will be able to view samples of the required surveys and will also provide details on culturing practices at their specific institutions. IRB-related questions will be addressed at this meeting as well. Once a participating site has IRB approval, a second meeting would take place to reinforce appropriate workflows. This series of meetings will allow us to ensure that all sites understand the requirements and that our data integrity goals are being met.

If you have any questions or concerns, please feel free to reach out to us anytime.

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AMERICAN SHOULDER AND ELBOW SURGEONS

Outline for Collaborating Sites

Multicenter Study on Clinical and Microbiologic Outcomes for Suspected Shoulder Periprosthetic Joint Infection

IRB# STUDY00010445

IRB Information

Brief Description of Study: The objective of this study is to collect clinical and microbiological outcomes in patients undergoing revision shoulder arthroplasty, especially for those suspected of shoulder prosthetic joint infection.

Participants: English speaking adults, 18 years of age or older, who are having or have had revision shoulder arthroplasty.

Recruitment Talking Points: If consent is being obtained for this study, potential subjects should be aware of the purpose of the study, what participation involves, the risks that are associated with the study, and that participation is completely voluntary.

Objective: The objective of this study is to collect 1-year, 2-year, 5-year, and 10-year clinical and microbiological outcomes in patients undergoing revision shoulder arthroplasty (repeat shoulder replacement surgery), especially for those suspected of shoulder prosthetic joint infection. It is often difficult to determine the existence of a shoulder joint infection around the prosthesis until the results of cultures taken during surgery are available, often up to two weeks after the operation. Therefore, surgeons are often making operative decisions and postoperative management decisions without knowledge of the presence of infection. Because of the difficulty in diagnosing and defining infection, there currently exists uncertainty in terms of optimal management of these patients. Diagnosis and management of these periprosthetic shoulder infections would be greatly enhanced by obtaining long-term clinical and microbiological outcomes for patients undergoing revision shoulder arthroplasty for suspected infection.

Study Procedures: Though the details of institutions' protocols may differ and will be approved by their respective IRBs, each protocol should allow for the following procedures.

- Subjects will receive follow-up questionnaires to be completed, ideally, at one year, two years, five years, and ten years after surgery. The subjects will receive the questionnaires at each timepoint either by email – using a secure web link to an online follow-up survey (using REDCap), by standard mail – including a pre-paid and addressed return envelope, by telephone contact, or in-person at their regular clinical follow-up appointment.
- As the coordinating site, the UW research team has created and will be managing the database for this study. A REDCap project will be used as the database for collecting subject data for all sites. This method will allow the coordinating site to analyze and view the data without viewing other sites subjects' PHI. If the follow-up surveys are sent by email, the UW research team will be providing the technology to send the emailed survey link via REDCap.

- The surgeon(s) or research personnel at each site will be entering any study data not gathered directly from subjects' follow-up surveys into REDCap. This includes baseline/demographic data and information relating to the subjects' surgery and surgical outcomes.
- The following questionnaires may be used as part of the follow-up surveys: the VR-12, the American Shoulder and Elbow Score (ASES), Simple Shoulder Test (SST), Single Assessment Numeric Evaluation (SANE) Score, and general health information questions.
- Subjects may share clinically important information about their surgical outcomes in their follow-up questionnaires. Because of this, the subjects' surgical team will be able to view the self-reported surgical outcomes and reach out to that patient, if needed.

Potential Data Variables*:

- Demographics: date of birth, age, sex, race, ethnicity, BMI, marital status, contact information
- Symptoms and clinical history: medical and surgical history, diagnoses, culture results, intra-operative findings, any X-rays or radiographic/MR images and treatments
- Social history: tobacco, alcohol, narcotic pain medications, workers' compensation status
- Post-operative: operative report, surgery outcomes, and progress at follow-up visits
- Outcomes questionnaires

*Please note that while PHI can be obtained and viewed through REDCap by the surgeon(s) or research personnel at each site, it will not be accessible by any other site.

General Information: There are no costs to the collaborating sites. Each site will be responsible for obtaining IRB approval at their own institution.

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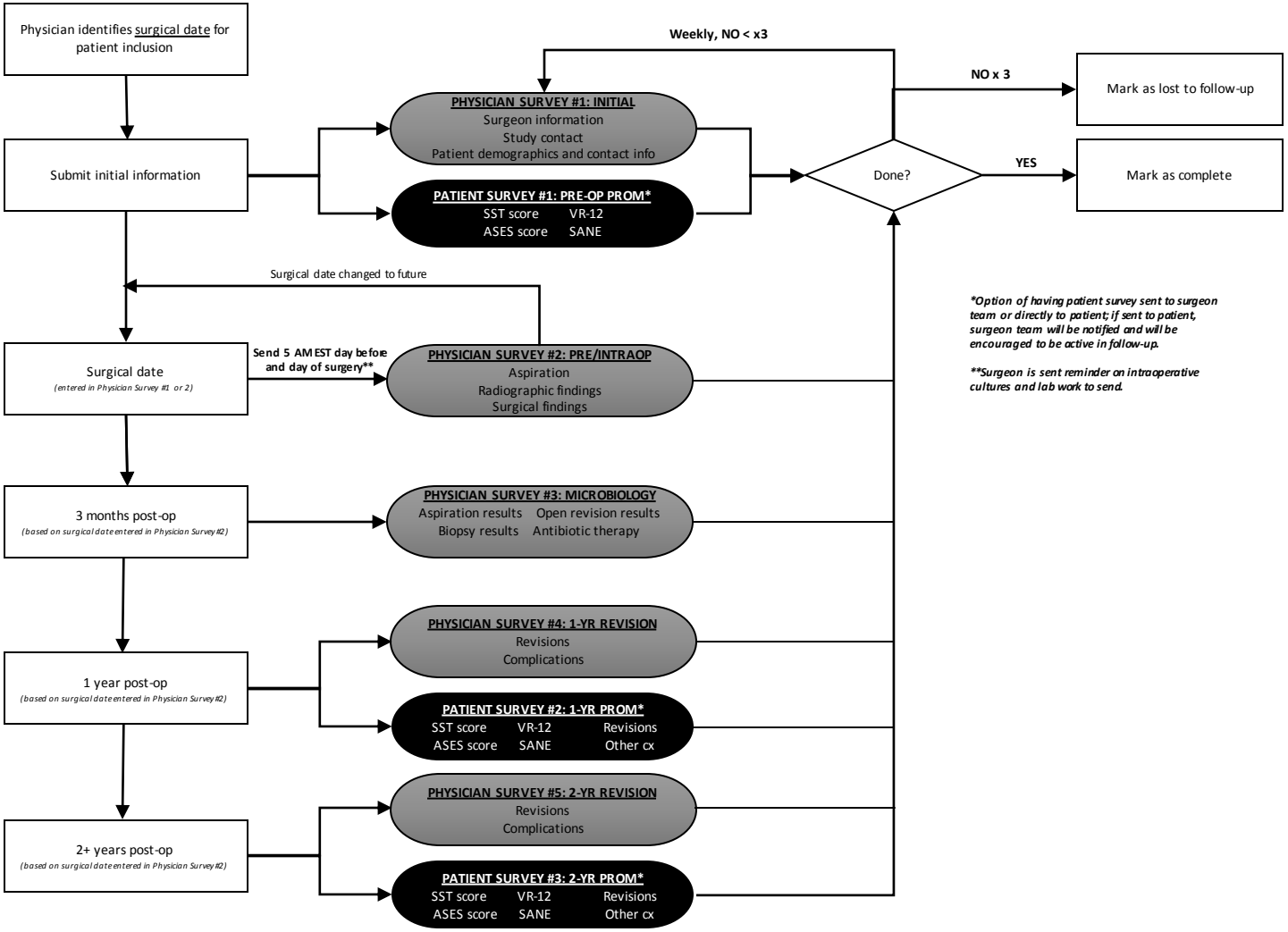
ASES Shoulder PJI Multicenter Database Workflow

Initial Surgeon Requirements:
- Must perform >10 revision shoulder arthroplasties annually
- Must obtain IRB approval within 6 months

Ongoing Surgeon Requirements:
- Must submit 5 or more revision arthroplasties annually into database
- >80% completion of physician surveys within 3 weeks
- >70% completion of patient surveys within 3 weeks



**Option of having patient survey sent to surgeon team or directly to patient; if sent to patient, surgeon team will be notified and will be encouraged to be active in follow-up.*

***Surgeon is sent reminder on intraoperative cultures and lab work to send.*