



## **Policy and Procedures for AOFAS Research Collaboration Program**

October 2020

Interest in utilizing the resources of the AOFAS for the conduct of research-related projects is rapidly expanding. The AOFAS recognizes the need for a well-defined policy on research collaboration and a procedure in place for systematically evaluating such proposals. To that end, the current chairs of the Research Committee, Evidence Based Medicine Committee (EBM), and Committee on Health Outcomes, Registries and Data (CHORD) offer the following proposal as a guide to policy and procedure for evaluation of research proposals from AOFAS members wishing to execute research-related projects that would in any way utilize AOFAS resources.

This policy and its procedures only concern research projects initiated by an active AOFAS member. They do not apply to quality assurance projects or initiatives submitted/directed by an AOFAS committee or the AOFAS Board of Directors.

### **I. Categories of Research Proposal**

- A. **Type 1: Membership Survey Projects** – Research proposal designs requesting a survey of AOFAS membership
- B. **Type 2: AOFAS Research Database Projects** – Small or large projects that intend to employ AOFAS resources to enable a database study. These may either utilize the existing OFAR database, or create a new database via the CHORD Consortium.
- C. **Type 3: Other Large Non-AOFAS Research Database Projects** – These are large retrospective or prospective studies that are not expected to require an AOFAS research database platform for execution but are expected to require significant AOFAS resources (personnel time, funding, administrative support, etc.).

## II. Policies for Research Collaboration Proposals

### A. Submission Criteria

1. Only proposals that meet all submission requirements outlined herein, are relevant to the field of orthopaedic foot and ankle surgery, advance the goals of the AOFAS, and have clear and demonstrated scientific merit will be considered for formal review.
2. The proposed research submission must explicitly outline coverage of all anticipated costs expected to be incurred by the AOFAS in relation to the project. If no resources are expected to be covered by AOFAS, it should be so stated. An itemized budget must be included with every submission.
3. All proposals must have language making it clear that AOFAS is protected from any liability throughout the course of the study.
4. All proposals must be submitted by an AOFAS active member in good standing. This person should be listed as the Principal Investigator (PI) for the proposed study.
5. Submissions will be reviewed on a quarterly basis through the process outlined herein by the Research Council, and all proposals to be considered for any given quarter must be submitted by the respective deadline for that quarter. Any completed proposal not meeting the deadline for a given quarter will automatically be considered within the submission pool for the subsequent quarter.

### B. Screening Process

1. All proposed research projects should be submitted to the AOFAS staff (specific contact, deadline, and communication details for submission to follow in this document). The AOFAS research staff will screen each application to ensure that it is complete and that it meets all eligibility criteria. It will be the responsibility of the PI of each proposal to confirm submission success.
2. All submissions must clearly indicate the intended research category (1, 2, or 3, as outlined above). Once a project is successfully submitted for consideration in a given category, it cannot be resubmitted later in a different category.
3. Submissions must be completed as outlined in **Appendix 1: AOFAS Research Collaboration Program Information and Guidelines**.The

proposal must include each of the elements listed or it will be rejected and returned to the submitter.

### III. Review Procedures for Proposals

#### A. The Review Committee

1. All eligible submitted proposals will undergo review by members of the Research Council and/or its designees. These may include members of the AOFAS Research, CHORD, and Evidence-Based Medicine Committees, as well as the *FAI* and *FAO* Editorial Boards, and/or the AOFAS Board of Directors as delegated by the Research Council. The review process will remain confidential, and all decisions will be final.
2. Reviews will generally be assigned based on the category of submission:
  - a. Surveys: Assigned to members of the Research Committee and/or Evidence- Based Medicine (EBM) Committee, as appropriate.
  - b. AOFAS Research Database Projects: Assigned to the CHORD committee.
  - c. Other Large Non-AOFAS Research Database Projects: Assigned to the Research Council for appointment to review committee of selected experts related to the proposed research topic.

#### B. The Review Process

1. All Categories of Proposals submissions will be reviewed on a quarterly basis. The timeline for submission and review is outline below:
  - a. Submission Deadlines
    - Quarter 1: January 1 through March 31. Deadline March 31. Committee review by May 30
    - Quarter 2: April 1 through June 30. Deadline June 30. Committee review by August 29
    - Quarter 3: July 1 through September 30. Deadline September 30. Committee review by November 29
    - Quarter 4: October 1 through December 31. Deadline December 31. Committee review by February 28

- b. Review Timeline Deadlines: Whenever possible, the PI of any successfully submitted proposal will be informed of a decision within 60 days of the submission deadline for the quarter in which the proposal was accepted.

In special circumstances, as determined by the Research Council, an ad-hoc review may be requested. A letter of justification must first be submitted to the attention of the AOFAS research staff before any consideration of Ad-Hoc review.

## 2. Survey Project Review

- a. Proposals in this category will be graded according to the guidelines of the AOFAS Research Grants Program.
- b. Once a proposal has been evaluated and graded by the reviewers, a summary statement including recommendation for either acceptance or rejection will be sent to the Research Council and AOFAS BOD for final consideration. Non-complicated survey projects may be approved by the Research Committee and do not need to be submitted to the Research Council unless Research Committee deems complexity of the survey study warrants further review by the Research Council or Board of Directors. The AOFAS research staff will thereafter be notified of the final decision and then communicate this decision to the proposal PI (study submitter).
- c. All surveys accepted for execution will be disseminated to AOFAS membership via email notification, which will include a survey link attached to the email.
- d. Note: The Research and EBM Committees reserve the right to set limits on the number of surveys conducted with the AOFAS membership on an annual basis to control survey fatigue and ensure that only quality studies are approved.

3. AOFAS Research Database Project Review
  - a. Proposals in this category will be reviewed by the CHORD committee through its existing project review infrastructure
  - b. Once a proposal has been evaluated and graded by the reviewers, a summary statement including recommendation for either acceptance or rejection will be sent to the AOFAS research staff who will then notify the proposal PI (study submitter) of this final decision.
  
4. Other Large Non-AOFAS Research Database Project Review
  - a. Proposals in this category which are accepted for review and propose to utilize significant AOFAS resources will be assigned directly to the Research Council for further consideration.
  - b. Any submitted proposal thereafter approved by the Research Council will then be sent to the AOFAS Board of Directors for final approval. The AOFAS research staff will then be notified of the final decision and be responsible for ultimately communicating this decision to the proposal PI (study submitter).
  - c. All AOFAS resources utilized must be reimbursed by the study budget or grant.
  - d. AOFAS resources can be committed toward development of the project and writing of the grant proposal, at the Board of Directors' discretion.
  - e. If the project is of significant value to AOFAS and its membership, AOFAS can elect to share some associated costs, at the sole discretion of the AOFAS Board of Directors.
  
5. In the event that additional expertise (e.g., for a unique procedure or technology) is needed for critical review of any proposal, an ad hoc reviewer may be assigned.

6. All reviews will be conducted in a blinded fashion, modeled after that used by the National Institutes of Health and AOFAS Research Grants Program, considering significance, innovation, approach, environment, and overall impact.

### C. Reviewer Decisions

1. Survey Projects: Upon review completion, the AOFAS research staff will, whenever possible, notify the proposal PI (study submitter) of the final decision within 60 days of the submission deadline for that quarter.

The decision to accept or reject will include a summary of comments by the reviewers for the purpose of feedback to the submitter, outlined by either the Chair or Vice Chair of the Research or EBM Committee.

2. AOFAS Research Database Projects: Upon review completion, the AOFAS research staff will, whenever possible, notify the proposal PI (study submitter) of the final decision within 60 days of the submission deadline for that quarter.

The decision to accept or reject will include a summary of comments by the research review process for the purpose of feedback to the submitter, outlined by either the Chair or Vice Chair of the CHORD committee.

3. Other Large Non-AOFAS Research Database Projects: Upon review completion, the AOFAS research staff will, whenever possible, notify the proposal PI (study submitter) of the final decision within 60 days of the submission deadline for that quarter.

The decision to accept or reject will include a summary of comments by the reviewers for the purpose of feedback to the submitter, outlined by either the Chair or Vice Chair of the Research Council.

4. Submitted projects that are accepted are unable to commence until such decision has been formally communicated through the AOFAS research staff following finalization of the Committee summary, the quarterly Research Council meeting, and/or any communication with the AOFAS Board of Directors, as necessary.
5. In the event that a submitted proposal is rejected, any applicant is welcome to resubmit a revised proposal during a subsequent quarterly cycle. If this opportunity is exercised, however, it should be noted that only one resubmission will be permitted.

#### IV. Presentations and Publications

- A. All posters, presentations, publications, or scientific representations of any kind emanating from this submission process must acknowledge the AOFAS.
- B. Any poster, presentation, publication, or scientific representation of any kind that results from successful approval of a survey through either the Research Committee, EBM Committee, or CHORD Committee must acknowledge the respective Committee accordingly.
- C. Any poster, presentation, publication, or scientific representation of any kind that results from successful approval through the AOFAS database platform of AOFAS must acknowledge the database platform.
- D. A summary of scientific findings and conclusions for all approved projects must be sent by the applicant to the AOFAS research staff within 6 months of project completion.
- E. Study Investigators of any approved project are strongly encouraged to submit a final manuscript for publication in either *Foot & Ankle International* or *Foot & Ankle Orthopaedics*.
- F. Study Investigators of any approved project are strongly encouraged to submit their findings for presentation at an AOFAS meeting.
- G. An annual list of recipients and completed projects will be posted on the AOFAS website.



## Appendix 1

### American Orthopaedic Foot & Ankle Society (AOFAS) Research Collaboration Program Information and Guidelines

#### I. Information

- A. The purpose of this program is to facilitate research collaboration and foster original scientific investigation from members who are interested in utilizing AOFAS resources.
- B. Proposals should include the information in the format outlined in the guidelines below.
- C. In order for a study proposal to be eligible for submission, the applicant must be an active AOFAS member in good standing and be listed as the Principal Investigator for the investigation.
- D. The signed application and associated documentation should be submitted electronically to the AOFAS research staff: [research@aofas.org](mailto:research@aofas.org). A call for proposals will open on a quarterly basis through the AOFAS website.
- E. All applicants are responsible for submitting a non-refundable application fee of US \$200 cover costs incurred by the AOFAS staff review process. The application fee will be charged prior to processing by AOFAS staff and committee review.
- F. Project proposals will be reviewed on a quarterly basis, and decisions will require approval by designees of the Research Council and/or AOFAS Board of Directors, as deemed appropriate. All decisions are final.
- G. Only proposals that meet all submission requirements, are relevant to the field of orthopaedic foot and ankle surgery, advance the goals of the AOFAS, and have clear and demonstrated scientific merit will be considered for formal review.
- H. The review process is modeled after that used by the National Institutes of Health and AOFAS Research Grants Program. All reviews will be conducted in a blinded fashion, considering significance, innovation, approach, environment, and overall impact.
- I. The Principal Investigator will assume full administrative, fiscal, ethical, and scientific responsibility for the conduct of the project.

- J. AOFAS strongly encourages scientific presentation and peer review scientific publication of any impactful research findings that emanate from approved research projects. All such scientific representations resulting in whole or in part from an approved project must include a statement acknowledging the AOFAS as outlined in the submission guidelines above.

## II. Collaborative Research Proposal Application Form

### A. Cover Page

1. AOFAS Category of Proposal (Survey, AOFAS Research Database, or Other Non-AOFAS Research Database Project)
2. Study Title
3. Principal Investigator, credentials, and contact information (name, title, institution, address, phone, and email)
4. Names, titles, and institutions of all co-investigators
5. Citation of any non-AOFAS support (industry, external grants, other agencies, etc.)

### B. Brief Summary

1. Concise Summary of the project including purpose, methods, study design and significance. Limit 200 words.
2. For surveys, this description will be included in the email announcements to participate.

C. Background: Describe previous work that was published or presented with references cited any relevant history behind current proposal, if applicable, and describe how existing studies relate to this project. Describe any relevant preliminary studies performed by the principal or co-investigators and provide citations.

D. Purpose/Specific Aims: State the purpose/specific aims/and hypothesis.

E. Study Design/Methods: Describe study design/methods and how data will be collected and analyzed. Define the population you wish to study. Strongly consider providing justification of patients/samples required. Discuss limitations and potential difficulties of the proposed project. Include specific description of all primary and secondary endpoints. Comment on any specific safety concerns. If AOFAS Research Database

data is required, clearly define the data and data analysis methodology.

- F. Significance of Study: State the importance of the research proposed and its potential impact on the field of foot and ankle surgery.
- G. Budget: If applicable, provide itemized budget and all intended sources of funding for this project, including any industry support.
- H. Timeline: Intended start date, anticipated end date, other relevant endpoints (e.g., desired number of respondents for surveys).
- I. Pertinent References: Cite all references and number in the order in which they appear in the proposal.
- J. Results Dissemination: Outline anticipated presentations and publications and/or other plans for dissemination of results.
- K. Appendix/Supplemental information. May include biosketch of the PI (not required for surveys), documentation of IRB approval, Conflict of Interest statement, copy of survey, research instruments, equipment specifications, publications related to the proposal, etc.
  - 1. Biographical Sketch: A biographical sketch for the Principal Investigator should be provided. This should include the name, institution, education, relevant past research, prior research funding, and relevant publications.
  - 2. Conflict of Interest: Include an up-to-date disclosure statement for each investigator to be involved with the study. Can be screenshot from AAOS website.
  - 3. Institutional Review Board (IRB) or Human Subjects Protection: Human Subjects approval of the proposed research project by your Institutional Review Board is required for submission. Please attach formal documentation of your institution's approval of this study, or waiver.