



# Research Collaboration

## Policies & Procedures

**Version 1.1**

Reviewed and Approved by the Scientific & Medical Advisory Committee on September 8, 2020

Version Date: September 1, 2020

## Table of Contents

<b><i>Purpose</i></b> .....	<b>3</b>
<b><i>Definitions of Research Involvement</i></b> .....	<b>3</b>
<b><i>Project Description &amp; Duration</i></b> .....	<b>3</b>
<b><i>Roles &amp; Responsibilities</i></b> .....	<b>3</b>
<b><i>Application Review, IRB-Components, and Agreements</i></b> .....	<b>4</b>
<b><i>Data Elements &amp; Sharing</i></b> .....	<b>5</b>
<b><i>Reporting &amp; Updates</i></b> .....	<b>5</b>
<b><i>Publication Review &amp; Authorship</i></b> .....	<b>5</b>
<b><i>Termination/Modification of Agreement</i></b> .....	<b>6</b>
<b><i>Updates</i></b> .....	<b>6</b>
<b><i>Appendix 1: Research Resource Application</i></b> .....	<b>7</b>
<b><i>Appendix 2: Research Partnership Application</i></b> .....	<b>9</b>
<b><i>Appendix 3: SciMAC Research Partnership Scoring Sheet</i></b> .....	<b>11</b>
<b><i>Appendix 4: Example of an Approved Research Agreement</i></b> .....	<b>13</b>

## Purpose

The Amputee Coalition (AC) believes in the power of transforming policy and practice for all People with Limb Loss/Limb Difference (PwLL/LD) through robust scientific evidence. As the nation's leading patient advocacy organization for PwLL/LD, the AC represents patient-defined research priorities by regularly evaluating constituent needs and soliciting community feedback. This policy and procedure document will guide and standardize our interactions with all stakeholders and will ensure that PwLL/LD needs are centered as a priority in upcoming research.

## Definitions of Research Involvement

The AC will focus on two types of research collaboration that further important, novel studies and activities that will improve prevention and health outcomes on behalf of the LL/LD community:

- **Research Partnerships** are collaborations that involve PwLL/LD data collected through AC outreach and/or AC staff as part of the design, implementation, analysis, and write up of research. The AC will act as an equitable partner. Research Partnerships will be reviewed by a sub-committee of our Scientific and Medical Advisory Committee (SciMAC), using importance and relevance of research questions as the metrics for scoring and approval.
- **Research Resources** are mechanisms for engaging PwLL/LD in research. AC staff will review and endorse enrolling studies, highlight ongoing research opportunities and resources, and provide a place for PwLL/LD to have an active Research Profile hosted on the AC's network. The AC will also consider letters of support requests.

Each type of collaboration has an application form (see Appendices 1 and 2) and we will disseminate collaboration information, including conflicts of interest, on our organization website.

## Project Description & Duration

All research collaborations will require a project description and definition of the project duration. We require this information so that our community members can assess the opportunities that best fit their needs. The Project Description should include the Title, Funder, Investigative Team, Grant Term (MM/YY – MM/YY), Primary Aims and Objectives, Outcomes, Location, and IRB number. The Project Duration should include a breakdown of Planning, Enrollment needs/expectations, Follow-Up, and Dissemination periods, as applicable. For Research Partnership activities, SciMAC will need a complete Project Summary (see Appendix 1).

## Roles & Responsibilities

For all research collaboration, the AC will help our partners to define Roles & Responsibilities through their application process. For Research Partnerships, the AC will act as an equitable

partner in study design and implementation. Roles should be fully described for each collaboration and may include the following:

- **Investigative Team:** Research collaborators should list out all investigators involved in the project, their respective institutions, contact information, and detailed information on their role (e.g. Principal Investigator, Co-Investigator, Research Manager, Biostatistician, Student Investigator, etc.). In addition, the applicant is responsible for confirming Conflict of Interest information for each team member. For Research Partnerships, the applicant is responsible for confirming that the entire Investigative Team has IRB-approval to engage in the proposed research project. Any project involving AC data, or utilizing AC staff time, should list the appropriate AC staff members as part of the investigative team.
- **Scientific & Medical Advisory Committee (SciMAC):** A subcommittee of SciMAC, supported by the AC's Research Department, will be responsible for reviewing all Research Partnerships, and scoring based on importance and relevance for PwLL/LD. Applications will be reviewed as they are submitted, and SciMAC will have four weeks to review and provide feedback. No Research Partnership will be initiated without this committee's approval. On a quarterly basis, the subcommittee will receive an update on all active Research Partnerships. In addition, the subcommittee will be notified of newly approved Research Resources and will receive quarterly reports on key indicators (number of featured studies, website statistics on Research Resource utilization, etc.).
- **AC Research Department:** The Director of Research & Education, the Senior Research Specialist, and other AC team members as relevant will review all Research Collaboration requests. The department is responsible for ensuring that PwLL/LD priorities are a key component of any research activity. To ensure PwLL/LD voices are amplified, the Senior Research Specialist will ensure that AC evaluation findings are featured and incorporated into research collaborations, as relevant. The department will host all information on our organization website and support the work of partners; the department is also responsible for communicating any changes to existing agreements or policies.

## Application Review, IRB-Components, and Agreements

The AC is responsible for reviewing all Research Collaboration requests (see Appendix 3 for scoring guidelines) and will issue Research Agreements for Research Partnerships and Resources that outline terms (see Appendix 4 for an example). The importance and relevance of the research to the Limb Loss/Limb Difference community will be used as part of each approval process and will be evaluated alongside the Amputee Coalition's Research Priorities. We will also prioritize collaborations that respond to priorities identified by the [Limb Loss Task Force White Papers](#).

In addition, the AC encourages best practice for all research activities. Review by and approval from an Institutional Review Board (IRB) or Ethics Committee should be secured at the start of any activity. For Research Partnerships, details on data security and de-identification, secure process for transmitting files, permissible data use, and data storage and access, should be

included in IRB applications and detailed in the application process. The AC should be listed on the IRB application when AC data or staff time will be utilized.

Research agreements will be issued and maintained by the AC research staff (see Appendix 4).

## Data Elements & Sharing

Any data collected by AC staff is property of the organization. All data will be de-identified before being shared with any partners and will be shared with Partners after IRB approval is obtained as a password-protected encrypted excel file.

All Research Collaborations are encouraged to collect the following data points (required for Research Partnerships):

- **Demographics:** *Sex, Race & Ethnicity, Age, Cause of Amputation (Dysvascular Disease, Dysvascular Disease with Comorbidity of Diabetes, Trauma, Cancer, Congenital Difference, Infection Related), Level of Amputation, Level of Limb Loss/Limb Difference*
- **Impact Indicators:** *Measures of Quality of Life and Self-Efficacy*

## Reporting & Updates

Collaborators who are approved as a Research Resource will be asked to provide quarterly updates to the AC's research department or more frequently if determined necessary for shorter project periods. They will also be responsible for notifying the AC when a featured study has concluded enrollment.

Research Partners will be asked to provide quarterly updates on approvals, enrollment, and summary findings to the AC research department. These updates will be shared with the SciMAC subcommittee.

## Publication Review & Authorship

The AC encourages all Research Collaborators to define publication plans and authorship agreements at the outset of research activity. Research Partnerships will adhere to the policy and criteria laid out by the International Committee of Medical Journal Editors (ICMJE). According to ICMJE, "an 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study, and biomedical authorship continues to have important academic, social, and financial implications." They go on to stress the four criteria for authorship: "*Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND Drafting the work or revising it critically for important intellectual content; AND Final approval of the version to be published; AND Agreement to be accountable for all aspects of the work in ensuring that*

questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.”<sup>1</sup>

The Director of Research & Education will be charged with reviewing all publications that arise from research collaborations and has the right to review and approve before manuscript submission. Details of this process will be included in the Approved Research Agreement for each collaborator (Appendix 4).

For publications that arise from Research Resources that are approved by the AC, where appropriate, the AC should be acknowledged as a non-author contributor in publications. The ICJME encourages non-author contributions for the following activities:

- Acquisition of funding
- General supervision of a research group or general administrative support
- Writing assistance, technical editing, language editing, and proofreading
- Assisting with study recruitment efforts through AC events or resources (e.g. website, print materials, social media, and events such as the National Conference)

When AC staff contribute to Research Resources in this way, the AC should be acknowledged in the publication as an organization under a single heading (e.g., “The Amputee Coalition served as expert advisors to represent patient-led priorities in development of this manuscript.”)

## Termination/Modification of Agreement

Existing agreements are subject to the terms of agreements and receipt of quarterly updates. Agreements can be terminated if Research Partnerships do not provide the agreed upon updates or adhere to the terms outlined in each Agreement.

## Updates

Version	Date	Updates Made
1.1	22Sept2020	Added detail about social media postings and Research Digest circulation

---

<sup>1</sup> International Committee of Medical Journal Editors. *Defining the Role of Authors and Contributors*. Accessed online on August 10, 2020 at <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

## Appendix 1: Research Resource Application

The Amputee Coalition (AC) welcomes research collaborations with partners engaging in important and relevant research work for the Limb Loss/Limb Difference Community. If you are interested in being featured on the AC website, included AC activities as a Research Resource, obtaining a letter of support, etc., please complete the application online at \_\_\_\_\_:

<b>Name of Applicant:</b>		<b>Email:</b>	
Phone Number:		Address:	
<b>Type of Research Resource:</b>			
<input type="checkbox"/>	IRB-Approved Research Projects	<input type="checkbox"/>	Educational Material/Guidelines
<input type="checkbox"/>	Advertisements	<input type="checkbox"/>	Request for Letters of Support
<input type="checkbox"/>	Other, Specify:		
<b>Investigative Team (for Research Projects):</b>			
Name and Email	Institution	Role (PI/co-PIs, Research Coordinator, Biostatistician, Etc.)	Conflict of Interest Disclosure (enter N/A if none)
<b>Research Resource Details</b>			
Title			
Short Title			
Funder			
Grant/Project Term (MM/YY-MM-YY)			
Primary Aims/Objectives/Goals			
Outcomes			
Location			
Participant Reimbursement (as applicable)			
Eligibility Criteria (as applicable)			
Duration of study participation (as applicable)			
	<b>Planning Period</b>	<b>Implementation/Enrollment Period</b>	<b>Dissemination Period</b>
Project Duration			

Please include a request letter on institutional letterhead signed by the primary point of contact, a copy of Institutional Review Board Approval (for approved research projects), and copies of the Research

Resource you would like to be linked to (materials to be posted online by the applicant, not on the AC's website). Payments and timelines associated with advertising in the AC's print materials are detailed in the Partner & Sponsor Opportunities.

Research Projects should include the Demographic and Impact Indicators as detailed Research Collaboration Policies and Procedures document as part of their data collection *if possible*.

The AC will review applications for Research Resources and return a confirmed Research Agreement, with a four-week turnaround time for review. The AC reserves the right to request updates to the Research Resource to highlight PwLL/LD voices and/or concerns.

Once approved, your study will be included in as part of a Research Digest on the AC's website, which may be circulated via the AC's social media platforms, at the organization's discretion.

## Appendix 2: Research Partnership Application

The Amputee Coalition (AC) welcomes research collaborations with partners engaging in important and relevant research work for the Limb Loss/Limb Difference Community. Research Partnerships will be established with stakeholders external to the AC and involve the use of AC data and/or staff time. All Research Partnership applications are subject to review and approval by the AC’s Scientific & Medical Advisory Committee (SciMAC). Please complete the application online at:

<b>Name of Applicant:</b>		<b>Email:</b>	
Phone Number:		Address:	
<b>Type of Research Resource:</b>	<input type="checkbox"/> Research Project	<input type="checkbox"/> Other, Specify:	
<b>Investigative Team:</b>			
<b>Name and Email</b>	<b>Institution</b>	<b>Role (PI/co-PIs, Research Coordinator, Biostatistician, Etc.)</b>	<b>Conflict of Interest Disclosure (enter N/A if none)</b>
<b>Research Project Details</b>			
<b>Title</b>			
<b>Short Title</b>			
<b>Funder</b>			
<b>Grant/Project Term (MM/YY-MM-YY)</b>			
<b>Protocol Précis (limit to 800 words)</b>			
<b>Primary Aims/Objectives</b>			
<b>Population</b>			
<b>Description of Intervention(s)</b>			
<b>Outcomes</b>			
<b>Location</b>			
	<b>Planning Period</b>	<b>Implementation Period</b>	<b>Dissemination Period</b>
<b>Project Duration</b>			

Please include a request letter on institutional letterhead signed by the primary point of contact, a copy of Institutional Review Board Application **and** Approval Letter, and copies of the protocol and case report forms and any other surveys, instruments, or interview guides. If you do not yet have IRB approval, please include documentation that you will submit for review. The AC will initiate the partnership after SciMAC review and once institutional IRB approval has been received.

Research Projects should include the Demographic and Impact Indicators as detailed in the Research Collaboration Policies and Procedures document as part of their data collection.

The SciMAC subcommittee will review applications for Research Partnership and return a confirmed Research Agreement after approval. Importance and relevance to the limb loss community for the proposal must be confirmed before approval. SciMAC reserves the right to request additions or modifications to proposed procedures in order to ensure patient voices are centered. Any use of AC data or staff time will follow the Research Collaboration policies and procedures.

Payments and timelines associated with advertising online or in the AC's print materials are detailed in the Partner & Sponsor Opportunities.

AC Staff time will be charged at a rate of \$100 per hour; each Research Partnership application should include an estimate of hours needed for AC staff time for the following activities:

- Study design:
- Survey/tool development:
- Data collection:
- Data cleaning:
- Data analysis:
- Manuscript development:
- Manuscript review:

The approved research agreement will include a description of these hours and total approximate budget; the \$100 per hour rate is exclusive of our organization's 27% overhead rate.

## Appendix 3: SciMAC Research Partnership Scoring Sheet

The Amputee Coalition (AC) welcomes research collaborations with partners engaging in important and relevant research work for the Limb Loss/Limb Difference Community. Research Partnerships will be established with stakeholders external to the AC and involve the use of AC data and/or staff time. All Research Partnership applications are subject to review and approval by the AC's SciMAC members who will use the scoring sheet below:

### DETAILED INSTRUCTIONS

#### 1. General

Please consider the following criteria when reviewing the applications and assigning scores and an overall recommendation:

- **Importance of the Research Project to the People with Limb Loss or Limb Difference (PwLL/LD) Community (based on application and cover letter):** Consider the strength of the applicant's focus on a research question that is important to the limb loss community and is likely to advance the evidence base.
- **Relevance of the Research Project to the PwLL/LD Community (based on application and cover letter):** Consider the applicant's ability to convey the relevance of their research question to the limb loss community and assess originality and feasibility of long-term goals. Does the proposed project center PwLL/LD voices?
- **Partnership Potential (based on application):** Signs of partner growth or promise in the fields of prevention of limb loss, quality of life, independence, and overall well-being. Ideally all partnerships will involve projects and colleagues who are focused on the AC's mission for all PwLL/LD achieve their full potential.
- **Study Quality (based on application):** Consider the strength of the study design and how much impact it is likely to yield worthwhile results. Concerns about sample size, or the impact of the research question, should be noted here.

**For the Applicant Scoring Table**, please use at 5-point scale for each of the evaluation areas listed above, with 5 being 'Excellent' and 1 being 'Poor'. There is a section for comments by each topic—please use this to add thoughts/concerns/additional insights that may not be captured by the quantitative score. If you feel you have a conflict of interest for any of the evaluation areas, feel free to note that in comments without assigning a score. If you feel that you do not have enough information to assess an evaluation area, you can select 'Not enough information' in the comments, which would equate with a score of 0 (instead of a '1' for 'Poor'). Your total score will be averaged with those of other reviewers. For approval, we will require that an applicant has an average of at least 3 in Importance and Relevance.

We are also asking you to note any Conflict of Interest concerns, and if there are any, to provide recommendations for those concerns to be addressed before approval.

**Reviewer Name:**

**Overall Recommendation:**      Approve                  Approve with Revisions                  Do Not Approve

Applicant Scoring Table						
Evaluation Area	Scale:					Comments:
Importance	<b>5</b> Excellent	<b>4</b> Very good	<b>3</b> Good	<b>2</b> Not good	<b>1</b> Poor	
Relevance	<b>5</b> Excellent	<b>4</b> Very good	<b>3</b> Good	<b>2</b> Not good	<b>1</b> Poor	
Partnership Potential	<b>5</b> Excellent	<b>4</b> Very good	<b>3</b> Good	<b>2</b> Not good	<b>1</b> Poor	
Study Quality	<b>5</b> Excellent	<b>4</b> Very good	<b>3</b> Good	<b>2</b> Not good	<b>1</b> Poor	

**Conflict of Interest**

Any Conflict of Interest Concerns to be addressed by the Applicant? If yes, please detail your recommendations below:

**Additional Comments:**

## Appendix 4: Example of an Approved Research Agreement

### AC RESEARCH AGREEMENT

This Agreement is made and entered into, effective as of the date of the last signature on this Agreement (“Effective Date”) by and between: The Amputee Coalition, a non-profit patient advocacy organization for People with Limb Loss/Limb Difference (hereinafter referred to as "AC"); and \_\_\_\_\_, a organized and existing under the laws of the State of \_\_\_\_\_, having its principal offices at \_\_\_\_\_ (hereinafter referred to as "RESEARCH PARTNER") each a “Party” or collectively the “Parties” of this Agreement.

WHEREAS, AC has expertise in \_\_\_\_\_ and is interested in conducting additional research utilizing this expertise in furtherance of its charitable purposes; and

WHEREAS, PARTNER is interested in having this research conducted through the use of AC staff time and/or data collected through AC activities;

NOW, THEREFORE, in consideration of the premises, covenants and agreements set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

#### **1. PROJECT WORK**

The Parties shall perform the Project in accordance with the Research Collaboration Application. The Research Partner Principal Investigator will not materially deviate from Research Collaboration details without prior written approval from the PARTNER and visa versa.

In the event that the AC/PARTNER Principal Investigator becomes unable or unwilling to continue the Project, or leaves the employ of AC, AC or PARTNER each have the option to terminate the Project unless a mutually acceptable substitute can be found within a sixty (60) day period following notice to PARTNER of the inability of the AC Principal Investigator to continue the Project.

#### **2. REPORTS**

Unless provided otherwise in the Statement of Work, the PARTNER shall issue a detailed report summarizing the results of the data outlined in the Research Collaboration Policies and Procedures every quarter until the conclusion of the term.

#### **3. TECHNICAL MATERIAL**

All Technical Material conceived and reduced to practice arising out of the performance of the Project shall be jointly owned by the Parties.

#### **4. CONFIDENTIALITY**

The Parties acknowledge that, prior to and during the Term of this Agreement, the Parties may disclose to one another scientific, technical, trade secret, business, or other information which is treated by the disclosing Party as confidential (hereinafter referred to as “Confidential Information”). The AC is a HIPPA-compliant organization, and depending on this agreement, may develop a Business Service Agreement depending on the scope of the project.

The obligation of the receiving Party to maintain confidentiality under this Agreement will survive its expiration or termination and will endure for three (3) years from the date of disclosure.

#### **5. PUBLICATIONS**

A publication agreement will be established between the AC and PARTNER, according to authorship as outlined in the Research Collaboration Policies and Procedures document.

The AC will not have an opportunity to change, alter or redact the contents of any student thesis, dissertation, or presentation thereof, but all publications are subject to review and approval by the SciMAC subcommittee for publications.

#### **6. ACCOUNTING AND PAYMENT**

PARTNER will pay AC a total of \$ \_\_\_\_\_ US (inclusive of all and any taxes), per rates below:

- Study design:
- Survey/tool development:
- Data collection:
- Data cleaning:
- Data analysis:
- Manuscript development:
- Manuscript review:

All payments should include an overhead rate of *TBD*.

#### **7. TERM AND TERMINATION**

This Agreement shall become effective on the Effective Date and shall continue in effect for the full duration of the Term unless terminated earlier in accordance with the provisions of this Article. The Parties hereto may, however, extend the Term for additional periods as desired under mutually agreeable terms and conditions.

The signatures of the undersigned indicate that they have read, understand and agree with the terms of this Agreement and have the authority to execute this Agreement on behalf of their represented Party and to bind their Party to all the terms of this Agreement.

For AC

For PARTNER

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_