



# Research Collaboration

## Policies & Procedures

**Version 2.0**

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## 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 the research we choose to engage in.

## Definitions of Research Involvement

The AC will focus on three 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 AC staff in part of the design, implementation, analysis, or write up of a research study. The AC will act as an equitable partner once entered into a research partnership agreement. 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.
- **Volunteer Research Opportunities** are mechanisms for engaging PwLL/LD in research. AC staff will review and endorse these approved research studies on our organization website.
- **Letters of Support** are used to validate the credibility of research through a third-party testimonial. The AC will consider letters of support requests for researchers who have demonstrated importance and relevance to PwLL/LD in their study proposal. To be considered for a letter of support, all requests must be accompanied by an application and provide either a draft letter or outline containing the specific information that is to be included in the letter.

Each type of collaboration has a separate application form (see Appendices 1-3). Applications are available on our [Research webpage](#).

## Requirements for Research Partnerships

For Research Partnerships, applicants will need to submit an Application for Research Partnership (see Appendix 1) and include an IRB-approval letter and project proposal. If the IRB decision is pending, please upload a letter explaining the intent to submit the project to the IRB for review. This letter must appear on institutional letterhead and be signed by the Primary Investigator.

## Requirements for Volunteer Research Opportunities

For Volunteer Research Opportunities, applicants will need to submit an Application for Volunteer Research Opportunity (see Appendix 2). Approved Volunteer Research Opportunities

will require a standardized description for promotion on our organization website, which will be drafted by the applicant within the application form. We require this information so that our community members can assess the opportunities that best fit their needs. The project description must include the following: an informative title, location of the research study, study objectives, eligibility criteria, compensation (if available), open enrollment period, estimated time commitment for study participants, instructions for study enrollment/screening, and contact information for the Primary Investigator (PI) or Study Coordinator (SC). A study recruitment flyer and URL link to a survey or webpage may also be included on the study listing.

## Requirements for Letter of Support (LOS) Requests

Requests for Letters of Support (LOS) will be considered for researchers who have demonstrated importance and relevance to PwLL/LD in their study proposal. All LOS requests must be accompanied by a Letter of Support Request Form (see Appendix 3) and provide either a draft letter or outline containing the specific information that is to be included in the letter.

## Advertising and Paid Marketing Options

All research studies must be approved through the processes outlined in this Research Policy and Procedures Manual prior to seeking advertising options in our print and online resources. Once approved, your study will be included on the AC's website, and may be circulated via the AC's emailed newsletter and on our various social media platforms, at the organization's discretion. Other paid advertising options are available in our print and online resources including:

- **Thrive Blog** (online only): resource for visitors and subscribers to receive news, updates, events and education about LL/LD.
- **Thrive eNewsletter** (online only): weekly emails provide subscribers timely news, updates, policies, regulations and stories about LL/LD.
- **inMotion Magazine** (print and online): bi-monthly publication to provide readers with new resources, support, and education for living well with LL/LD.

Additional information regarding payments and timelines associated with advertising in the AC's print and online materials are detailed in the [Media Guide](#).

## Roles & Responsibilities

For all research collaborations, 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 all investigators involved in the project, their contact information, and detailed information on their role (e.g., Principal Investigator, Co-Investigator, Biostatistician, etc.). In addition, the applicant is responsible for disclosing any Conflict of Interest 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 minimum of two members of SciMAC, supported by the AC staff, will be responsible for reviewing all Research Partnerships and may be asked to provide periodic review of Volunteer Research Opportunities. Reviews will be submitted using a standardized Research Review Form (see Appendix 4). Scoring is 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 SciMAC's approval. Once yearly, applicants are expected to provide the Annual Update Report (see Appendix 7) for all active Research Partnerships and Volunteer Research Opportunities.
- **AC Research Staff:** Two members of the AC staff will be appointed as Level 1 and Level 2 reviewers for all Research Partnerships and Volunteer Research Opportunities. Other members of the AC staff, including but not limited to the Chief Programs Officer, the Chief Executive Officer, and/or the Medical Director will provide the executive authority for all decisions regarding Research Partnerships. This team of reviewers are responsible for ensuring that the priorities of PwLL/LD are a key component of any research activity that the AC engages in, and that the AC is well-positioned to be an equitable partner in any Research Partnership Agreement that we choose to enter. The AC will host information about our Research Partnerships and Volunteer Research Opportunities on our organization website. Members of the AC staff are also responsible for communicating any changes to existing agreements or policies with our current research partners and applicants.

## Application Review, IRB-Components, and Agreements

The AC is responsible for reviewing all Research Partnerships, Volunteer Research Opportunities, and Letter of Support requests (see Appendix 4 for scoring guidelines) and will issue a Research Partnerships Agreement (Appendix 5) and a Volunteer Research Opportunities Agreement (Appendix 6) that outline the terms and conditions of the collaboration. 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.

In addition, the AC encourages best practice for all research activities. Review by and approval from an Institutional Review Board (IRB) or Ethics Committee must 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 AC staff time will be utilized.

Research Partnership Agreements and Volunteer Research Opportunity Agreements will be issued and maintained by the AC research staff.

## 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:

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

## Annual Updates & Reporting

All research collaborators are required to provide Annual Update Reports (or more frequently if determined necessary for shorter project periods). The Annual Update Reports will be distributed to the applicant's email address on file. These reports will request information about study enrollment (including the Demographics listed above) and preliminary findings (including the Impact Indicators listed above). The Annual Update Report is provided in Appendix 7.

## Publication Review & Authorship

The AC encourages all research partners to define publication plans and authorship agreements at the outset of a 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>

An AC staff member will be charged with reviewing all publications that arise from Research Partnerships and has the right to review and approve before manuscript submission. Details of this process will be included in the Research Partnership Agreement.

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<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>

For publications that arise from approved Volunteer Research Opportunities, the AC should be acknowledged as a non-author contributor in publications, where appropriate. 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 Volunteer Research Opportunities 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 annual update reports. Agreements can be terminated if Research Partners or applicants of Volunteer Research Opportunities 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
2.0	12Sept2023	Added processes for Letter of Support requests and Paid Marketing Requests Changed 'Research Resources' to 'Volunteer Research Opportunities' Updated procedures to reflect changes in the new SciMAC charter, the discontinuation of the AC Research Department, and migration from Survey Monkey Apply portal to Asana.



## Appendix 1: Research Partnership Application

Please use this form if you would like to enter into a Research Partnership Agreement with the Amputee Coalition. Research Partnerships are collaborations that involve members of the AC staff as equitable partners involved in the design, implementation, analysis, and/or write up of a research study.

This [Research Partnership Application](https://www.amputee-coalition.org/research/) and other information about research activities can be found online <https://www.amputee-coalition.org/research/>. Questions? Email us at [research@amputee-coalition.org](mailto:research@amputee-coalition.org).

### Applicant Information

Name of Applicant

Email Address

Phone Number

### Study Information

Study Title

Institutional Affiliation

Institution Name, Department

Mailing Address

City, State ZIP

### Upload IRB-approval letter

IRB-approval or IRB-exemption is required for all research partnerships with the Amputee Coalition, prior to engagement. If your IRB decision is pending, please submit a letter from the Primary Investigator (on institutional letter head) indicating your intent to submit for IRB-review. We will not enter into any research partnership agreement until IRB-approval is obtained.

or drag and drop files here

Conflict of Interest Disclosure(s)

## Research Partnership Proposal

### Upload your Project Proposal

There is no required format for your research proposal, but we ask that you consider including the following elements:

- Investigative Team
- Project Funding Information
- Research Question(s)/Purpose
- Protocol Precis/ Summary of Methods
- Recruitment Plan/ Eligibility Criteria
- Research Objectives/ Aims
- Project Duration/ Timeline

Select files...

or drag and drop files here

### Required Outcomes

#### Demographic Data Collection

All Research Partnerships are required to collect the following data points for the subjects enrolled in the study. Please indicate which of the following will be collected. (Select all that apply)

- Sex
- Race & Ethnicity
- Age
- Cause of Limb Loss/ Limb Difference
- Level of Limb Loss/ Limb Difference

#### Impact Indicators

Describe any measures of Quality of Life and/or Self-Efficacy that will be collected as part of your research study.

### Resource Allocation

#### Anticipated AC staff time (allocate hours and funds to the following activities)

AC staff time will be charged at a rate of \$100 per hour (exclusive of our organization's 27% overhead rate).

- Study Design
- Survey/ Tool Development
- Data Collection
- Data Cleaning
- Data Analysis
- Manuscript Development
- Manuscript Review
- Other: (please describe)

#### Anticipated Project Budget (Total for all activities)

Provide the total budget that will be paid to the AC for this partnership for the activities outlined above. AC staff time will be charged at a rate of \$100 per hour (exclusive of our organization's 27% overhead rate).

## Additional Information

Provide the URL link to website or survey (optional)

## Letter of Support Request

Are you also requesting a Letter of Support for this research?

- Yes
- No

## Upload your Letter of Support Request

To be considered for a letter of support, all requests must be accompanied by either a draft letter or an outline containing the specific information that is to be included in the letter.

or drag and drop files here

## Appendix 2: Volunteer Research Opportunities Application

Please use this form if you would like to have your IRB-approved or IRB-exempt research study included on our webpage for subject recruitment purposes. This [Volunteer Research Opportunity Application](#) and other information about research activities can be found at <https://www.amputee-coalition.org/research/>. Questions? Email us at [research@amputee-coalition.org](mailto:research@amputee-coalition.org).

### Applicant Information (For Reviewers Only)

Name of Applicant

Email Address

Phone Number

Institutional Affiliation

Institution Name, Department

Mailing Address

City, State ZIP

### Upload IRB-approval letter

IRB-approval or IRB-exemption is required for all research studies to be promoted by the Amputee Coalition. If your IRB decision is pending, please submit a letter from the Primary Investigator (on institutional letter head) indicating your intent to submit for IRB-review.

Select files...

or drag and drop files here

### Upload your Project Proposal

There is no required format for your proposal, but we recommend that your submission include the following elements:

- Investigative Team
- Project Funding Information
- Research Question(s)/ Purpose
- Protocol Precis/ Summary of Methods
- Recruitment Plan/ Eligibility Criteria
- Research Objectives/ Aims
- Project Duration/ Timeline

Select files...

or drag and drop files here

### Conflict of Interest Disclosure(s)

### Search Filters (Select all that apply)

These will be used by prospective subjects to sort through the list of research studies they wish to participate in.

- Online Only                       Upper Limb                       Compensation Available  
 In-person Research               Lower Limb                       None of the above

### Study Information (For Webpage Listing)

The following information will be displayed on the webpage for Volunteer Research Opportunities exactly as it is provided in this application. Please be concise in your responses to ensure uniformity with the other research studies listed. Please confirm that your spelling and information provided is correct prior to submitting this application.

#### Study Title

#### Study Location

#### Research Objectives

#### Eligibility Criteria

#### Compensation Details

#### Enrollment Closes

Web listing will automatically expire on this date.

#### Time Commitment

Please describe the frequency and duration of all required study visits.

#### Contact Person

Name and preferred contact method.

## How to Participate

Provide instructions on how participants are to enroll (i.e., see recruitment flyer, visit our webpage, call or email us).

## Upload Recruitment Flyer (optional)

or drag and drop files here

## Provide the URL link to website or survey (optional)

## Letter of Support Request

Are you requesting a Letter of Support from the Amputee Coalition?

- Yes
- No

## Upload your Letter of Support Request

To be considered for a letter of support, all requests must be accompanied by either a draft letter or an outline containing the specific information that is to be included in the letter.

or drag and drop files here

## Appendix 3: Letter of Support Request

Complete this form to request a Letter of Support for your research study. Please DO NOT use this form if you also plan to enter a Research Partnership Agreement with the Amputee Coalition or if you have plans to promote this study on our Volunteer Research Opportunities webpage for subject recruitment purposes. Use the corresponding application forms (available on our webpage) for these other research collaborations. All application forms and other information about research activities can be found at <https://www.amputee-coalition.org/research/>.

Questions? Email us at [research@amputee-coalition.org](mailto:research@amputee-coalition.org).

### Applicant Information (For Reviewers Only)

Name of Applicant

Email Address

Phone Number

Institutional Affiliation

Institution Name, Department

Mailing Address

City, State ZIP

### Upload IRB-approval letter

IRB-approval or IRB-exemption is required for all research studies to be promoted by the Amputee Coalition. If your IRB decision is pending, please submit a letter from the Primary Investigator (on institutional letter head) indicating your intent to submit for IRB-review.

Select files...

or drag and drop files here

### Upload your Letter of Support Request

To be considered for a letter of support, all requests must be accompanied by either a draft letter or an outline containing the specific information that is to be included in the letter.

Select files...

or drag and drop files here

## Upload your Project Proposal:

There is no required format for your proposal, but we recommend that your submission include the following elements:

- Investigative Team
- Project Funding Information
- Research Question(s)/ Purpose
- Protocol Precis/ Summary of Methods
- Recruitment Plan/ Eligibility Criteria
- Research Objectives/ Aims
- Project Duration/ Timeline

Select files...

or drag and drop files here



## Appendix 4: Research Review Form

Please use the following 5-point scale for each of the evaluation areas:

- 5 = Excellent
- 4 = Very Good
- 3 = Good
- 2 = Not Good
- 1 = Poor

There is a section for comments beside each question. Please use this to add your thoughts, concerns, or additional insights that may not be captured by the quantitative score.

- If you feel that you do not have enough information to assess an evaluation area, you can select 'Not enough information', which will equate with a score of 0.
- If you feel you have a conflict of interest for any of the evaluation areas, feel free to note that in the comments without assigning a score.

Your total score will be averaged with those of the 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 Information

Reviewer Name

### Applicant Information

Applicant's Name

Study Title

### Application Review

Overall Recommendation?

- Approve
- Approve with Revisions
- Do Not Approve

### Importance

Importance of the Research Project to the People with Limb Loss or Limb Difference (PwLL/LD) Community: 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.

- 5. Excellent
- 4. Very Good
- 3. Good
- 2. Not Good
- 1. Poor
  
- 0. Not enough information
- I have a conflict of interest

### Relevance

Relevance of the Research Project to the PwLL/LD Community: 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?

- 5. Excellent
- 4. Very Good
- 3. Good
- 2. Not Good
- 1. Poor
  
- 0. Not enough information
- I have a conflict of interest

### Partnership Potential

Partnership Potential: Signs of partner growth or promise in the fields of prevention of limb loss, quality of life, independence, and overall well-being. Ideally all collaborations will involve projects and colleagues who are focused on the AC's mission for all PwLL/LD to achieve their full potential.

- 5. Excellent
- 4. Very Good
- 3. Good
- 2. Not Good
- 1. Poor
  
- 0. Not enough information
- I have a conflict of interest

### Study Quality

Study Quality: Strength of the study design and how much impact it is likely to yield worthwhile results.

- 5. Excellent
- 4. Very Good
- 3. Good
- 2. Not Good
- 1. Poor
  
- 0. Not enough information
- I have a conflict of interest

Total Score:

Are there any Conflict-of-Interest concerns to be addressed by the applicant?

- Yes – Provide Recommendation to address these concerns.
- No

## Appendix 5: Research Partnership Agreement

### Amputee Coalition Research Partnership 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 \_\_\_\_\_, an 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 vice 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 year 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 HIPAA-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 27%.

## 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: \_\_\_\_\_

## Appendix 6: Volunteer Research Opportunity Agreement

### Volunteer Research Opportunity Agreement

The Amputee Coalition, the only non-profit patient advocacy organization for People with Limb Loss/Limb Difference (hereinafter referred to as "AC"), reviewed your Volunteer Research Opportunity Application based on the following criteria:

- **Importance of the Research Project to People with Limb Loss/ Limb Difference (PwLL/LD):** 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:** 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:** Signs of partner growth or promise in the fields of prevention of limb loss, quality of life, independence, and overall well-being. Ideally all collaborations will involve projects and colleagues who are focused on the AC's mission for all PwLL/LD to achieve their full potential.
- **Study Quality:** Strength of the study design and how much impact it is likely to yield worthwhile results.

Your application has been **approved** based on our review, and we are happy to highlight your work. Please note the following conditions:

#### 1. HIGHLIGHTING THE STUDY ON THE AC WEBSITE

The AC will include a summary of your study information on our website. We will also include your study as part of a digest that we may circulate via email and on our social media platforms, at our discretion. If you would like to pay for your study to be advertised in our online and printed materials, please visit our [Media Guide](#).

#### 2. REPORTS

You will be requested to submit an Annual Update Report according to Research Collaboration Policies and Procedures until the conclusion of the study period. When your enrollment period closes, we will remove your study from our website.

When you publish or present your results, please inform the AC so that we can highlight your work with our Scientific and Medical Advisory Committee, and other platforms, again at the organization's discretion.

#### 3. PUBLICATION ACKNOWLEDGEMENT

*The AC should be acknowledged as a non-author contributor for publications that include data from participants that learned about the study through our website and social media digests. Per our Policies and Procedures, we ask that the AC be acknowledged in the publication as an organization under a single heading (e.g., "The Amputee Coalition helped to recruit participants through its website and social media platforms.").*

#### 4. TERM AND TERMINATION

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. The agreement will be terminated upon the end of the study period, or upon the request of the partner. The AC may terminate this agreement and remove the study from our website if the partner does not turn in annual reports.

For AC

For PARTNER

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

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

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

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

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

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

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

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

## Appendix 7: Annual Update Report

As part of your Research Agreement with the Amputee Coalition, you are required to submit an Annual Update Report. Failure to do so may result in termination of your Research Agreement. Please contact [research@amputee-coalition.org](mailto:research@amputee-coalition.org) if you have any questions.

Research Correspondent (First, Last Name)

Email address

Phone Number

### Study Information

Study Title

How many subjects have been enrolled in your study?

To reach your recruitment goal, how many more subjects are still needed for enrollment?

Approximately how many subjects that have been enrolled were recruited as a result of your collaboration with the Amputee Coalition? (If unknown, leave this section blank).

When does the subject enrollment period end?

Which of the following Demographics datapoints are you collecting?

- Sex
- Age
- Race & Ethnicity
- Cause of Limb Loss/ Limb Difference
- Level of Limb Loss/ Limb Difference
- Other: (describe)

### Impact Indicators

List any measures of Quality of Life and/or Self-Efficacy that are included as outcomes in your research study.

Upload a summary of the Demographic Data and Impact Indicators that have been collected thus far (if applicable).

This information will not be made public and will be used for our informational purposes only to measure the impact of our research outreach efforts.

Select files...

or drag and drop files here

Have any publications resulted from this research study since entering into a Research Agreement with the Amputee Coalition?

- Yes – Attach any publication(s) here that you wish to share with our members (optional).
- No