

Cavernous Malformation Biobank Biological Sample Request Instructions

The Alliance to Cure Cavernous Malformation (ACCM) funds and manages a biobank of CCM patient samples as a resource for CCM researchers. Collection and sharing of biological samples and information are done in accordance with the patient informed consent procedures of our IRB approved protocol. ACCM will provide de-identified biological samples and accompanying clinical information to researchers upon request.

Eligibility:

Investigators must have an MD, PhD, MD/PhD or equivalent and be employed at an accredited or otherwise nationally recognized academic, non-profit, or governmental institution. Investigators may be based in the United States or abroad, and applicants need not be United States citizens.

Sample Request Procedure:

Sample requests must be approved by ACCM prior to distribution of the samples. Investigators may email Angela Glading (angela.glading@alliancetocure.org) to discuss availability of a specific sample type prior to submitting a formal request.

To request samples, all researchers must complete two documents:

- 1) Biological Sample Request Form (with associated documentation)
- 2) Material Transfer Agreement

One of Alliance to Cure's important functions is to inform members about advances in research into cerebral cavernous malformations (CCM). Please note that the Layman's Summary and Significance sections may be made public if your request is approved. These sections need not reveal anything that would jeopardize any confidentiality associated with your project. The Alliance reserves the right to edit these descriptions for length and clarity prior to publication. If you have confidentiality concerns, please contact Angela Glading (angela.glading@alliancetocure.org).

Biological Sample Request Form Instructions:

A. Cover Page

1. Title of Project

Enter a brief descriptive title of the project.

2. Principal Investigator

The PD/PI is the individual responsible for the overall scientific and technical direction of the project and will be the main contact for the project.

3. IRB Approved Protocol Title

ACCM typically provides only de-identified biological samples. However, all studies are required to be reviewed/approved by the investigator's institutional IRB (or equivalent), even if the study is eventually determined to be exempt. Please provide the protocol title submitted to the IRB.

4. Number of samples requested.

Please provide the number of samples needed for the study. A minimum and maximum range may be provided. Justification for the sample size should be included in the Scientific Description of Proposed Use.

5. Sample Type and Specifications.

List sample type (plasma, DNA, RNA, CCM surgical specimens, etc.) and any demographic or natural history specifications necessary for the study. Specifications may include age, sex, region, mutation status, family history of CCM, etc.

The CCM Biobank collects and stores several sample types. To determine sample type availability, investigators may email questions to Angela Glading (angela.glading@alliancetocure.org) prior to submitting a formal request.

6. Applicant Organization

Please list the name and mailing address of the PI's primary organization.

7. Type of Organization

Please check the box associated with the PI's primary organization type.

8. Applicant Certification and Acceptance.

Applicants must sign and date the form prior to submission.

B. Layman's Summary

Provide a brief description of your study for dissemination to our members in our newsletter (if application is approved). In ten lines or less, describe the goals, methods, and predicted outcome(s) of your study to a lay audience.

C. Significance

Briefly highlight the proposal's significance to the CCM community, including its potential impact on diagnosis, clinical care, and treatment of CCM. This section should also include a description of how the study results will be disseminated to a) the participants* and b) the CCM community as a whole, and a projected timeline.

**Investigators are discouraged from contacting participants directly. ACCM can and will communicate sample-specific results to participants on behalf of the investigator.*

Scientific Description of Proposed Use

Describe your proposal in sufficient scientific detail for evaluation by the ACCM. Please do not exceed one page*. A suggested format is listed below.

1. Rationale and hypothesis: State critical background information that prompted the study and the primary hypothesis to be tested.
2. Methods: Describe study design, methods, and data analysis.
3. Next steps: Describe how you plan to utilize the knowledge gained from the project, i.e. publication, further grant applications, etc.

**A bibliography may be appended as a second page.*

Other required documentation:

1. All applicants must submit documentation that their research protocol has been reviewed/approved by their local IRB or equivalent.
2. Applicants must submit documentation of grants, contracts, or other funds that support the proposed study (i.e. NIH Other Support or equivalent).

Material Transfer Agreement

The Material Transfer Agreement must be signed by the investigator and their institutional representative. Please ensure that the correct address is listed under 'shipping address' as this will be used to ship materials.

Submission and Review Process:

Email your sample request form, signed MTA, and any accompanying documentation to Holly Blei (hblei@alliancetocure.org). Complete requests will be reviewed within 30 days. If there are questions about your request during review, someone from ACCM will contact you directly.

You will be notified of approval or rejection of your request by email. Samples meeting the indicated specifications will be identified by Biobank/Registry staff, who will closely coordinate the shipment of samples from our Biobank facility and the transmission of sample associated information.

Shipping Information:

Shipment methods shall be coordinated as required for domestic and/or international transfer. Notification of shipping and tracking information will be provided by email. All appropriate biologic material transfer requirements of the CDC, OSHA, DOT, etc., and the transit carrier shall be adhered to. All shipping and handling costs will be borne by the applicant for materials transfer. The Alliance is not responsible for loss, damage, or mishandling once materials leave the Bank. The transit carrier shall be responsible for materials during shipping.