

Jackson Heart Study

Policies and Procedures for the Research Disposition of Participant Archived Blood and DNA Specimens

Policy

The Jackson Heart Study (JHS) has an irreplaceable and non-renewable archive of participant blood and DNA specimens. As guardians and custodians of this valuable resource, we have established the following procedures, which are propagated and developed to assure their appropriate use for research purposes.

The archive of specimens provides a unique opportunity to comply with the JHS goals and purposes today and in years to come for the scientific elucidation of more and more risk factors for cardiovascular and cerebrovascular disease. This document specifically defines the process for requesting specimens, criteria for the evaluation of the request, and assurances that the specimens will meet the expected goals of the research proposal.

Procedure

The applicant for the JHS archived specimens submits the completed application: "Application to Jackson Heart Study Archived Specimens" available on the JHS website <https://www.jacksonheartstudy.org> along with the Ancillary Studies Application. The Ancillary Studies Subcommittee will submit the "Specimen Application" to the JHS Lab Subcommittee for review. After an administrative review to determine the completeness of the application, nature of the request, and review of records to assure that the request is not a duplication of other JHS research, the application is reviewed by the committee to determine the following:

1. Documentation of the scientific authenticity for the request for participant blood or DNA specimen
 - a. Are the goals and objectives compatible with those of the JHS?
 - b. Are the scientific methods described sufficiently to evaluate the potential for success?
 - c. Are the methods correct for the goals of the research?
 - d. Is there sufficient information to ascertain the potential for success?
 - e. Is the literature review appropriate?
2. Availability of the requested specimen in accordance with the updated Specimen Tracking Table
3. Impact of the request on the archive:
 - a. Does sample to be used exhaust that specific volume of archived sample, or after freeze thaw, can the residual specimen be used for other research?
 - b. What kind of sample is left for future research?
 - c. Do the goals and outcome of the research justify the use of this limited specimen?
4. Impact of request on future requests for these kinds of samples as they relate to the permanent threshold for a sample to be archived in perpetuity.
5. Does this request exhaust our archive except for that archived in perpetuity?
6. Does the researcher have resources to properly store the specimen:

a. Example: When stored at freezing temperatures until analyzed, -70⁰ C, does the laboratory have emergency power to the freezer 24/7 to prevent loss of the specimen with the loss of electricity?

7. What will happen to any residual specimen?

Criteria Required to Establish Priority Order

For studies involving serum and plasma, smaller volume requests are viewed favorably. V250 uL or less.

1. The sample type (serum, EDTA, citrate) in greatest abundance will be approved first; justification is needed to approve samples with lesser abundance.
2. The priority order for approval of samples is first Exam 2 and 3 samples and last Exam 1 (baseline) samples. Justification is needed to approve baseline samples.
3. Release of a scarce sample may be delayed until there is more than one user of the specimen at the same time.
4. Release of a scarce sample may be delayed because of the need for sample analysis (e.g., genotyping) to be conducted within a study or lab of an already existing study, with the agreement that the investigator proposing the new analyte or SNP analysis will be provided the data(e.g., SNP or analyte) through the JHS data release policy.
5. Small sample required with small impact on archive
6. DNA methods not using plasma or serum
7. New method providing better analysis of a controversial parameter
8. Directly related to known and accepted risk factors for the JHS population
9. Results will have immediate impact on patient interventions
10. New parameter (risk factor) identification in the JHS population
11. Risk factor or parameter for comparison to another study
12. New parameter that would validate or explain findings in another study

General Requirements for Approval

1. The application has been properly submitted on a "JHS Archived Specimen Application Form", with an acknowledgement from prospective investigators that the policies and conditions specified by the JHS will be followed.
2. There is documentation that after analyses are completed, any residual specimens will be returned without delay to the Central Laboratory for re-inventory and storage.
3. Documentation is provided indicating that JHS is the best resource available
4. The project is consistent with the JHS mission and goals and will add substantially to the JHS

Scenarios for Disapproval

1. The study exhausts a very limited specimen supply, preventing future research
2. The details on how the samples are to be stored and maintained at the research site is not evident in the proposal
3. Use of the last thawed aliquot of DNA will not be approved
4. Proposals for pilot studies using JHS specimens will not be considered
5. Based on expert analysis the proposed research cannot be done as described

Committee Action

Upon completion of the written response to the assessment questions and their documentation, the committee will review the documents and determine whether the specimens should be made available.

Approved: The archiving center is notified in writing or electronically that these specimens are to be sent to the applicant. All important telephone numbers and any known specimen handling issues etc are on file. The Archiving Center will make written and verbal contact with the applicant to assure proper receipt of the specimens.

Approved but delayed: The committee will notify the applicant that the request is approved, but must be delayed because of the limited specimen volume, and the need to have more than one user of the specimen at the same time.

Not Approved: The committee will notify the applicant in writing that the request is not approved and why. Reapplications will be encouraged.

Audit Process

1. Quarterly Rectification of Specimen Releases and Notification of Available Specimens
2. Quarterly Audit of the Requests of the Last Quarter, and Yearly, and Request Dispositions