

Huntington Study Group Policy for Storage and Use of Biological Human Research Samples

Background and Rationale:

The Huntington Study Group (founded in 1993) is an international consortium of scientific investigators from academic and research centers who are committed to the cooperative planning, implementation, analysis and reporting of controlled clinical trials and therapeutic research for Huntington's Disease (HD). The goal of the HSG is to advance knowledge about the cause, pathogenesis and clinical impact of HD, and to systematically examine promising therapeutic interventions that may lead to a cure or amelioration of symptoms.

The HSG was founded on the basis of collaborative academic research and the premise that our whole is greater than the sum of our individual investigators and their institutions. The sharing of materials and data among our members is a cornerstone of the HSG's collaborative efforts and is essential to our goal of advancing knowledge. The benchmark principles of the HSG are as follows:

1. free and unrestricted right to access and publish data
2. strict conflict-of-interest policies and full disclosure of actual and potential conflicts
3. democratic governance
4. open meetings for scientists, HD individuals, and their families

Over the past five years, the HSG has collected and stored biological material, primarily blood, DNA samples and related data, which were collected in the context of our multi-center studies and under the informed consent provisions of our institutional review boards. This document will set forth the principles under which such samples shall be stored and utilized both during the course of the study in which it was collected and for future research endeavors.

Principles Concerning the Storage and Utilization of Biological Materials:

Statement of Position

It is the stated position of the HSG that the rationale for collecting and storing biological materials is to make these materials widely available for current and future use by researchers based at academic institutions with proposals of scientific merit as evaluated by their peers (the HSG Steering and Executive Committees as described below). Nothing in this policy should be viewed or used as an impediment to additional meritorious HD research, in keeping with the informed consent provisions agreed to by study subjects. All research using the biological materials and accompanying data shall be performed in compliance with research regulations and ethical principals, including, but not limited to, review and approval by an appropriate Institutional Review Board ("IRB").

Storage, Oversight and Usage of DNA and other Biological Materials During the Course of a Study:

1. For all DNA and other biological materials collected during the course of a study, the Huntington Study Group Executive Committee and its duly appointed Steering Committees shall be responsible for the storage, monitoring and distribution of all samples. "During the course of the study" shall commence at the time when a contract or award is executed and shall continue until 30 days after publication of the major scientific report, including publication of all primary and secondary study results.
2. DNA and other biological materials may be used only as authorized by the study subject as set forth in the informed consent document. Research subjects will be offered a minimum of two options with regard to the future use of their biological materials:
 - a. Subjects may give permission to the HSG to keep their blood sample indefinitely and for the HSG and/or other individuals and entities to use the sample for future HD-related research; or
 - b. Subjects may request that their sample be destroyed after the specific testing required for the study has been completed.

Subjects that elect option "a" may also later elect to rescind permission for the sample to be used in future research, provided that the HSG will use its best efforts to stop any additional studies. However, the HSG may not be able to guarantee that it will be possible in every instance to locate and stop such future research once materials have been shared with other investigators.

3. During the course of the study, additional requests to use blood, DNA or other biological materials or associated data collected during the study shall be presented to the study Steering Committee. The Steering Committee will determine whether such additional use is appropriate, and will evaluate such requests upon consideration of the scientific merit of the proposal, the conflict or burden such request would place upon the primary study (if any), the provisions of the informed consent document(s), the credentials of the proposed collaborator(s), the financial resources available to the proposer to support the costs of such a substudy, and the likelihood of publication or public dissemination of the results of such a substudy.
4. For potential access to correlative study data, the Steering Committee may permit access when the criteria set forth in Section 3 have been met, and the requesting party agrees to comply with the following additional requirements:
 - a. confidentiality of testing results and/or other data are appropriately protected;
 - b. adequate protections to maintain necessary blindness are in place to ensure the integrity of the trial;
 - c. individual test results are never released directly to individual study subjects. In some cases, as specified by study protocol, individual test results shall also not be released to study personnel who are required to remain blinded to test results.

5. For biological proposals that are approved by the study Steering Committee, the transfer or provision of biological materials to the collaborators shall be via Material Transfer Agreement ("MTA") between the institution where the chair of the Executive Committee is primarily affiliated (currently the University of Rochester) on behalf of the Huntington Study Group, and the non-profit academic institution representing the proposed collaborator(s). Such MTA shall follow the format and principles devised by the National Institutes of Health as set forth in the Uniform Biological Material Transfer Agreement ("UBMTA") (which was developed as a model transfer agreement to simplify the process of sharing biological materials with other academic researchers). The major principles of the UBMTA are that: non-profit institutions agree to expeditiously arrange the transfer of the material(s) so as not to delay scientific efforts; materials are to be used solely for teaching and academic research purposes and shall not be used for commercial purposes without an appropriate licensing agreement with the provider; the provider retains ownership of the materials, but the recipient has ownership rights to modifications or work created in part with the materials; materials shall be provided at cost to non-profit institutions; and a statement that the UBMTA provisions are not to be interpreted to prevent or delay publication of research findings resulting from the use of the material provided pursuant to the agreement.

6. For MTA's with non-profit, academic institutions and entities, the fee for providing such biological materials will be that necessary to compensate for the costs of storage, transfer and handling incurred by the HSG. Such non-profit entities shall agree not to use the biological materials for any commercial purposes, including but not limited to the sale, lease, license, or other transfer of the materials to a for-profit organization. Materials transferred to for-profit entities shall be transferred via a licensing agreement which sets forth the terms and conditions, including financial terms, under which the samples will be transferred, utilized and commercialized. All funds obtained from the licensing of biological materials will be used by the HSG to offset the expenses of maintaining the samples and to further the goals and objectives of the HSG.

7. During the course of a study, the samples collected for the study shall be stored and maintained at the laboratory or laboratories conducting the primary analysis of the samples as specified by the study Steering Committee. The samples remain the property of the HSG and not of the laboratories performing specific assays or maintaining the samples as a repository. The laboratories shall ensure that the samples are stored and maintained in such a fashion as to permit destruction of individual samples if such a request is received on behalf of a study subject. The Steering Committee and HSG Executive Committee shall be responsible for ensuring that samples are appropriately protected, stored, maintained, and used only as authorized by the Steering Committee. The Steering and Executive Committees shall be authorized to appoint consultant(s) who shall be charged with auditing the laboratory(ies) to ensure compliance with the standards and guidelines set forth by those committees. All laboratories that analyze or store samples on behalf of the HSG will sign this document, indicating their acceptance of the terms contained herein and signifying their agreement to abide by those terms.

Storage, Oversight and Usage of DNA and other Biological Materials Following the Completion of a Study:

1. Following the conclusion of a study (as defined in Section 1, above), all samples that subjects agreed would become the property of the HSG shall be overseen by the Executive Committee or its duly appointed representative. The Executive Committee is duly authorized to maintain the samples in one or more designated repository(ies), and is also authorized to appoint a Biological Materials Oversight Committee which shall report back to the Executive Committee concerning the storage, inventory, monitoring and distribution of all samples.

2. The principles set forth above regarding review of scientific proposals for use of biological materials and the evaluation of the merit (of same) shall remain in place following the conclusion of a study. Materials may only be utilized or transferred from the repository in keeping with the Material Transfer and Licensing Agreement principles set forth in Sections 5 and 6 above.

3. During the course of storage of samples, the HSG shall be authorized to evaluate the merits of continued retention of samples. If, in the opinion of the Executive Committee and Biological Materials Oversight Committee, continued retention of some or all of the samples would be unlikely to lead to scientific advances due to redundancy, aging of the sample(s) or other factors, the HSG shall transfer or dispose of the samples in an appropriate fashion.

4. In the event of dissolution of the HSG, the samples shall be transferred, if possible, to another academic or non-profit institution or entity engaged in research related to Huntington's Disease and/or other related neurological conditions.

Reviewed and approved by the Huntington Study Group Executive Committee on April 24, 2001.