



Delaware Health and Social Services Human Subjects Review Board Procedures/Guidance

Updated August 30, 2017

Overview

- **Policy:** In compliance with [Delaware Health and Social Services \(DHSS\) Policy Memorandum 55](#), regardless of funding source, all research projects involving DHSS clients as subjects must be approved by the Human Subjects Review Board (HSRB).
- **Ethical principles:** This research, and the Board's activities, are guided by the ethical principles in: 1) [The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#) of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; and 2) other appropriate ethical standards recognized by federal departments and agencies that have adopted the [Federal Policy for the Protection of Human Subjects](#), known as the Common Rule.
- **Regulations:** The HSRB is the DHSS Privacy Board, and all research projects pertaining to DHSS and coming under the auspices of the [Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 \(HIPAA\)](#) are reviewed to assure their compliance with the requirements of 45 CFR 160 and 164.
- **Research definition:** According to [federal regulations](#), "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."
- **Resources:** Additional information about research and privacy standards can be found on the following websites: [Department of Health and Human Services, Office for Human Research Protections](#) and [Department of Health and Human Services, Health Information Privacy \(HIPAA Information\)](#).

Responsibilities of Researchers

- **Application:** Researchers must complete and submit a [DPH/HSRB Application](#) prior to initiating research activities. Instructions for completing the application are included on the application form.
- **Training:** The HSRB requires that researchers complete training on human subject protection and privacy rights. Documentation of the completion of training must be included as part of the HSRB application. The HSRB recommends [Protecting Human Research Participants](#), a free online tutorial provided by the National Institute of Health but also considers other formal training completed by researchers.
- **Coordination with affected DHSS Divisions:** Researchers must obtain the cooperation of the Divisions whose clients and data are the subjects of proposed research. As indicated on the

application instructions, projects must be approved by appropriate Division Directors before applications are submitted to the HSRB.

- **Appearance at HSRB Meetings:** Researcher or representatives are expected to be present (in person or by phone) when projects are being considered by the HSRB.
- **Ongoing interaction with the HSRB:** Once projects are approved, researchers are required to maintain ongoing relationships with the HSRB until projects are completed, as indicated on HSRB approval letters. Researchers are required to inform the HSRB Chairperson as soon as possible in the event of unanticipated problems involving risks to subjects or others. Electronic communication is the preferred medium with telephone follow-up, as necessary.
- **Protocol revisions:** Researchers are required to report any proposed changes in approved research protocols prior to initiating them except on a temporary basis when necessary to avoid immediate hazards to subjects.
- **Continuing review and final report:** Researchers are required to report to the HSRB on an annual basis (or more frequently, if warranted by the degree of risk posed by the project or when otherwise required by the HSRB) using the [HSRB Report Form](#).

Responsibilities of DHSS Divisions

- **Initial review and determination:** DHSS divisions whose clients and data are the subjects of proposed research projects make initial determinations regarding these projects based on considerations such as the value of the projects, the time commitment required, and the resources being made available by researchers. Divisions also must consider any HIPAA-related obligations and be prepared to carry out associated recordkeeping.
- **Review by Attorney General's Office:** Divisions determine whether consultation is required from the Attorney General's Office regarding any possible legal implications of projects and should not approve projects until a satisfactory resolution of legal issues is reached.

Responsibilities of the HSRB

- **Initial Screening:** The HSRB Chairperson performs an initial screening of all applications and ensures that they are complete prior to distributing them to HSRB members. When necessary and in collaboration with another member of the HSRB, the Chairperson determines if proposed activities qualify for exemptions from the requirements of the Common Rule or HIPAA's Privacy Rule. In such cases, all relevant parties are notified that no further HSRB involvement is needed.
- **Expedited Review:** The HSRB does not use expedited review for new projects.
 - **Board meetings:** Meetings are scheduled on a monthly basis for both initial and continuing reviews. Research applications submitted to the HSRB in sufficient time for distribution to members two weeks prior to meetings are included on meeting agendas. Teleconference lines are established for meetings to allow members and researchers the option of participating by phone.

- **HSRB decisions:** During HSRB meetings, proposed projects are either: 1) approved as submitted; 2) determined to require modifications; or 3) disapproved. No appeal process is made available for projects which are disapproved, but researchers are free to revise projects and resubmit them. For projects which are approved, the HSRB decides if continuing review needs to take place more frequently than once a year. (Decisions are based on such criteria as whether projects pose a significantly high risk to participants or if there have been negative prior experiences with researchers.) Minutes are taken to document all HSRB decisions.
 - **Decision notifications:** The HSRB Chairperson is responsible for notifying the DHSS Cabinet Secretary, who has final sign-off authority regarding HSRB decisions. The Secretary is not authorized to approve projects that the HSRB has rejected but can reject projects for reasons unrelated to the protection of human subjects. Such rejections are subject to reconsideration. Once the Secretary makes these decisions, the HSRB Chairperson informs researchers in writing.
 - **Protocol changes:** Notification letters specify that no changes may be made prior to HSRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects.
 - **Ongoing interaction with researchers:** Researchers are required to notify the HSRB Chairperson immediately if unanticipated problems involving risks to subjects or others occur, as described above under “Responsibilities of Researchers.” The HSRB has the authority to withdraw approval and terminate projects if appropriate safeguards to protect client rights are not being followed. As with the initial approval process, researchers can develop and submit revised procedures to avoid project termination. Also, as specified above, researchers must notify the HSRB Chairperson of any plan to modify the project.
 - **Notification of violations:** The HSRB Chairperson is responsible for promptly informing the DHSS Cabinet Secretary and the federal Office of Human Research Protection (when federally-funded projects are involved) in writing of: 1) unanticipated problems involving risks to subjects or others; 2) serious or continuing noncompliance with the federal regulations or HSRB requirements; or 3) suspension or termination of HSRB approval.

HIPAA-Specific Policies

- **Minimum Necessary rule:** Researchers requests for access to protected health information are reviewed to ensure that approval is given to release only such information which is reasonably necessary to accomplish the purposes for which requests are made.
- **Preparatory to research provisions:** HIPAA regulations give institutions the authority to allow external researchers to view client/patient/consumer files that contain protected health information during the research planning phase if the external researcher meets certain conditions, such as not removing the protected health information from the premises. However, DHSS has a more restrictive policy toward such disclosures and will not permit access unless warranted by the nature of the research and unless all other possible ways of accessing the information have been exhausted.
- **Guidelines for authorization:** See the [HRSB’s HIPAA Guidelines for Authorization](#) for detailed information about requirements for HIPAA-related authorization and notification.

Responsibilities of HSRB Members

- **Appointments:** HSRB members are appointed for two-year terms with no term limitations.
- **Training:** All HSRB members are required to complete the [Protecting Human Research Participants](#) training provided by the National Institute of Health.
 - **Recusal:** In accordance with federal regulations, HSRB members may not participate in the initial or continuing review of projects in which they have a personal financial conflict of interest, except to provide information requested by the HSRB. In such cases, members absent themselves from meetings after providing requested information and remain absent during further discussion and voting.

HSRB Contact Information

- **Administrative contact:** The HSRB is administered by the Planning and Quality Control Unit at the DHSS Division of Management Services (DMS). See the DMS website for [Planning and Quality Control contact information](#).
- **Chairperson contact:** The HSRB Chairperson is Janet Villarreal, who can be contacted at janet.villarreal@delaware.gov