Issuing Department: Human Subjects Protection Program
Policy Number: 2011-019.0
Policy Title: Research Registries and Repositories

Purpose

The purpose of this policy is to outline the general framework for obtaining approval from the Institutional Review Board for a research registry and/or repository (often referred to as a bank).

Definitions

See policy 2011-007.0 for definitions of the following terms:

Individually Identifiable Health Information | IRB Approval | Registry | Repository

Policy

Clinical Care Data: Information that is collected and stored in clinical registries/repositories in the course of clinical care and for clinical purposes does not require IRB approval. De-identified information/samples may be released for research by an individual authorized to have clinical access to the information, e.g. a treating physician or clinical data manager, when this person is not involved in the research project making use of the information/sample. The information / samples may be coded such that the authorized individual granting the release can link the information back to the individual but the recipient cannot. The code cannot be comprised of any identifiable information and the recipient cannot at any time know the mechanism for creating the code. Furthermore individually identifiable health information / samples within the clinical registry/repository may not be used for research purposes without first obtaining IRB approval.

Research Data: IRB approval must be obtained for the creation of a research registry or repository. IRB approval must also be sought for each subsequent research project that will make use of the individually identifiable health information in the registry or repository prior to any research being implemented.

An individual or individuals must be designated as the data manager for a registry/repository. Only those designated as the Principal Investigator (PI) and/or data manager will be allowed to release identifiable registry data on individuals for purposes of recruiting those registry participants into other IRB approved studies.

The PI or data manager of the registry/repository may de-identify information for release to researchers, and the researchers do not have to have IRB approval to receive the de-identified data. The data may be coded such that the PI or manager can link the information back to the individual but the recipient cannot. The code cannot be comprised of any identifiable information. The researchers cannot at any time know the mechanism for creating the code or how to link the code to the individual and must sign a statement to that effect. In this scenario the PI cannot be a part of the research team receiving the de-identified information unless specific approval by the IRB of a human subject research determination form has been obtained. In order to grant such approval the IRB must determine that adequate measures are in place to keep the data de-identified to the PI. If the IRB cannot make this determination, the PI must submit a complete IRB application.

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If data or samples will be stored at an external site, e.g. become the property of the sponsor, the IRB may require that a copy of that site's policies for confidentiality and use of the samples be submitted for review.

Research registries / repositories may be approved through expedited review if one of the expedited categories is applicable. The IRB reserves the right to require review by the convened board.

Procedure

To obtain IRB approval for a research registry / repository the PI completes the IRB application for such and submits it along with corresponding documents as noted on the application submission checklist to the IRB for review and approval.

The IRB follows its routine practice for conducting reviews.

Related Policies

2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board - Review by Convened Board
2011-009.12 – Institutional Review Board – Criteria for Approval

Basis

45 CFR 46.111
OHRP Guidance on Biological Materials and Data available at
http://www.hhs.gov/ohrp/policy/biodata/index.html

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