Registries, Databases, and Repositories

Definitions

Database: a collection of information (i.e., data) arranged for ease of search and retrieval of information.

Registry: a collection of information or databases whose organizers receive information from multiple sources, maintain the information over time, and control access to the information.

Repository: a collection of biospecimens whose organizers receive specimens from multiple sources, maintain the specimens over time, and control access to the specimens.

Registries, data banks, and tissue banks are all considered "repositories" for regulatory purposes.

Non-research repositories

IRB approval is not required for creation or use of a non-research database or biospecimen collection but is required to use these resources for research purposes.

IRB Review

Creation or use of a repository or registry for research requires IRB review (either expedited or full board review, depending on the protocol submitted). Woman's does not allow exempt categories 7 and 8 at this time.

A research database may also be created specifically as a resource for future research. IRB oversight is required to set up and maintain a research database.

Biospecimens in research studies – leftover or future use

Biospecimens may be collected to achieve one or more of the objectives of a single study with disposal of the leftover materials at the end of the study. A repository is created if the leftover materials are stored for future use. If there is an intent to set up a repository, then the informed consent document should include language for subjects to opt-in or opt-out of storage of their data for future research purposes, a statement that the subject's biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit, and whether the research will or might include whole genome sequencing. The subject's decision as indicated on the consent/authorization must be respected and tracked.

Please note that exempt categories 7 and 8 are not used at Woman's at this time.

Specimens may also be collected specifically for the purposes of future research either as part of a current research protocol, or as a standalone activity. IRB submission is required for each research protocol that creates a repository.

Creating a biospecimen/data repository

A repository protocol may be submitted to the IRB either to:

- Define the operating parameters for establishing and maintaining a research repository; or
- Convert an existing research database, non-research database, or non-research repository into a research repository.

The IRB can approve relatively broad parameters for collecting, storing, sharing, and using the repository's information and/or specimens in research. To maximize the utility of the data/biospecimens retained in the repository requires careful planning and clear operating policies and procedures (SOP). The mechanisms put in place will determine the requirements for IRB oversight of future uses of the materials in the repository.

Investigators who collect the data/biospecimens (the collector) that will be stored in a repository must agree in writing to specific conditions stipulated by the Repository IRB (the IRB exercising oversight of the repository). Collectors other responsibilities include:

- Obtaining appropriate IRB approval from their local IRB
- Obtaining and documenting informed consent/authorization as required by their IRB;
- Following the protocol procedures including:
- Obtaining the required data/biospecimens in the appropriate form and storage medium and at the specified timepoints;
- Coding and labeling the samples before shipping or uploading the data/biospecimens to the registry/repository;
- Removing all unnecessary PHI from the data/biospecimens;
- Methods for maintaining and securing PHI associated with the data/biospecimens sent to the registry/repository and any links (key) between the donor and the data/biospecimens as specified in the protocol.

Codes

Specimen repositories may include phenotypic data (demographic and/or medical information) about the individuals from whom the specimens were obtained. When they do contain phenotype data, the repository is both a registry and a biospecimen repository. These types of repositories may often maintain codes that link the information and specimens to the donors' identities. The key to the code may be maintained by either the registry or by the provider of the data/biospecimen.

Writing a repository protocol

Under a repository protocol, the IRB can approve relatively broad parameters for collecting, storing, sharing, and using the repository's information and/or specimens in research. A repository protocol should include the following:

- The purpose and aims of the repository
- The operating parameters for establishing and maintaining the research repository, or for converting an existing research database, non-research database, or non-research repository into a research repository.
- The specific conditions under which data/specimens may be accepted into the repository, including submission to the repository of a copy of each subject's signed authorization and signed consent document; include subject eligibility and procedure(s) for procuring data/specimens
- Examples of the types of research to be conducted, if known
- Description of any genetic analysis of specimens, if applicable
- Where and how long the specimens/data will be stored
- Conditions under which data/specimens will be shared with Woman's researchers and researchers outside Woman's, including use of a Limited Data Set (if applicable)
- A detailed description of the physical and procedural mechanisms for the secure receipt, storage, and transmission of information and specimens to ensure the protection of subjects' privacy and the confidentiality of subjects' data/specimens,
- Possible risks and management of risks, including risks to privacy and confidentiality, and procedures for protecting the privacy of subjects and maintaining the confidentiality of data.
- Procedure for withdrawal of consent and disposition of any remaining specimens.
- Any coding of specimens/data (note: Codes and numbers assigned to specimens or data may not be derived from or related to information about the subject)
- The repository's policy (and process) regarding return of individual research results to subjects, including provisions for counseling.
- Any costs or payments to subjects.

Investigators may want to obtain a Certificate of Confidentiality from NIH, if applicable, to protect the confidentiality of repository specimens and data. Information can be accessed at http://grants.nih.gov/grants/policy/coc/

Broad consent

Standard treatment and surgical consents rarely meet the regulatory requirements for informed consent for research. If collection for research use of any leftover surgery specimens or any

prospective collection of specimens or data for research purposes is anticipated, the subject should be consented for research use of their specimens and/or data.

The IRB may require researchers to obtain the informed consent of subjects for research involving information or specimens contained in non-research databases or repositories. If the research activity meets the criteria for waiver of informed consent and/or waiver of authorization, then the researcher may not need to obtain consent to access the information or biospecimens in the repository. More information about the criteria can be found in the Waiver of Consent and Waiver of HIPAA Authorization policies.

If a researcher wishes to create a biospecimen and/or data repository for future research use (either for a specific type of research or for a broader research use), a broad consent should be incorporated into the research plan to consent participants for this storage, maintenance, and use of their biospecimens. Broad consent (consent for unspecified future research) is permissible only for storage, maintenance, and secondary research use of identifiable private information and/or identifiable biospecimens. If the samples were collected for research purposes or are associated with information that can identify the donor, then informed consent must be obtained from the donor unless appropriately waived by the IRB.

Broad consent is an optional alternative that an investigator may choose instead, for example, conducting the research on non-identified information and non-identified biospecimens, having an IRB waive the requirement for informed consent, or obtaining consent for a specific study.

A repository consent form should include:

- A description of the purpose of the repository
- The types of research supported by the repository
- How participants' privacy will be protected and how the confidentiality of the data will be maintained
- How participants may withdraw their specimens/data from the repository
- The conditions and requirements under which repository information or materials will be shared with recipient-investigators inside and outside the institution
- And specific risks related to participating in the repository, mainly breach of confidentiality of the data being collected
- A description of any coding of specimens/data, if used
- Where human genetic research is anticipated, information about the consequences of DNA typing (e.g., regarding possible paternity determinations) and related confidentiality risks
- Return of any research results to participants, if applicable
- A statement that the subject's biospecimens may be used for commercial profit, if applicable, and if the subject will or will not share in this commercial profit

For more information about broad consent and required elements, refer to the policy Informed Consent Form Elements and Requirements.

HIPAA Considerations

Written HIPAA authorization for research use and disclosure of Protected Health Information (PHI) should be obtained from subjects who consent to participate in the repository, unless this requirement meets the criteria for waiver by the IRB.

PHI in non-research repositories may not be used or disclosed for research purposes unless:

- Written authorization for use and disclosure of PHI for research has been obtained from the subject, or
- The IRB approves and documents a waiver of the authorization, or
- The holder of the PHI receives and documents the HIPAA-required representations from the investigator and determines that the research involves only one or more of the following:

1) decedents' information
2) de-identified information
3) limited data sets, or
4) review preparatory research

Use of repositories by outside institutions

The information and specimens can be accessed by multiple investigators for multiple research projects. Some of the potential research uses may be anticipated at the time of collection but most cannot be specified at the time the repository is created. Investigators should have a written Data Use Agreement with Woman's to access any Woman's repository. The Data Use Agreement should specify under what conditions the data is being released to the recipient-investigators. (See the policy Limited Data Sets and Data Use Agreements for more information.)

When a repository is not human subjects research

From OHRP:

Human subjects would not be involved when material submitted to a repository satisfies both of the following conditions:

1) The material, in its entirety, was collected for purposes other than submission to the Repository (e.g., the material was collected solely for clinical purposes, or for legitimate

but unrelated research purposes, with no "extra" material collected for submission to the Repository)
and

2) The material is submitted to the Repository without any identifiable private data or information (i.e., no codes or linkers of any sort may be maintained, either by the Submitter or by the Repository, that would permit access to identifiable private data or information about the living individual from whom the material was obtained).

Additional Guidance:

NIH Guidance on Research Repositories:

https://privacyruleandresearch.nih.gov/research_repositories.asp

Tissue and Data Repositories: Issues and IRB Concerns:

https://orra.rutgers.edu/sites/orra.rutgers.edu/files/HSPP/Webinars/educ_HSPP_Conf_Tissue_%20Data_Repositories_03.2007_NB.pdf

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