Northwestern University IRB Guidelines for Registries, Student Subject Pools, and Specimen Repositories

These guidelines apply to proposals to store data and/or specimens for future research use. When designing a protocol and consent form to store and use data and/or specimens for future research use, considering these guidelines will help both to minimize compliance problems and ensure the greatest possible value for the stored data and/or specimens.

Terms and Definitions

For consistency, the NU IRB will use the following terms as defined below (in other contexts, you may sometimes find these terms used differently).

***Registry**:*

A registry is a tool used to identify and track a group of individuals who have similar characteristics. A recruitment registry is a registry whose primary purpose is to provide investigators with pools of potential study participants. Recruitment registries are often set by departments or research groups who have ongoing recruitment initiatives for multiple studies and fit it useful to have a pool of potential participants who may be eligible for multiple studies. Some NU units use the term "subject pool" -- subject pools are a type of recruitment registry. Information collected and stored in a recruitment registry varies and can include health history, screening information, and demographics, as well as contact information.

The organizers of a registry:

- May receive information from multiple sources;
- Maintain the information over time;
- Control access to the information;
- Permit multiple individuals to use the information for a variety of purposes

***Repository**:*

A specimen repository (also known as a tissue bank) is a mechanism for maintaining biological specimens (e.g., tissue, blood, other biological samples) for future research use. Biospecimens stored in a repository may be collected through research studies or clinical procedures, and may be collected retrospectively, prospectively, or both.

Activities of a Repository include:

- Maintaining the specimens over time.
- Controlling access to the biospecimens.
- Permitting multiple individuals to use the biospecimens for a variety of purposes, which may evolve over time.

- Including phenotypic data (demographic and/or medical information) about the individuals from whom the specimens were obtained. NOTE: When a repository includes phenotype data for biospecimens, the repository is considered both a registry and a biospecimen repository.
- Oftentimes maintaining codes that link the information and specimens to their donor's identity. The key to the code may be maintained by either the repository or by the provider of the data/biospecimen.

Research vs. Non-Research Databases and Repositories

Databases and repositories are frequently created and maintained for purposes unrelated to research. For example, NU maintains a variety of records intended for diagnosis, treatment, billing, marketing, and quality improvement/control purposes. IRB oversight is required only when there is a **research** aspect to the database or repository. If a registry/repository is (a) solely for research, (b) developed for multiple purposes that include research objectives, or (c) includes additional variables that are collected purely for research, then an element of the activity is research and the registry/repository requires IRB oversight.

IRB protocols for registries and repositories that are designed to be used and/or shared for not-yet-specified future research should not also include specific hypotheses and planned analyses. (One exception is if the repository has the resources to conduct some up-front specimen analyses *solely* to provide additional value to future researchers.)

Proposals to use the data/specimens in a registry/repository for specific aims should be *submitted separately* to the IRB, unless the recipient will receive no identifiers per the registry/repository policies and procedures, in which case the recipient may not be doing human subjects research. All such specific aims must be within the scope of the registry or repository protocol (and consent, if applicable) – the scope of the registry/repository protocol and (if applicable) consent may be very broad.

IRB Review and HIPAA Requirements for Registries and Repositories: Registries and repositories to be used for research purposes require IRB approval for the creation and maintenance of the registry/repository. If protected health information (PHI), as defined by the HIPAA Privacy Rule, will be stored in the registry/repository, HIPAA Authorization must also be obtained from individuals for storage and use of their PHI. The IRB may waive HIPAA Authorization in certain situations in which data/specimens are being collected retrospectively. Future research projects that wish to use an established registry or repository must explain in the IRB protocol for the particular research project the plan to use the registry/repository.

For recruitment registries: Maintaining a one-time list of individuals who participated in a particular research study and are willing to be contacted for future research does **not** typically constitute a recruitment registry. However, if the list of participants is going to be added to over time, used by more than one researcher, and/or participants are specifically recruited to be in the registry, then this activity requires IRB review and oversight.

Considerations for Student Subject Pools:

IRB review is required for student subject pools that meet the definition of a recruitment registry.

Student subject pools must meet the following conditions to ensure that the student subjects voluntarily choose to participate:

• Student participation must be entirely voluntary; instructors, research lab supervisors or faculty advisors cannot require students to participate in a particular study.

• When research participation is introduced as a part of class curriculum, alternative, equivalent assignments must be offered to students. Such assignments must be agreed to by the course instructor before the protocol is submitted for review and, rather than being graded, these assignments must count as "complete" or "incomplete."

• When course credit is offered in exchange for participation, alternate means of earning equivalent credit for an equivalent commitment of time and effort must be provided to students.

• If a student does not show up for a scheduled experiment, federal regulations do not permit the student to be penalized (e.g. deduct credits previously earned by the student for taking part in other studies, or increase the number of credits that the student would have to earn in order to receive an equivalent amount of course credit). Students must be free to choose not to take part in research at any time prior to the start of their involvement.

• The consent form/script should detail the consequences of withdrawing from a study prior to completing the research activities. As a general rule, the student should receive credit even if the student withdraws before completing the research activities, unless the student withdraws immediately upon starting the research activities or there is clear evidence of bad faith on the part of the student.

IRB Protocol Requirements for Registries and Repositories

Protocols for creating registries and repositories for research purposes should include the following detailed information, as applicable:

- Purpose of collecting and storing data/specimens
- Inclusion/exclusion criteria and type(s) of data/specimens to be collected and stored. Include a list of the data variables to be stored in the registry/repository. Many research teams that maintain recruitment registries enroll people who screen-failed eligibility screenings for other specific studies – if you plan to include data in a registry from people who failed the eligibility screening process in specific studies, explain this in the registry protocol, along with how screen-failed participants will be informed about the registry.
- Recruitment strategies that will be used to recruit participants for the registry/repository.
- Source(s) and circumstances of data/specimen collection (obtained directly from participants, clinical pathology, ongoing research studies, etc.)

- Whether you intend to collect any follow-up data/specimens from participants (e.g., follow-up phone calls, questionnaires, additional data/specimens from standard of care visits, etc.)
- The consent process (and HIPAA Authorization process, if applicable) that will be used with participants whose data/specimens will be placed in the registry/repository. If you are seeking a waiver of consent and/or HIPAA Authorization, you must justify the reasons for a waiver in the protocol.
- Whether data/specimens will be linked to identifying information (i.e., direct identifiers, coding system with a key, de-identified)
- If the data include individually identifiable protected health information (PHI)
- Security provisions, including physical location and data security measures
- Length of time data/specimens are anticipated to be stored
- Any limits on intended future uses of data/specimens (e.g., for cancer research only)
- With whom data/specimens may be shared (including non-NU researchers, if applicable)
- Process for requesting and releasing data/specimens
- How data/specimens will be released (identifiable, coded, de-identified)
- Whether a specimen repository will receive the results of any genetic or other testing that may be performed with specimens accessed through the repository, and whether any incidental findings might be communicated to individuals whose specimens and data are contained in the repository
- Procedures by which participants can withdraw their data/specimens from the registry/repository, or whether de-identification would make withdrawal impossible
- Plan for continuing repository operations in absence (or departure) of the principal investigator
- Process for destruction or de-identification of identifiable or coded data/specimens at the end of the retention period.

Confidentiality and Data Security Considerations

The IRB will give careful consideration to the proposed confidentiality and security procedures for registries and repositories to ensure that the risks of a breach of information/specimens are minimized. Methods for handling and storing data stored in registries and repositories must comply with applicable NU/NMHC data policies.

Consideration should be given to obtaining a Certificate of Confidentiality (CoC) to protect the confidentiality of banked identifiable or coded data/specimens. Certificates of Confidentiality protect the privacy of research participants by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the participant consents or in a few other specific situations. Research studies funded by the National Institutes of Health (NIH) are automatically issued a CoC through their award. Other Department of Health and Human Services (HHS) agencies (FDA, CDC, SAMSHA, HRSA, IHS) issue CoCs for research they fund. Researchers can request a CoC from NIH for health-related studies that are not funded by HHS.

For more information, see NIH Certificate of Confidentiality kiosk.

Informed Consent and HIPAA Authorization

As a general rule, informed consent must be obtained for collection and storage of data and/or specimens for future research and should generally be obtained separately from consent to other research participation. HIPAA Authorization is also required when the data include protected health information. If a waiver of consent and/or HIPAA Authorization is requested, the protocol must justify why a waiver is appropriate.

Investigators should balance the ethical obligation to provide sufficient information regarding possible future research uses of stored data/specimens during the consent process with the practical issues of trying to anticipate and describe possible research uses of the materials. The consent process should be as specific as possible regarding the circumstances and any risks associated with data/specimen collection, and the procedures for maintaining security and confidentiality of the stored materials. In addition to the required elements of informed consent, the consent process should include the following information, as applicable:

- Any limits on data/specimens' intended future use (e.g., for cancer research only)
- Whether any identifying information will be kept, and if so, how it might be shared
- Certificate of Confidentiality information (if the study has a Certificate of Confidentiality)
- How long the data/specimens will be stored
- With whom the data/specimens may be shared (including non-NU researchers)
- How to withdraw data/specimens from the registry/repository (if possible – if de-identification of data/specimens would make withdrawal impossible, this must be explained)
- Whether participants in the registry/repository might be re-contacted in the future (e.g., for consent to future research, to return research results, etc.)
- When identifiable specimens and/or genetic information are stored and may be shared for future research, include a description of the protections of the Genetic Information Nondiscrimination Act
- Explain if data and/or specimens may be commercialized