HRP-337 | 3/29/2024

WORKSHEET: Database, Registry, Repository

The purpose of this worksheet is to provide support for IRB members reviewing requests to create a research database, registry, or repository.

1. Considerations for Research Databases, Registries, and Repositories.

**Justification and Significance.** The protocol provides sufficient justification for the need to develop a research database, registry, or repository by providing evidence regarding the need.

**Governance and Oversight.** The protocol includes:

Inclusion of adequate resources to develop, manage, and sustain the research database, registry, or repository.

A plan for continuing operations in the absence or departure of the PI.

Quality Assurance resource or plan to ensure the quality and integrity of the data or specimens collected and stored.

When applicable, includes an Honest Broker of Identifiable Information, who will have the authority and responsibility to act on behalf of the database/registry/repository to remove the link to research identifiers and clinical identifiers in order to provide data, specimens or images to researchers without revealing the identity of participants. The protocol should also reference the policies and procedures that enable the honest broker to perform his/her function.

When applicable, includes a Custodian of Specimens, who will be responsible for the management of a biospecimen resource. The protocol should also describe how the custodian will work with other key stakeholders in the management of the resource including the tracking of all relevant documentation for the resource and for ensuring that policies regarding access to the resource are in place and implemented according to appropriate guidelines.

**Data/Specimen Collection.** Consider the following:

If identifiable information will be collected outside of the Information Exchange, the investigator must have a plan for verifying that the patients have not opted out of research participation, and permission for or justification of authority for the investigator to collect the records for a research database, registry, or repository is evident.

If pre-existing data or specimens from research protocols will be transferred to the research database, registry, or repository, the protocol includes a list of those protocols, from which the data or specimens were originally collected, and includes reference from the original informed consent document(s) that allow for banking of information/specimens.

If specimens and/or health information will be included that derives from persons living outside the United States, the protocol includes justification for their inclusion and outlines the international laws that permit such a transfer of specimens and/or health information.

If there is an intent to update participant data in the future, the protocol includes a plan for verifying that the participant has not opted out of research participation.

**Data/Specimen Storage and Retention.** The protocol includes a plan for the storage, retention, and destruction of data / specimens, including reference to any standard operating procedures that will facilitate these processes.

**Data/Specimen Access and Release.** The protocol should:

Indicate who will have access to (inside and outside of the institution) the information/specimens.

Outline the process by which data/biospecimens will be shared with investigators.

Clarify whether the repository will or will not provide individually identifiable information or specimens to recipient investigators.

Include protections to prevent employers or insurers to gain access to research data. The protections should be consistent with GINA (Genetics Information Nondiscrimination Act).

**Confidentiality and Data Security.** The protocol should:

Describe the process for coding data and where the coding will be executed (e.g., at the site, by an honest broker, by the Registry personnel).

Who, if anyone, will retain the key to code linking subjects to identifiers. For example, the honest broker could be responsible for the key.

If the database, registry, or repository will maintain any information that can directly or indirectly (via the key to the code) identify the participants, the investigator must provide a justification.

Describe the intended duration for maintaining the link between individually identifiable data and the dataset and the process for destroying the link.

If protected health information will be collected, the obtaining and maintaining of the information must comply with relevant HIPAA provisions.

The protocol includes a plan to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) for storage, use, and transmission of data.

**Informed Consent.** For research databases, registries, or repositories that will prospectively collect directly from interacting or intervening with research participants, specimens or identifiable information, for the purpose of the database, registry, or repository, ensure that the process and documentation meets the requirements set forth in **WORKSHEET: Criteria for Approval (HRP-314)**.