Virginia Commonwealth University

Registries in Research

Data Collection Details

1. * **Select all involved in the study:**

☐ Specimen/Biologic Sample Collection
☐ Protected Health Information (PHI)
☐ Audio/Video
☐ Existing Data or Specimens Not From a Registry or Repository
☐ Use of Internet for Data Collection
☑ Registries/Repositories (Includes Accessing, Contributing or Creating)
☐ None of the Above

Registry/Repository Details

1. * **Select all that apply:**

☐ Contributing to an Existing Registry or Repository
☐ Creating a New Registry or Repository
☐ Accessing a Registry or Repository (Usage Protocol)
☐ Submitting Data to the NIH GWAS Registry

Establishing a Registry

Registry

- An organized collection of **retrievable, identifiable information** that is **intentionally maintained** for use as a prospective instrument for the conduct of research.
  - Also called "repository" or "data or specimen bank."
- Data/specimens collected for future research purposes
  - The collection of data or specimens DOES NOT constitute a registry IF the data or specimens will not be saved for future unspecified research purposes.
- Collaborative Research

IRB Consideration

- Responsibility for the integrity and management of the registry
- Access to the registry for research purposes and how is access granted?
- Identifiers (including codes)
- Future Use – any stipulations? Option to contact participants prior to future use?
- Access data for future use?
  - If so, how other researchers will be able to request access
  - How codes or identifiable data will be released to others
- Subjects' request to use, destroy or remove data
- How long the registry will be maintained
- Note: For contribution to Genome Wide Association Studies (GWAS) see WPP XVII-5 Genetic Research, Section D.

Privacy & Confidentiality

- Plan for protecting confidentiality (greatest risk for registry protocols):
  - Sending data/specimens outside of VCU?
  - Methods to organize and store information
  - Safeguards to prevent accidental or inappropriate release of information
  - Training of people who collect information for the registry;
  - ID & qualifications of people who are authorized to access or grant access to the registry
  - Conditions when registry information may be released for usage protocols.

Privacy & Confidentiality

- Example Methods for Preserving Confidentiality:
  - Coding system
  - Access to the key is available to limited authorized individuals who are trained
  - One or several passwords for access
  - Limiting knowledge of the passwords to authorized person(s).
  - A computer without internet access and a rigorous back-up method
  - Portable data drive - methods to secure data via password and other mechanisms.
  - Certificate of Confidentiality if inappropriate release of information in the registry would be greater than minimal risk and/or information being collected and maintained is sensitive or potentially incriminating.

Informed Consent

- Minors: In order to collect and maintain information pertaining to a minor within a human subject registry, the PI is asked to supply at the time of submission:
  - Relevant Children's category (usually 45CFR46.404) for the registry
  - Parental permission (or LAR)
  - Assent by minors
  - Whether data or tissues maintained in the registry are subject to informed consent upon the child reaching the age of majority.
- HIPAA
- DNA testing. See WPP XVII-5 for information to be included in the consent form.

IRB Reviews

- Most reviews → Expedited
  - If collecting and storing sensitive data or specimens (greater than minimal risk) → full board review

- Continuing Review: A list of all usage protocols that accessed the registry should be provided in the IRB submission.

Accessing a General Registry

Accessing a General Registry

- May be a separate protocol, or may be an amendment to the protocol containing the research registry.
- *Associated VCU IRB Protocol

- Note: The VCU IRB may determine that a usage protocol is not covered by this policy if the data/specimens in the registry cannot be linked, directly or indirectly (via code), to any living human entity or if the dataset to be obtained will have no codes or identifiers AND if the registry data was not obtained for the specific protocol in question. The OHRP Guidance Document: "Research Involving Coded Private Information or Biological Specimens", will be used to determine applicability for IRB review.

IRB Considerations

- Who has the responsibility of maintaining the registry
- What types of data or specimens will be collected
- Coded or identifiable information obtained
  - Linked directly?
- VCU Registry: Protocol should reference the IRB number of the registry in the application and in the VCU Research Plan/Synopsis
- Non-VCU Registry: Describe location, how specimens/data were obtained, and the management of the registry
- Initial Review: If a usage protocol is determined by the IRB to be 'no greater than minimal risk,' expedited review is permitted under **Expedited Category 9**.

Informed Consent

- Original Registry Consent
- New Consent for this protocol
  - Apply for a Waiver of Informed Consent