RSPP GUIDANCE ON DATABASES AND REPOSITORIES: STORING HEALTH CARE DATA OR BIOSPECIMENS FOR FUTURE SPECIFIED OR UNSPECIFIED RESEARCH PURPOSES

**Non-Research Databases and Repositories**

Databases, registries (data banks), and repositories (tissue/specimen banks) all involve the collection and storage of information and/or biological specimens over time. Some database/repositories serve diagnostic or clinical purposes, some collect diagnostic/clinical data/samples but are used for research also, while others are solely for research. The future research intentions of the databases/repositories may be specified or unspecified at the time of establishment. Many serve more than one purpose.

**Non-Research Databases and Repositories**

Databases and repositories are frequently created and maintained for purposes completely unrelated to research. **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.**

- Typically, IRB approval is not needed before establishing a new Quality Improvement Registry, however, the nature of the protocol design could affect this. The following scenarios outline some of the many possible situations.
  - Registries Developed and Used Exclusively at Aurora
    - If the protocol only includes Quality Improvement objectives for the registry, this is hospital operations and does not require IRB oversight. Further information about what is considered a Quality Improvement project and how to submit an application for a Not Human Subjects Research Determination can be found [here](#).
    - If the protocol also includes research objectives or if additional variables are collected purely for research, then an element of the activity is research and requires IRB oversight.
  - External Registry in Which Aurora is a Participant
    - If the protocol includes Quality Improvement objectives but also includes research objectives; the registry might require IRB oversight at Aurora depending on if the personnel at Aurora are engaged in the research. If the Aurora personnel are merely data providers and will not serve in the role of an investigator (participate in planning, execution, analysis, and publication), then Aurora is only a data provider and is not engaged in the research and Aurora IRB oversight is only required for a HIPAA waiver determination. The HIPAA waiver request form can be found [here](#). (See for example, [OHRP Guidance on Engagement in Human Subjects Research III.B.6](#)). If any Aurora employee intends to serve as an investigator, then the Aurora IRB must review the protocol as human subjects research.
    - Receipt of de-identified data/biospecimens does not engage Aurora or its investigators in human subjects research. See the [GLOSSARY](#) for the definition of de-identified.

**Research Databases and Repositories**

Research use of data/specimen that are stored in databases and repositories is governed by the federal human subject protection regulations known as the Common Rule ([45 CFR 46](#)) and the HIPAA Privacy Rule ([45 CRF 160 & 164](#)) and by Aurora IRB Policies. Specific requirements depend upon how and why the information or specimens in the resource are collected, stored, used, and shared.

The requirements for and extent of IRB oversight depends on the whether or not the data/specimen include or are linked to individually identifiable health information and the terms of the informed consent under which the data/specimen were originally collected.

- **CREATION:** A research database/repository may be created specifically as a resource for future research. Recruitment or other research data/specimen banks must have IRB approval prior to creation and use. To be included in a recruitment or research data/specimen bank, subjects typically must have given prior consent. IRB oversight is required to set up and maintain a research database/repository.
  - Aurora research databases and repositories require Aurora IRB oversight.
o Outside research databases and repositories using Aurora patient information require IRB oversight. The holder of the research database/repository must be able to provide proof of IRB review/approval. Aurora IRB oversight is required for HIPAA determination.

- **USE:** Additional research questions may arise in the future that could be addressed using an already established dataset or previously obtained specimen. If there is intent to set up a registry, then the informed consent document should include language for subjects to opt-in or opt-out of storage of their data/specimen for future research purposes. The subject's decision as indicated on the consent/authorization must be respected and tracked. IRB oversight is required for each new research protocol that uses identifiable or re-identifiable (coded) information contained in the database/repository. Aurora policy also allows for an Honest Broker system to be set up. An Honest Broker is an individual or system where identifiable Protected Health Information (PHI)/specimens are collected but only deidentified data is released to research investigators in such a manner whereby it would not be reasonably feasible for the investigators or others to identify the subjects directly or indirectly. The Aurora Honest Broker Policy can be found [here](#). The Honest Broker Request Forms can be found [here](#).

An investigator should obtain IRB review of a database or repository through a stand-alone application (e.g. for the creation and maintenance of a tissue bank). If the data/specimen collection occurs in conjunction with a specific research project, two separate IRB submissions applications are required (e.g. one for the main study and one for the tissue storage element) if the database/repository is being maintained by Aurora. If the database/repository is being maintained outside of Aurora and has approval by another IRB, then one application may be submitted by explicitly building into the IRB application the intent to store data/tissue for future use. Evidence of IRB oversight is required. Data/specimens may be collected in a research study to achieve one or more of the objectives of the study. A repository is created if the leftover materials are stored for future use.

Data/specimens may also be collected specifically for the purposes of future research. IRB oversight is required for each new research protocol that creates a database or repository.

The Aurora IRB reviews research involving banked specimens and data to determine whether:
- The source of the data/samples raises any ethical concerns such that Aurora would not wish to be associated with such research; and
- Explicit consent was obtained from the individuals for the use of their data/specimens in research.
  - The rights and welfare of subjects whose data/specimens have been banked are more difficult to safeguard than the rights and welfare of subjects participating in focused studies. For this reason, the IRB is generally reluctant to waive the informed consent process for banking activities.
- Additional considerations:
  - Future studies utilizing the banked data/specimen(s) must obtain separate IRB approval or exemption
  - Under the HIPAA Privacy Rule separate permission is required for the storage of biological materials as well as each research use of identifiable materials. Written authorization from subjects for each research use of their protected health information must be obtained or a waiver of such authorization sought from the IRB.

**Related Policies:**
- For specific information on requests to access existing medical records, charts or databases maintained by Aurora for the purpose of research or research related activities such as recruitment please refer to Policy SC 502: REQUEST TO ACCESS EXISTING MEDICAL RECORDS, CHARTS OR DATABASES FOR RESEARCH.
- An investigator who desires to access medical records, charts or databases for research or in a manner preparatory to research (e.g. to determine the feasibility of conducting a research protocol or identify prospective research subjects) must submit to the IRB a Form SC 502-A. Approval of Form SC 502-A must be obtained prior to accessing the medical records, charts and/or databases.
- Form 502-A must be completed if the investigator is requesting a Waiver or Alteration of HIPAA Authorization.