POLICY STATEMENT: The establishment of databases and data repositories registries for research purposes that contain protected health information (PHI) within Mercy Health must be done in accordance with all applicable federal regulations including HIPAA Regulations and must be reviewed and approved by the Mercy Health Institutional Review Board (IRB) prior to any collection of information.

The Mercy Health IRB has jurisdiction over databases and registries being used for research purposes. The IRB acknowledges that some databases and registries may only have a quality improvement objective or purpose. Databases or registries that meet the definition of clinical quality improvement will not be approved by the Mercy Health IRB. Databases or registries that meet the definition of clinical quality improvement must be discussed with the Director of Organizational Integrity and Security prior to the collection of any data.

GENERAL PROVISIONS:
Databases and registries are used to store data for future use. When the use is for clinical purposes or quality improvement (QI), IRB approval is not required. However, when the use is for research purposes, the databases or registries must be approved by the IRB. The databases or registries must satisfy the requirements of the Common Rule (45CFR46) for protection of human research subjects and the requirements of the Privacy Rule, i.e., the Health Insurance Portability and Accountability Act (HIPAA) (45CFR160 and 164), for protection of health information.

Research databases or registries require consent and authorization by participants for the storage and future research use of their data or a waiver of consent and authorization by the Mercy Health IRB.

The role of the Institutional Review Board varies with the intent and use of a database or registry. IRB approval and oversight are not required for registries and databases created and operated for non-research purposes. Such purposes may include diagnosis, treatment, billing, quality assurance and quality improvement, and public health surveillance. These data cannot be used for research unless the registry or database is reviewed and approved by the IRB, or IRB approval is sought prospectively on a study-by-study basis. IRB approval of a protocol wishing to use identifiable information from a database or registry created for non-research purposes will be made on a case-by-case basis. An example might include use of a clinic’s patient database to identify and recruit potential research participants.

Registries and databases created and maintained with the known intent for present or future research purposes must obtain IRB approval prior to their implementation.

Informed Consent
Since a database or repository with linked or identifiable information may be used by many researchers and for many studies over time, informed consent should be gathered from the participants whose data will be collected and should include the following information in simple language:

• The general concept and purpose of registry or database:
Institutional Policy & Procedure

- Name and purpose of specific registry or database for which consent is requested.
- How the registry or database will work.
- Types of research the registry or database supports.

- Conditions and requirements under which data will be shared with researchers.
- How participants' privacy and confidentiality will be protected.
- Specific risks related to use and storage of data, particularly if personal identifiers are retained.
- Potential benefits, if any:
  - Inform participants if there is no direct benefit.
  - Include other potential benefits such as societal benefit through the advancement of knowledge.

- Where applicable, the fact that data may be:
  - Used for future research not yet identified.
  - Shared with or transferred to other institutions.

- A statement that participants may withdraw their consent at any time either by requesting that data be destroyed or that all personal identifiers be removed.
- Information about the length of time the database or registry will be active.
- When consent to use information will expire.

- Obtaining informed consent to use data stored in a registry or database created for non-research purposes may be problematic since research was not intended at the time of collection. Where feasible, the IRB may require a researcher to obtain informed consent. However, the IRB may approve a waiver of consent and waiver of authorization requirements if:
  - The research involves no more than minimal risk (e.g. anonymous use of samples); and
  - The waiver will not adversely affect participants' rights and welfare; and
  - The research could not practically be carried out without the waiver.

When information is provided to researchers outside Mercy Health and its affiliates, use of the data must comply with any additional requirements of the recipient institution and its Institutional Review Board. Likewise, the recipient institution must agree to comply with all terms stipulated by the donor institution.

DEFINITIONS:

Databases

Databases are collections of information elements (i.e. data) arranged for ease and speed of search and retrieval. Databases may be maintained electronically or as paper-based systems. Examples of databases include:

- A set of observations (i.e. data) from a longitudinal research study.
- An electronic file of elements of a clinic patients medical record.
- A collection of diagnosis, treatment and follow-up information on a sub-set of hospital patients, for example patients with diabetes or admissions to an intensive care unit.
- A file of outcomes information compiled for quality assurance activities.
- Names, diagnosis and contact information of potential research participants in specific research fields

Registries

Registries or data banks are collections of information or databases whose organizers:

- Receive information from multiple sources.
- Maintain the information over time.
- Control access to and use of the information by multiple users or for multiple purposes which may change over time.

Registries often contain codes that link information and to a patient or participants identity.

REFERENCE:

45 CFR 46
45 CFR 160 and 164
## ATTACHMENTS:
SC 511-A Notice of Clinical Quality Improvement Measurement Designation

## PROCEDURE: All Mercy Health Campuses

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
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<tbody>
<tr>
<td>IRB Specialist/IRB Coordinator</td>
<td>1. Review all incoming submissions and determine if they are specifically for a registry or database only purpose. 2. Add items to the next IRB meeting agenda as requested by the IRB Chairperson. 3. Provide assigned reviewers with proposal review package including checklists and worksheets needed to conduct proper review. 4. Issue correspondence as advised by the IRB Chairperson.</td>
</tr>
<tr>
<td>IRB Chairperson (or designee)</td>
<td>1. Review the IRB submission 2. Determine if database or registry is for quality or research specific purpose. 3. If research, determine if study meets expedited review criteria. 4. If study is greater than minimal risk, request IRB CRA place on next IRB meeting agenda.</td>
</tr>
<tr>
<td>IRB Committee</td>
<td>1. Review registries and databases that are designated as research and require full board review.</td>
</tr>
<tr>
<td>Investigator</td>
<td>1. Submit registries and databases that collect protected health information to the Office of the IRB for review even if you believe they may meet quality criteria.</td>
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</table>

### CONCURRENT CONSENTS:

Institutional Official

[Signature]