

Identifying the type of database

We have identified several types of databases and each would have its own approval requirements (see diagram attached).

1. Clinical database: This is a specialized database created for the purpose of documenting and following patients' progress by a certain specialty or service, and is considered an integral part of the medical record. This database is governed by Medical Records and its creation needs approval from Medical Records Department in coordination with appropriate other departments. It may include specific **electronic forms** to facilitate data collection and retrieval for clinical care purposes. It should be accessible to all clinicians at AUBMC as part of the medical record for a specific patient care question. Collection of data beyond documentation of usual and standard clinical care is not permitted without proper approval for effort and time spent by staff, unless it is also a research database and funded/approved independently. Creation and maintenance of a pure clinical database does not require prior IRB approval, unless the database is created as a dual-purpose clinical and research database with an IRB-approved protocol and consent form. A retrospective review of database records for research purposes does require an IRB approval, which needs to be secured before it is queried for a research question, even by a PI or group in charge of the database.
2. Quality improvement/quality assurance registry: Data collected for QI/QA purposes needs approval by the hospital director or designee regardless of whether the registry is funded by the hospital or through external grants. This is to ensure quality of data, and also to ensure that it is aligned with hospital's policies, standards and goals. Creation and collection of data for such registries do not require prior IRB approval. Data collection effort and time need to be appropriate and could be part of the effort of a member(s) of the clinical care team with proper administrative approval. The clinical care team could include a clinical data manager to assist with data entry and maintenance. A job description for the clinical data manager will need to be created by HR. Patient consent is not required for these registries.

Note: Data from QI/QA registries could be used for research purposes in a retrospective manner, by applying to IRB for a waiver of informed consent

(which would be applicable in almost all cases) or for exempt level approval (for use of de-identified extracted data). Specific language to be used in publications is exemplified in published articles from international registries such as the STS-CHSD or NSQIP [1-3]. In case of ambiguity or concern, an IRB determination letter can be requested when setting such a QA/QI database to help establish whether human subjects research is being conducted.

3. Research registry: Data is collected for research purposes and could be cross-sectional or longitudinal, retrospective or prospective. IRB approval and **individual consent** by the patient are required in all prospective collections and in some circumstances, in retrospective studies. Investigators are encouraged to include bio-samples and create bio-repositories whenever feasible. Subjects consent forms may include separate boxes for approval of data, blood, DNA, or other samples. The IRB can provide PIs with templates and examples. Investigators are encouraged to include a box asking the subject's approval for sharing coded data with other investigators and permission to re-contact for research purposes. Such research registries are important for AUBMC research strategic goals.
4. Registries mandated by governmental agencies: such as the infectious disease registry mandated by MOH. Data in this registry is de-identified at the national level, but could remain coded at the level of the institution. These registries do not require IRB approval. In case of ambiguity or concern, an IRB determination letter can be requested. Data kept on file may be used for research purposes but would require prior IRB approval.