

REVIEW OF QUALITY MEASUREMENT INITIATIVES

Federal regulations require the Partners Human Research Committee (PHRC) to review and approve all activities that involve the systematic collection of information about living individuals if the collection may contribute to generalizable knowledge and if the information is recorded in any way that allows the individuals, directly or indirectly, to be identified*[see below].

Accordingly, the Partners PHRC requires submission of any quality measurement initiative or database if the primary (or part of a dual) intent is to conduct or support research (i.e., internal or external analyses of identifiable clinical information for a generalizable purpose, such as a scientific publication). Alternatively, if the only purpose of a quality measurement initiative or database is quality measurement (including publication of benchmarking analyses or reports), then no submission to the PHRC is required. Note, however, that if at some point the purpose of such an initiative or database changes to include research conducted by someone at or outside a Partners institution, then the initiative/database must be submitted for PHRC review at that time.

In situations when PHRC submission is required, the PHRC will review protocols on an expedited basis under agency guidelines permitting expedited review for minimal-risk research involving identifiable data collected solely for nonresearch purposes. When more than one research project is to be performed through one database, and the projects are sufficiently similar and involve a similar level of risk to participants, the PHRC will generally require only one protocol to be submitted for the database. See the Research Data Repository submission form within [Insight/eIRB](#) for submitting databases for review.

The following examples help illustrate the PHRC's policy on review of quality measurement initiatives.

Examples of Initiatives That Need Not Be Submitted for PHRC Review:

- Initiatives in which Partners institutions submit identifiable (including coded) clinical data to a database maintained by an outside entity that will aggregate the data with information from other hospitals and report benchmarking standards to participating institutions. If this is the sole purpose of the database, and the database will not be used by anyone (whether at or outside of Partners institutions) for research projects, then the initiative/database does not need PHRC review.
- Initiatives (whether for benchmarking or other purposes) that use **anonymized** information (i.e., there is no way for anyone, anywhere, even someone at a Partners institution, to link the information back to a specific individual).
- Initiatives that are required by state or federal law, if the identifiable data collected will be used solely for quality measurement purposes. For example, if the Centers for Disease Control and Prevention mandates that hospitals report to the agency or to a database maintained by a third party all incidences of meningococemia they treat, that reporting effort does not require PHRC review if the information will be used by the hospital, the agency, and/or any third party only for quality assurance or improvement purposes. Similarly, if a state agency requires hospitals to report all maternal deaths to the agency or a third party for those limited purposes, PHRC review is not required.

Examples of Initiatives That Should Be Submitted for Review:

- An initiative in which a Partners physician proposes to collect and/or study a set of identifiable (including coded) clinical data, analyze the data for general trends, and publish a paper in a scientific or other professional journal based on his or her work.
- An initiative in which Partners institutions submit identifiable (including coded) clinical data to a database maintained by an outside entity that will use and/or share the data for research purposes in addition to providing any benchmarking analyses to participating institutions.

- An initiative that is required by law, but in which the hospital, the relevant state or federal agency/government body, and/or a third party will be using or sharing the data for research purposes in addition to quality measurement purposes.

Tips for Submission of Quality Measurement Protocols:

- As noted above, PHRC review generally may be sought for each database rather than for each separate research project to be performed through the database. To the extent that the submission demonstrates that the projects to be performed through the database are sufficiently similar to one another and involve a similar level of risk to participants, all of them may be covered by the same protocol and PHRC review.
- If a project involves data of a sensitive personal nature (e.g., abortions, sexually transmitted diseases, or elder or child abuse) or otherwise presents more than minimal risk to patients (e.g., alterations in standard confidentiality precautions or coding practices or potential for contact of patients), then a separate protocol encompassing that project should be submitted for PHRC review.

To the extent that a database involves clinical data from more than one hospital in the Partners network, the use of cooperative PHRC/IRB agreements may permit the review and approval of the project by one institution's PHRC/IRB.

- If it is not clear based upon this policy whether a particular quality measurement initiative should be submitted for PHRC review, contact the PHRC for guidance.

In practice, and in light of HIPAA Privacy Rule Requirements, the PHRC also requires review of such activities when they involve deceased individuals or both deceased and living individuals.