MEDICAL COLLEGE OF WISCONSIN

MCW Office of Research Standard Operating Procedure

QUALITY ASSURANCE/ QUALITY IMPROVEMENT PROJECTS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE:
QA/QI initiatives are a mandated function of our hospital. Some of these initiatives are implemented after thorough evidenced-based best practices are identified, in response to an identified safety issue, or to improve the delivery of care and avoid potential safety issues. The overarching intent of the initiatives is continuous monitoring of hospital operations and improved care of our patients here at Froedtert and the Medical College of Wisconsin (MCW).

DEFINITIONS: N/A

PROCEDURE:

A. QA/QI initiatives

The following activities are not considered research activities at Froedtert and MCW. The responsible conduct of the activities described below falls under the jurisdiction of the Froedtert system-recognized departmental quality assurance committee (collectively referred to from this point on as 'Hospital QA'):

- Any hospital QA initiatives, and presentation/publication of results thereof, that are conducted within Froedtert system only, and that serve to:
  - measure or improve Froedtert and MCW's ability to meet or exceed an existing national standard of care or benchmark (JCAHO, etc)
    OR
  - develop a standard of care or benchmark for applicability within Froedtert and MCW.
- Submission of data to a national or state registry/database:
  - that is mandated at the state or federal level.
    OR
  - That directly impacts reimbursements and funding available from the state, Department of Health, or federal Centers for Medicare & Medicaid Services (CMS) based on performance and/or clinical or quality outcomes.
    OR
  - That is maintained by an organization/consortium, formally recognized by Froedtert and MCW administration, the principal purpose of which is benchmarking and/or performance improvement, and the use of which is for internal Froedtert and MCW activities.
- Froedtert and MCW QA use of data from a registry/database, meeting any of the criteria above, for the purpose of:
  - measuring or improving Froedtert and MCW's ability to meet or exceed an existing national standard of care or benchmark (JCAHO, etc).
    OR
  - developing a standard of care or benchmark for applicability within Froedtert and MCW.

B. Research Activities:

The following activities are considered research activities. The responsible conduct of the activities below fall under the jurisdiction of the MCW/Froedtert Institutional Review Board (IRB) and/or the Froedtert Office of Clinical Research and Innovative Care Compliance (OCRICC):

- Any hospital QA initiative, conducted within Froedtert and MCW only, designed to develop a standard of care or benchmark for general applicability (i.e., not only for operations within Froedtert and MCW, but to outside entities as well).
- Any QA or QI initiatives (including those proposing to develop an operational standard of care of benchmark) that are "investigator-initiated", i.e., that have not been vetted through, and endorsed by, a hospital-recognized general or departmental QA committee).
- Submission of data to a registry/database that is not covered by those described above.
- Use of data from any registry/database for the purpose of measuring, improving or developing a standard or benchmark, under any condition not defined as QA/QI activity above, including the use of registry data for the purpose of research.
- Any activity that proposes comparisons of one or more prospective interventions that are deliberately administered or made available (through a randomization or other process) to some patients (if within Froedtert and MCW) or some hospitals (if part of a consortium or organizational effort) and not to others. This does not include, e.g., initiating a QI process in a small percent of patients at Froedtert and MCW first to ensure feasibility, before introducing it to the entire patient population.

Activities that have a mix of both QA/QI and Research Components

When an activity involves a mix of activities from Sections A and B, the investigator must ensure compliance with all applicable entities, i.e., including the MCW/Froedtert IRB and OCRICC, for the research aspects of the activity (including securing approval prior to conducting the research aspect)

For any 'questionable' (QA vs. Research) activity not described above, please consult with the MCW/Froedtert IRB.

REFERENCES: N/A

SUPPORTING DOCUMENTS: N/A

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