

Chapter 25

Guidelines for Conducting Performance Measurement Activities Involving Human Subjects

A. Introduction

The CAMC Health System must ensure that individuals are protected in all public health and health care research activities it conducts. When an activity is classified as research involving human subjects, CAMC will comply with 45 CFR 46 and DHHS regulations in protecting human research subjects. Some performance measurement activities involving human subjects are not research; others are. Although general guidance can be given to assist in classifying these activities as either research or non-research, no one criterion can be applied universally. It is customary to utilize as a distinguishing feature the *purpose* of conducting the activity. In cases of doubt as to whether an activity is to be considered 'research', it is customary to rely on the judgment of the IRB.

The CAMC WVU-Charleston Division IRB acknowledges the results of the Education/Communication Health Services Task Force in its conclusion that "IRB's need to learn more about health services and outcomes research, outcomes and quality improvement research, i.e., who conducts it, how is it conducted, who are the subjects, and how the potential risks and benefits are evaluated. Likewise, health services and outcomes researchers need to learn about how an IRB can make studies safer for subjects and more ethically 'sufficient'". Due to the increasing complexity of QA/QI initiatives nationally and at CAMC, the CAMC WVU IRB is committed to supporting the continuation of these system initiatives that are without new obstacles for individuals who are interested in improving the quality of health care provided by CAMC.

B. Intent

The intent of this document is to set forth local guidelines that will assist in standardizing the procedures for those who are responsible for the conduct and reporting of performance improvement and measurement activities when human subjects are involved, and to recognize and define the differences between research and performance improvement and measurement activities.

C. Applicability

These guidelines are applicable to all medical staff, health care professionals and employees of the CAMC Health Care System who are responsible for the design, conduct, or reporting of performance improvement and measurement activities. The CAMC Health System shall mean CAMC, Inc., Charleston Area Medical Center, Inc., Strategic Health Services, Inc., Charleston Area Medical Center Foundation, Inc., Charleston Area Health Plan, Inc. (Carelink), Integrated Health Care Providers, Inc., Braxton County Memorial Hospital, Inc., Oak Hill Hospital, Inc., WomenCare, Inc., and Health Plus Professionals, Inc., and any other entity which controls, is controlled by, or is under common control with CAMC, Inc.

D. Use of Employees in Research

All medical and personal information regarding CAMC employees must be safeguarded at all times. Employee anonymity and confidentiality is to be preserved as best we can. It is difficult to maintain the

confidentiality of personal medical information or research data when the subjects are also employees, particularly when the employer is also a medical institution.

The issues with respect to employees as research subjects raise the possibility that the decision will effect performance evaluations or job advancement. It is recommended that employees of CAMC be excluded from organized research studies whenever possible. Research staff should never reveal information, including incidental observations about fellow employees receiving care at CAMC. Employees who have requested not to be contacted for survey projects should be eliminated from study populations.

E. Examples for Determining if IRB Approval is Necessary

The attached examples are designed to provide reasonable parameters for determining whether or not a project will be classified as reviewable by an IRB and therefore subject/not subject to IRB approval.

1. Strictly Not Under IRB Purview

- a. Data collection, analysis or release of data required of the Institution (CAMC) to comply with external quality standards and clinical quality assurance requirements (ie. to payors, government agencies, system and clinical accreditation bodies such as ORYX, HEDIS, JCAHO]. Publication, presentation or reporting of these data would be permitted to these bodies to maintain system/departmental accreditation and licensing.
- b. Data collection, analysis or reporting of data for internal system initiated management or clinical initiatives only to enhance or improve institutional performance. These studies are conducted with no intent to publish or present these data external to the system. However, the presentation and publication of these initiatives and their impact are allowable when the information is descriptive in nature (ex. Identification of the clinical/administrative problem, literature review, process and procedures for implementation and evaluation of the change, and summary of outcome).
- c. Patient/Member/Customer satisfaction surveys related to services rendered by the organization and to be utilized solely for Quality Improvement/Quality Assurance initiatives
- d. Single clinical case reports of a provider's own patient

2. Strictly Under the IRB Purview

- a. An intent of the project/study is to collect, analyze and generate externally-generalizable data for public dissemination and presentation or publication outside of the CAMC system.
- b. Upon conclusion of a system-initiated project, review of data for a secondary purpose other than was originally intended, is subject to IRB review and approval prior to submission of abstracts for presentation and publication purposes, or collection of additional medical/patient information. A non-research project may generate generalizable knowledge after the project is undertaken even though generating this knowledge was not part of the original primary intent. In this case, since the primary intent was not to generate or contribute to generalizable knowledge the project is not classified as research at the outset. However, if subsequent analysis of identifiable private information is undertaken in order to

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generate or contribute to generalizable knowledge, the analysis constitutes human subjects research that requires IRB review. (In most cases, the IRB may conclude that waiver of the usual requirements for informed consent is justifiable under 45 CFR 46.116© or (d).

3. Factors Which May Suggest a Need for IRB Review

- a. New active patient intervention, or prospective patient randomization study design for patient enrollment
- b. Data is to be pooled beyond institutional boundaries outside of the context of external accreditation accountabilities (collaborative registry, external database for public access to data, pharmaceutical company registry)
- c. Research component is initiated by an individual who has no official institutional directive to perform QA/QI/Performance Improvement
- d. Review of medical records of members/patients for whom one has not provided direct care, except as part of approved management activities
- e. Inclusion of CAMC employees in the research component

Note: If an example of your project is not listed, please contact the IRB office for assistance at 388-9970.

F. Definitions

These definitions have been compiled to assist Research and Grants Administration , the CAMC WVU IRB and participants in these activities in understanding terminology that may be representative of the type of performance measurement activities conducted at this institution and includes research-related definitions as contained in the federal regulations.

1. **Benchmarking:** The structured, comparative trending of performances that represent best-known practices and the identification of goals against which all other levels of performance are measured. Source: NAHQ resource center.
2. **Continuous Quality Improvement (CQI):** A management philosophy and management method using “a structured organizational process for involving personnel in planning and executing a continuous stream of improvements in systems in order to provide quality health care that meets or exceeds customer expectations.” CQI is the label most frequently used to describe Total Quality Management (TQM) programs used in clinical settings. Source: McLaughlin, C.P & Kaluzny, A.D. (1994) *Continuous Quality Improvement in Health Care*. Gaithersburg, MD: Aspen, pp 3-4)
3. **Evidence-based health care:** Is the conscientious, explicit, and judicious use of current best evidence from health care research in making decisions that fit the circumstances and wishes of individual patients or groups. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. Source: Sackett, DL, Richardson, WS, Rosenberg, W. Haynes, R.B. *Evidence Based Medicine: How to practice and teach. EBM*. New York, NY, Churchill Livingstone; 1997

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4. **Existing data:** Requires that the information exists on the shelf or in the patient’s medical record or, for laboratory specimens, in the freezer, at the time the idea for the study is conceived. Source: OPRR

5. **Generalizable knowledge:** Findings which may extend beyond the participants being studied, possibly to society. Source: Centers for Disease Control: Defining public health research and public health non-research, Washington, D.C. **[For our purposes, the CAMC WVU-Charleston Division IRB defines “extending beyond the participants” as extending externally beyond CAMC patients and Carelink Members. Please also note that while contributing to generalizable knowledge does not always imply publication of results, peer reviewed journals may not accept research for publication conducted without adherence to human subject protection regulations such as Institutional Review Board (IRB) review.]**

6. **Health Services Research:** Research that is designed to describe or evaluate various aspects of a system that delivers medical or other health care. This includes evaluation of some component(s) of the system, formal comparison of two or more methods of accomplishing the same health care objectives, and evaluation of new methods to ‘improve’ the health care system. Source: PRIM&R Guidelines for the Conduct of Health Services Research, November 22, 1997, R.J. Levine.

7. **Human Subject:** Means a living individual about whom an investigator (whether professional or student) conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information [45 CFR 46.102(e)].

8. **Intervention:** Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes [45CFR46.102(f)(2)].

9. **Interaction:** Includes communication or interpersonal contact between investigator and subject [45CFR46.102(f)(2)].

10. **Narrow Scope:** Only the amount of data necessary for the assessment and care of an individual or defined group of individuals [Centers for Disease Control, Defining Public Health Research and Public Health Non-research, Washington, D.C.].

11. **Outcomes Research:** This research attempts to combine the theories of quality management and scientific methodology to form an analysis of clinical practice.

12. **Performance Improvement:** The continuous study and adaptation of functions and processes of a health care organization to increase the probability of achieving desired outcomes and to better meet the needs of patients and other users of services.” Performance improvement is dependent upon performance measurement and assessment of the health care organization’s functions and processes. Source: Joint Commission of Accreditation of Health Care Organizations (JCAHO).

13. **Performance/Outcomes Measurement:** Performance/outcomes measurement is the calculation and valuation of what is done and how well it is done in healthcare.

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Performance measures are those standards or indicators used to assess the performance of a function or process of any organization. An outcome measure is the result of the performance. Source: NAHQ Resource Center

14. **Practice Guidelines:** A systematically developed clinical set of recommendations or algorithms, intended to guide healthcare practitioners in their selection of appropriate preventive, diagnostic, therapeutic, and patient education decisions. Guidelines provide the caregiver with specific treatment options or steps when faced with a particular set of clinical symptoms, signs, or laboratory data. Source: NAHQ Resource Center
15. **Private/non-public information:** Includes information about behavior that occurs in a context in which a individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (eg. A medical record) Source: [45 CFR 46.102(f)(2)].
16. **Program Evaluation:** The systematic application of scientific and statistical procedures for measuring program conceptualization, design, implementation, and utility; making comparisons based on these measurements; and the use of the resulting information to optimize program outcomes. Source: Rossi, P.H & Freeman, HE (1993). *Evaluation: A systematic approach*. Newberry Park, CA: Sage Publications, Inc. and Fink, A. (1993). *Evaluation fundamentals*. Newberg Park, CA: Sage Publication, Inc. In Centers for Disease Control, *Defining public health research and public health non-research*, Washington, D.C.]
17. **Prospective Study:** Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data. IRB Handbook.
18. **Quality Assurance:** Refers to a traditional evaluation of performance that relies on inspection to detect conformance to standards.” Source: Tindill, B., S.& Stewart, D.W. (1993) Integration of total quality and quality assurance. In Al-Assaf, A.F. and Schmele, J.A. (Eds.) *The Textbook of Total Quality in Healthcare*. St. Lucie Press: Del Ray Beach, FL.
19. **Quality Standards:** Pre-established statements of measurement which define the performance expectations, structures, or processes that must be in place to attain desired health outcomes that are consistent with current professional knowledge. Source: National Association of Healthcare Quality.
20. **Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR 46 The Belmont Report further clarifies by stating “research designates an activity designed to test an hypothesis, permit conclusions to be drawn and thereby contribute to generalizable knowledge’.
21. **Research Utilization:** A systematic method of implementing sound, research-based innovations in clinical practice, evaluating the outcomes, and sharing the

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knowledge through the process of research dissemination.” Source: LoBiondo-Wood, G.& Haber, J. (1994). Nursing Research: Methods, critical appraisal, and utilization. St. Louis: Mosby, p. 56.

22. **Surveillance:** The ongoing, systematic collection, analysis, and interpretation of outcome-specific data, closely integrated with the timely dissemination of these data to those responsible for preventing and controlling disease or injury. Source: Thacker, SD & Bekelman, RL (1988). Public health surveillance in the United States. Epidemiologic Review, 10, 164-190. C