Guidelines for Research Limited to Retrospective Medical Record Reviews

Please note that the focus of these guidelines is limited solely to retrospective medical record reviews for research purposes.

Research studies involving the retrospective review, collection and analysis of medical record information are descriptive studies that ordinarily seek to evaluate relationships between one or more biomedical, treatment, and/or demographic variables and one or more outcome measures in patients. Data may include a wide range of information from the medical record (e.g., results of lab tests, nursing and physician notes, summary reports – including intake and discharge summaries and consultant reports, raw data from electrophysiological or imaging tests, etc.) Because this is research, Ethics Committee oversight is required.

Recording of Medical Information, Without Identifiers, By or Under the Oversight of a Principal Investigator Who Would Normally Have Access to this Information by Virtue of His/ Her Patient Care Responsibilities:

An investigator may personally review medical records and abstract relevant data from the medical records if **ALL** of the following conditions are met:

1. All medical records to be accessed for study are currently in existence at the time of the NCRHA Ethics Committee submission.

2. The desired medical record data is recorded by the investigator in such a way that the respective patients cannot be identified (i.e., by the investigator or others) either directly, or indirectly via linkage codes assigned to the data. **This means that the investigator cannot record names, social security numbers, or any other patient identifiers and link this information to the data set**. As a consequence, the resulting research data set is necessarily completely **anonymous**. For that reason, once the information has been extracted from the medical record, it will not be possible for the investigator to go back to the medical record and add other patient-specific information to this research dataset.

3. The principal investigator (P.I.) of the research study has legitimate access to the desired medical information insofar as he or she is a staff member of the facility the research is being conducted and/or has been granted privileges and provides related care (i.e., related to the information desired) to the patients, or is in the position to provide related care (including treatment, and/or diagnostic services) to the patients.

For example, any health professional providing patient care to a particular set of patients (e.g., all patients treated in the Emergency Department; all patients with aphasia; all patients undergoing CT scans), would ordinarily have access to the related medical record information of those patients, as part of his or her current or future job responsibilities, and hence would be in a position to serve as the P.I. of a research study involving a retrospective review of those medical records (regardless of whether he or she actually provided direct care to those particular patients). For example, if the research study is directed at obtaining neurological information and the P.I. is a cardiologist, the research submission to the NCRHA Ethics Committee must address the relationship of the information desired to the normal patient care responsibilities of this cardiologist-P.I. **Note that the Ethics Committee will not approve a retrospective medical record research study if the medical record information desired is not in some way related to the patient care responsibilities of the listed P.I.**

4. **Applications where the Principal Investigator and the Primary supervisor are not part of the NCRHA workforce, must liaise with the Department where research is conducted and have a co-supervisor or liaison person listed in the protocol, in order to get access to the case notes /charts. Only applications listing such person(s) will be accepted for review by the REC.**

It is recognized that health care professional students (including medical students, residents and fellows) may be required to perform a research project and that many of these projects will involve retrospective medical record reviews. It is further recognized that these students may have had limited or transient involvement in the care of these patients. Thus, if the researcher is a health care professional student, the **P.I.** for the retrospective medical record research study ***must*** be a staff member or privileged professional who provides related care, or is in the position to provide related care, to the particular patient population to be studied by the student. In this example, the P.I. on the NCRHA Ethics Committee submission will be the faculty member, and the student will be listed as a co-investigator (or as a Co-Principal Investigator). Please note that in this situation the student could be the first author on any publication resulting from this retrospective research study.

It is further recognized that investigators often employ research staff members (e.g., nurse coordinators, research assistants or associates) who may be involved in accessing and recording the medical record information as part of their ordinary job responsibilities. Thus, research coordinators or other research staff may have access to, and may record, medical record information, provided that the P.I. of the research study is a staff member or privileged professional who provides related care, or is in the position to provide related care, to the respective patient population.

Regardless of who is involved in accessing and recording the medical information, the P.I. of the research study is responsible, and will be held accountable, for ensuring the confidentiality of the patients' medical record information.

Request for Approval of a Waiver of Informed Consent

In order for the NCRHA Ethics Committee to grant a waiver of informed consent the criteria are as follows:

(1) The research involves no more than minimal risk to the subjects
(2) The waiver of consent will not adversely affect the rights and welfare of the subjects
(3) The research could not practicably be carried out without the waiver