CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 2.1: Review of Research: DETERMINING LEVEL OF REVIEW	
Original Date: May 2006	**Date of Last Revision:** 02-07, 01-08, 8-14, 8-23
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To describe how the Carilion Institutional Review Board (IRB) differentiates human subjects research from non-human subjects research, and how it determines the level of review needed for each proposal that is received and how each submission is processed.

General Description:

Except for certain emergency use situations, all research involving human subjects must have IRB review and approval prior to initiation of research. The Carilion IRB Regulatory Affairs Administrator or other HRPO staff, as appropriate, will review all materials submitted by an investigator for a particular study. By reviewing these materials, the staff will determine if the study requires full board review or expedited review, or if it can be considered either exempt from review or a non-human subjects research project. When necessary, the staff will confer with the IRB Chair and/or the Human Protections Administrator (HPA) to determine the level of review. The IRB does not have the authority to approve human subjects research that has already been conducted.

Procedure:

Human Subjects Research vs. Non-Human Subjects Research

Research is defined by federal regulations as "a systematic investigation designed to develop or contribute to generalizable knowledge." To contribute to generalizable knowledge, information gathered and analyzed normally needs to be disseminated via a publication or presentation to those who can use the knowledge.

A human subject is defined as "a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual; or identifiable private information."

Additionally, the IRB's obligation to protect human subjects may apply to situations where body tissue is being collected. This includes such things as:

- Any human tissue and/or bodily materials, such as cells, blood, urine, saliva, organs, hair, nail clippings, etc. being collected prospectively for research purposes
- Residual diagnostic or pathology specimens, including specimens obtained for routine patient care that would have been discarded if not used for research
- Private information, such as medical information that can be readily identified with individuals, even if the information was not specifically collected for the study in question.

- Research on cell lines or DNA samples that can be associated with individuals falls into this category.

Research involving only coded private information or specimens is considered unidentifiable and therefore does not require IRB review if one of the following conditions are met:

- The key to decipher the code is destroyed before the research begins
- The investigator and the holder of the key enter into an agreement prohibiting the release of the key to the investigator under any circumstances
- There are written policies and operating procedures for a repository or data management center that have been IRB approved and that prohibit the release of the key to the investigator under any circumstances
- There are other legal requirements prohibiting the release of the key to the investigator

In the case where coded data or specimens provided to an investigator are to be rendered unidentifiable by written documentation, the documentation must be submitted to the IRB office. IRB staff will verify what level of review is required. For further information, see OHRP "Guidance on Research Involving Coded Private Information or Biological Specimens" at http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf

The emergency use of an investigational drug or biological product does not require prior IRB review and approval. Please see the Carilion IRB Emergency and Treatment Use of Investigational Drug SOG or the Investigational Medical Devices SOG for further information.

Initial Submissions

The application, protocol (if included) and consent form(s), if required, and all related study documents will initially be assessed by the staff for level of risk and purpose of the study.

All required items will be verified including human research protections training completion for all research staff listed on the application, reported conflict of interest, principal investigator's CV received within the last 2 years of the submission, and approval from the Department of Research & Development.

Quality Assurance/Quality Improvement (QA/QI)

For studies that appear to assess, analyze, critique or improve a current process of health care delivery in an institutional setting, the review category of QA/QI may be considered. Information provided by the investigator will be assessed for completeness and the investigator will be advised of any information that needs to be clarified or provided. Once all documentation has been received, a letter will be sent to the investigator advising that the proposal qualifies as QA/QI and that further IRB review is not required. A copy of this letter will be forwarded to the Research and Development Department, Institutional Official, and other involved departments, if appropriate. When approved, the title of the study, the name of the investigator and the approval date will be reported as an information item to the IRB members.

Full Board Reviews

For studies involving more than minimal risk to subjects, a full board review will be considered. Consent forms will be reviewed based on content, readability, grammar, and the other elements required by the Department of Health and Human Services (DHHS) and the Federal Drug Administration (FDA). Changes to the consent, if necessary, will be communicated to the

investigator outlining the necessary changes.

When changes are received, the information will be verified for accuracy and completeness. The investigator will be notified about the IRB meeting date/time and asked to be available in the event there are questions from the committee.

IRB members will be sent an agenda packet listing studies requiring full-board review. In addition to the application and consent form(s), the IRB committee will have access to all related study materials. Checklists will accompany the reviewers' information and will be provided approximately one week before the scheduled meeting date.

For studies that have received full board review, the board may vote to approve the study as is, approve the study pending minor changes, defer the study until more information is received, or disapprove the study. For each scenario, a letter will be sent to the investigator describing the outcome and any action that may be required. A copy of the letter containing the decision of the IRB will be forwarded to the Research Department, the Institutional Official, and other involved departments, if appropriate. When approved, the title of the study, the name of the investigator and the approval date will be reported as an information item to the IRB members.

Expedited Reviews

For studies that present no more than minimal risk to subjects and involve only procedures listed under 45 CFR 46.110 and 21 CFR 56.110, expedited review may be considered. The IRB staff will review consent forms in order to verify content, readability, grammar, and the other elements required by DHHS and the FDA. Changes to the consent, if necessary, will be communicated to the investigator outlining the necessary changes.

Once changes have been appropriately made, the IRB chair, IRB Regulatory Affairs Administrator, or other HRPO staff, as appropriate, will review the study and will be able to grant approval. An approval letter will be sent to the investigator citing the appropriate expedited category. If the reviewer does not approve the study, the study will be scheduled for a review by the full board.

A copy of the letter containing the decision of the IRB will be forwarded to the Research and Development Department, the Institutional Official, and other involved departments, if appropriate. When approved, the title of the study, the name of the investigator and the approval date will be reported as an information item to the IRB members.

Exempt Reviews

Under certain circumstances, studies that present no more than minimal risk to subjects may be eligible for exempt review. Information provided by the investigator will be assessed for completeness and the investigator will be advised of any information that needs to be clarified or provided. Once all documentation has been received, an approval letter will be sent to the investigator citing the appropriate subsection of 45 CFR 46.101 that the study has been approved under. Copies of this letter will also be forwarded to the Research and Development Department, the Institutional Official, and other involved departments, if appropriate. When approved, the title of the study, the name of the investigator and the approval date will be reported as an information item to the IRB members.

The study will remain active in the Carilion Clinic IRB office for one year from the date of approval. The investigator must report to the IRB any changes to the study if those changes

could affect the IRB's determination of exempt status.