CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 2.4: Review of Research: FULL-BOARD REVIEW	
Original Date: February 2006	**Date of Last Revision:** 02-07, 01-08, 04-08, 06-14, 08-23, 05-24
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To provide researchers with the process for applying for full-board review of their research proposal with the Carilion Institutional Review Board (IRB).

General Description:

Federal regulations mandate that any research must be reviewed and approved by an IRB prior to its initiation. It is the responsibility of the principal investigator to provide the IRB with sufficient information to make this determination. Full board review of research is conducted when the research does not meet the criteria for exemption of review or expedited review or otherwise is determined to necessitate review at a convened meeting of an IRB committee. Carilion Clinic IRB approves research according to 45 CFR 46.111 and/or 21 CFR 56.111.

Procedure:

Items reviewed at full board meetings include new submissions, continuing reviews, amendments and revisions, serious adverse events/unanticipated problems, non-compliance, and other business as necessary. The board members receive an agenda outlining the items for full board review as well as items which have been previously approved by expedited review prior to the meeting. Additionally, the members will receive in sufficient time all supporting materials necessary to conduct proper review. Convened meetings of the Carilion Clinic IRB may be conducted via Microsoft Teams. The meetings are called to order by the chair or designee once a quorum has been established. A quorum of members is also necessary to review research and vote on actions. Quorum is met when a majority of members of the convened board, including at least one Non-scientist, are present. The chair or designee will ask if any member has a conflict of interest with any of the items being reviewed at the meeting. If so, the member will recuse him/herself during final review and vote.

All new research is submitted to the IRB on the IRB Research Application, which can be found in the Carilion IRB electronic submission system PRIS3M. All appropriate sections of the form must be filled out prior to submission.

According to the IRB submission schedule, which can be found on the Carilion IRB website, the following items must be submitted to the IRB Office on the first deadline prior to the IRB meeting at which the research is to be presented:

- IRB Research Application*
- Protocol

- Consent form
- Recruitment information (flyers, brochures, advertisements, surveys, scripts)
- Data Collection Tool
- Questionnaire
- Investigator Brochure, if an investigational drug study
- Grant application, if federally funded
- IND approval letter, when applicable
- A copy of the Form 1572 Statement of Investigator (study conducted under an IND application), if applicable
- Payment for the review, if applicable
- For new investigators, an electronic Curriculum Vitae or resume

**Note: Unless the study is sponsored or if the researcher will use a separate protocol to conduct his or her research, the IRB will consider the IRB Research Application to be the study protocol.*

The IRB may request additional information as it determines to be appropriate, including requesting verification from other sources if the study is complex, if it involves unusual levels or types of risk to the subjects or if there is an investigator history of non-compliance.

Once the information is received, the IRB administrator will send a confirmation email to the principal investigator. IRB staff will review the application, protocol, consent form, and other materials and may request that revisions be made to the documents to meet the basic requirements of the IRB. Either an email will be sent to the principal investigator detailing these changes or the stipulation function in PRIS3M will be used, and a time will be assigned for presenting at the IRB meeting. The protocol may not be assigned to the next scheduled meeting but to a subsequent one in the case of high new protocol volume or other scheduling conflicts.

Once preliminary revisions are made (if necessary), the following will need to be submitted according to the submission schedule for final deadline based on feedback from the IRB Office:

- Consent form
- IRB Research Application
- Protocol (not required, only if principal investigator prefers)
- Recruitment materials
- Data collection tools
- Questionnaires
- Any other study related materials as applicable

Prior to the meeting, the principal investigator will be notified if a reviewer or member has specific questions or concerns about the proposed research. At the IRB meeting, the principal investigator, or designee confirmed with the IRB Office, may be given the opportunity to give a brief presentation. There will be time to address questions from IRB members. There will be one or more reviewers assigned to review the protocol who have appropriate scientific knowledge and experience and who will lead the discussion with the chair or designee. After the presentation and/or questions, the principal investigator will be dismissed so the IRB can continue its discussion and voting.

The criteria that must be satisfied for the IRB to approve research includes:

- Risks to subjects are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or

treatment purposes;

- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116 and 21 CFR 50.20.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 and 21 CFR 50.27.
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects

Additionally, the IRB will determine that the frequency and extent of continuing review for each study is adequate to ensure the continued protection of the rights and welfare of research subjects. The duration for which IRB approval is granted is based on the level of risk to subjects and, if applicable, the analysis of this risk compared to the risk of alternative care, or standard care if such a standard exists. Factors considered in setting the frequency of review include the degree of risk involved and the vulnerability of the study subject population

The IRB performs this risk assessment as part of the review of each protocol, either by the reviewer using the expedited procedure for protocols qualifying for such a review, or at a convened meeting. When the risk is great, particularly in relation to the risk associated with receiving standard care, the IRB will consider requiring that continuing review be conducted in less than one year, either determined by the time interval from approval or the number of subjects entered on the study. Some examples of protocols that may be considered for review more frequently than annually include:

- Studies involving planned emergency research (21 CFR 50.24);
- Studies involving a significant risk device;
- Studies in which a healthy volunteer may undergo anesthesia or a medical procedure involving sedation, but with no direct health benefits;
- Studies in which individuals with impaired decision making capacity will be enrolled;
- Studies for which there is little external oversight or data safety monitoring; or
- Studies involving gene transfer or xeno-transplantation.

The period of IRB approval, whether annually or more frequently than annually, will be documented in the written minutes of the convened meeting. The approval notification sent to the investigator will also specify the time/date determined by the IRB for when the protocol's

IRB approval will expire.

Within five business days after the IRB meeting, the principal investigator will be notified by email regarding the IRB's decision. The board may issue approval of a research project contingent upon conditions being met by the investigator. The IRB will only issue a contingent approval when it is able to specifically stipulate in its motion the action requested before approval will be granted. If any of these conditions require substantive modifications or clarifications that are directly relevant to the determinations made by the IRB to satisfy federal regulations, then once the changes have been made, the research will again be brought before the convened IRB. Any approval of the proposed research will be deferred pending subsequent review by the convened IRB. If the required changes do not involve substantive modifications or clarifications that are directly relevant to the determinations made by the IRB to satisfy federal regulations, then once the changes have been made and reviewed by the IRB chair or designee, an approval can be granted. These changes need to be made within 30 days from the date of the email requesting the changes to be made. If these changes are not made within the appointed time, the principal investigator will receive an email stating that approval has not yet been granted. Once these changes are made, an approval letter will be sent to the principal investigator. Copies of this letter will be sent to the Carilion Clinic Department of Research and Development, the Institutional Official, if appropriate, and another copy will be kept on file. If the proposed research is disapproved, specific reasons will be explained to the principal investigator in writing. In addition, if current research is suspended or terminated, the principal investigator will be notified of the reasons in writing.

The original consent will be marked with the Carilion Clinic IRB approval date and will be provided in PRISM, the electronic IRB submission system. This consent form is to be used as a master copy. A copy of the form should be used when enrolling new subjects. The consent will be valid until a new consent form is approved due to a modification or until the study is closed to enrollment.

If the protocol is not approved, the principal investigator may accept the disapproval, modify and resubmit the study, or appeal (please see the IRB Appeal Process guideline). If a protocol is not approved, the reasons for the decision will be documented. If a protocol requires modification, the items of concern will be detailed to assist the principal investigator.

In order to ensure study staff has a minimum level of research ethics training, all investigators and study coordinators listed on the IRB application must complete the online Collaborative IRB Training Initiative (CITI). Other personnel assisting in the research will also be required to take the exam.

Sponsors conduct periodic monitoring visits and audits of researchers' files for each protocol. The results of these monitoring visits and audits should be sent to the IRB Regulatory Affairs Administrator within seven business days of receipt.