# CARILION CLINIC INSTITUTIONAL REVIEW BOARD
# Standard Operating Guidelines

| **Title:** 2.8: Review of Research: HOW TO NOTIFY IRB OF CHANGES/UPDATES TO RESEARCH PROJECTS, PRINCIPAL INVESTIGATOR AND PERSONNEL CHANGES | |
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| **Original Date:** April 2006 | **Revision Date: 1-08, 8-23, 1-24, 2-26** |
| **Primary Sponsor:** Human Research Protections Office | **Approved By:** Director of the Human Research Protections Office |

## Objective:

To provide guidance on how to notify the Carilion Institutional Review Board (IRB) with any change or update to approved research projects.

## General Description:

Any changes that need to take place in a research study must be approved by the IRB before those changes may be implemented. This includes amendments, revisions, updates, addendums, study status changes, modifications due to protocol deviations/violations, and local personnel changes. If the changes directly influence the safety of a patient, immediate action may be taken, and then the change submitted to the IRB within seven business days.

## Procedures:

A Research Change/Update Form is used to report study changes to the IRB. These changes should be submitted as soon as the principal investigator is made aware of them. The changes will be reviewed in an expedited manner if the changes are minor, and with full IRB review if the changes are determined to be major. This form should note whether the change affects the protocol and/or the consent form, and a description of the change.

A Minor change is defined as a change that would not adversely alter the assessment of the risks and benefits of the study, or a change that would not alter the specific aims, methods or scientific validity of the study. Minor changes include, but are not limited to:

- Changes in personnel that do not alter the qualifications of the research team to conduct the research
- Contact (address/phone) changes
- Change to the enrollment goal
- Clarification of statements or typographical errors that do not change the content or intent of the consent, IRB application, or research documents

A major change is defined as a change that may potentially increase the risk to the subject, or that may significantly change the study design. Major changes may include, but are not limited to:

- Identification of new, potentially significant risks
- Additional research procedures
- Altering medications or increase/decrease in dosage

- Additional invasive procedures
- Inclusion of vulnerable subjects
- Exclusion or inclusion of a particular group of subjects which may alter the aims of the research
- Changes due to an unanticipated problem or noncompliance
- Changes to the data safety monitoring plan

The submission of changes will be reviewed by the IRB Committee that originally approved the study unless there is a participant safety issue. Please check with the IRB Regulatory Affairs Administrator for dates.

When the consent form has been modified, the document will be stamped with a new approval date in PRIS3M. Approval of an amendment does not change the expiration date of the consent.

The approval for the modified consent document will last the life of the study, or until it is amended; whichever comes first. All future participants must sign the current approved consent going forward, beginning on the approval date of the most recently approved consent amendment. It is the responsibility of the principal investigator and the research study team to ensure they are using the most current and recently approved version of the consent form when consenting and enrolling participants. It will also be the responsibility of the principal investigator and the research study team to ensure that no participant is enrolled if the expiration date for the study's IRB continuing review has been exceeded. The approved consent document must be accessed in PRIS3M.

The IRB will determine the need for subjects to be re-consented and how that is to occur. The IRB approval letter will include instructions regarding the re-consent process.

**If Requesting an Exception/Deviation to Protocol:**

Planned protocol exceptions/deviations are not intended to be a permanent change to the protocol and are not intended to be requested on a regular basis, i.e. multiple requests for the same exception/deviation. If multiple requests are submitted for the same exception/deviation or to the same protocol, the Principal Investigator may be required to submit an amendment to the IRB for review.

In order to obtain approval for a protocol exception/deviation, the principal investigator must submit a written request to the IRB. This request should provide a description of the requested exception/deviation and the justification for deviating from the protocol. All approved protocol exceptions/deviations should be listed on the continuing review document.

The Carilion IRB staff will process all protocol exception/deviation requests. Each request will be evaluated on a case-by-case basis by the IRB chair or designee. When appropriate, a protocol exception/deviation request will be reviewed by the convened IRB.

Investigators will be informed in writing of the IRB's decision. No exception/deviation may be implemented without IRB approval.

## Emergency Deviations

Emergency deviations are those occurring in an emergency situation, such as when a departure from the protocol is required immediately to protect the life or physical well-being of a participant. In such cases there is no time to prospectively seek the approval of the IRB. The Carilion Clinic IRB must be notified as soon as possible, but not later than 5 days after the emergency situation occurred (21 CFR 812.150(a)(4)). These events should be reported via a Promptly Reportable Information Form in PRIS3M. If the study is sponsored or has an IRB of Record other than the Carilion Clinic IRB, they must also be notified within 5 days of the deviation.

## Principal Investigator (PI) Changes

The Department Chair of the PI conducting the research assures that the department will assume responsibility for the conduct of the research should the Principal Investigator not remain with Carilion for the duration of the project.

The IRB must be notified by a Change Update Form within 7 business days when the need to change the status of the PI is recognized. The IRB will communicate with the Department Chair of the department overseeing the research regarding the preferred plan for continuing the research. If a new PI is identified, the IRB will facilitate the process for changing the PI in PRISM. The approval by the Department Chair and the acceptance of responsibilities of HRP 800 by the new PI will be documented.

The IRB recommends that a current, equally qualified research team member be identified to oversee the research when the PI is on extended leave (e.g., 30 days or longer). A Change Update Form should be submitted for the temporary status change and again when the PI returns.