

Policy on Closure of an IRB Approved Protocol

Purpose

To outline the Case Cancer Institutional Review Board (Case Cancer IRB) investigator requirements for closing IRB approved research that will ensure compliance with federal, state and local laws and regulations or determinations of the Case Cancer IRB.

Definition

Closure is an action taken by an investigator to permanently discontinue research activities for a study that has current IRB approval, where no more participants will be permitted to enroll onto the IRB approved study, and no patients are continuing to receive treatments prescribed by the protocol, and participant follow-up is being discontinued for participants who were enrolled.

Requirements

Investigators have the responsibility to formally close a study with current IRB approval once it is completed or discontinued. Notification must be sent to the IRB office by completing the *IRB Protocol Closure Form*. Any previously unreported adverse events should be reported at the time the *IRB Protocol Closure Form* is submitted. If the project was discontinued by the investigators, include an explanation of why the project was discontinued and statement of research results, if any. Once a protocol is permanently closed all research activities are considered complete, including data analysis (unless the data is de-identified). Once an IRB protocol has been closed, a participating institution is no longer required to submit annual updates/renewals to the IRB.

Where the Case Cancer IRB is IRB of Record, a protocol may remain open at one participating site and can be closed for another. The investigator must submit an *Amendment to Research Form* indicating the sites at which the protocol is closed. When requesting to remove and close a single site, investigators should consider whether revision to the research protocol and consent(s) are necessary to update contact information and update research records to only include actively participating sites.

A protocol that has been closed cannot be reopened. To resume research activities a new protocol must be reviewed and approved by the IRB. The investigator can keep a protocol open during data analysis by submitting an IRB request for continuing review.

Closures are included in the monthly report to the IRB of administrative actions and are reviewed and accepted by a vote of the full Board.

After a protocol has been closed the IRB does not accept reports of adverse events unless they impact the rights and welfare of enrolled subjects. The investigator should keep all non-reported adverse events on file for review by regulatory agencies.

After a study has been permanently closed, research records should be available for IRB inspection and maintained according to the IRB Policy on Record Retention. IRB records shall be retained as per the IRB Policy on Record Retention. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner (HHS 45 CFR 115 (b)).

Regulatory Citations:

45 CFR 46.115(b)