CHAPMAN UNIVERSITY | INSTITUTIONAL REVIEW BOARD

Post-approval Monitoring

Purpose

1) This policy describes Chapman University's post-approval monitoring program for research involving human participants. The purpose of the post-approval monitoring program is to:

   a) Ensure that researchers and the Institutional Review Board (IRB) follow ethical and regulatory requirements for research involving human participants.

   b) Improve the quality of research by ensuring congruence with what is described in the Cayuse submission and approved by the IRB, and what is occurring during the actual performance of research activities.

   c) Provide a mechanism for educating researchers and the IRB regarding the requirements for research involving human participants.

Policy

1) The IRB will monitor approved research to ensure protection of research involving human participants, assess the quality of the data, and determine whether the conduct of research is in accordance with applicable federal regulations, state law, and Chapman University policies.

2) There are two types of monitoring visits:

   a) Routine visits involve monitoring research based on random selection. The aim of routine monitoring is to verify compliance as well as to proactively identify and, if necessary, rectify potential problems.

   b) Directed visits involve monitoring that is directed by the Director for Research Integrity, IRB, IRB Chair, or the Institutional Official (IO). While directed monitoring is performed primarily to investigate concerns, a goal of this visit would be to provide researchers with increased knowledge into the conduct of research to ensure compliance.

3) The Director of Research Integrity provides oversight and management of the post-approval monitoring program and ensures the IRB and IO receive reports or updates on items of concern.

4) Post-approval monitoring is generally conducted by designated research integrity staff or consultants engaged by Chapman University.

   a) Monitors must not have a personal, professional, or financial conflict of interest with the research.

   b) Monitors are generally not members of the IRB; however, they may provide education or advice to the IRB regarding the management of any findings following the visit.

5) The designated monitors may perform any of the following activities, as appropriate: meet with principal investigator (PI) and their research team, review study records, observe research activity, prepare reports, provide recommendations for ensuring compliance, provide training or information on training options when needed, and assist in the execution of corrective and preventative actions, as necessary.

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6) The IRB Chair and Director of Research Integrity will review post-approval monitoring reports and determine if additional follow-up is needed. All post-approval monitoring reports are shared with the convened IRB as information.

Protocol Selection

1) All research involving human participants, even studies determined to qualify for exempt status, is subject to monitoring.

2) The Office of Research (OOR) may select any research study for review as part of the Human Research Protection Program.

3) PIs may also request a monitoring visit to ensure records and procedures are in compliance with federal regulations and institutional policies, or to prepare for an external audit by a sponsor or federal agency. Visits of this nature are encouraged. During these PI-requested monitoring visits, the monitor focuses on areas of improvement and provides education to the PI and research team.

Monitoring Process

1) Monitors schedule a post-approval monitoring visit with PIs and their research teams, making every attempt to accommodate schedules.

2) Prior to conducting a monitoring visit, the monitor will have a pre-monitoring meeting with the investigator during which time the monitor will explain the process to the PI and answer any questions raised by the PI/research team.

3) During the visit, the monitor reviews and assesses some or all the following, as deemed appropriate:

    a) Research team composition and training

    b) Recruitment procedures

    c) Screening procedures

    d) Current enrollment and signed informed consent documents

    e) Consent process

    f) Study procedures

    g) Incident reports in Cayuse and any other reports related to the research that may be available (e.g., reports from the study sponsor)

    h) Storage of study documents and data

    i) Participant payment

    j) Questions and concerns from the PI and research team

4) Monitors assist PIs in identifying any unanticipated problems and/or noncompliance, as well as provide guidance for self-reporting unapproved changes to the IRB protocol and implementing any necessary actions, such as submitting a protocol modification. In many cases, minor discrepancies observed during post-approval monitoring visits can be addressed through a modification or reverting to procedures that were originally approved; however, appropriate reporting of any unanticipated problems or modifications to the approved research must be reported to the IRB.

Information Sharing Process and Follow-Up

1) Following completion of the post-approval monitoring visit, monitors discuss observations with PIs. PIs must attend both the pre-visit and post-visit meetings with the monitor.
2) Issues that pose an immediate threat to research participants or that may constitute serious or continuing noncompliance are brought to the immediate attention of the Director of Research Integrity, IRB Chair, and IO.
3) Monitors prepare a written report of the post-approval monitoring visit within 7 working days. The goal of this report is to outline any discrepancies from the IRB-approved study and offer suggestions or recommendations for areas of improvement, including any suggested modifications needed.
    a) A draft copy of the report is shared with the PI for comment and review. Following review by the PI, the report is finalized, and a final copy is shared with the PI and attached to the study record in Cayuse.
    b) The final report is also shared with the Director of Research Integrity and the IRB Chair who review the report to determine whether additional follow-up is needed.
4) All post-approval monitoring visits and the resulting report are provided to the convened IRB as information.
5) The Research Integrity staff assists PIs, if needed, in completion of required actions resulting from the post-approval monitoring visit or IRB-determined corrective actions. Assistance may include providing guidance with protocol modifications and/or direction to appropriate training.

Appeals Process

1) If PIs disagree with the findings of the post-approval monitoring visit or required actions, they are invited to address the concerns with the monitor. If a satisfactory resolution has not been determined, PIs may then contact the Director of Research Integrity and/or IRB Chair to discuss these unresolved concerns within 30 days. Again, if no satisfactory resolution is agreed upon, PIs may address their concerns with the IRB in writing within a second 30-day period.

IRB Monitoring

1) While monitors are reviewing the research records for a given study, they will also review the IRB records to ensure the IRB complies with all applicable federal regulations, state law, and Chapman IRB policies.
2) IRB related items to be reviewed by the monitor include but are not limited to:
    a) The original submission approved by the IRB and all modifications, renewals, and incident reports
    b) IRB approval letter(s)
    c) Minutes from the convened meeting, if applicable
    d) IRB reviewer checklists
3) Items of concern will be brought to the attention of the Director of Research Integrity and IRB Chair for resolution. Minor issues observed during post-approval monitoring can be addressed through education for IRB members or IRB administrators.

Record Keeping

1) A copy of the final post-approval monitoring visit report is kept in Cayuse as an attachment to the study file.

Revision history:

May 2023 - Language broadened for greater flexibility as to who may conduct monitoring (e.g., Office of Research staff, consultants, IRB members)

22Jun2022 - original publication date

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