# Post Approval Monitoring

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<th>IRB SOP#</th>
<th>Date Issued</th>
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<td>012</td>
<td>September 12, 2019</td>
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<td>Director of Research Integrity</td>
<td>IRB Chairs</td>
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## Title
Post Approval Monitoring

## Scope
Human Research

## Responsibility
Vice President for Research (VPR); Director of Research Integrity; IRB Administrator; IRB Chair(s); IRB

## Objective
The goal of post-approval monitoring of studies involving human subject research is to confirm by observation and documentation comparison, an accurate and consistent protocol performance, conducted in accordance with an Institutional Review Board (IRB)-approved protocol. An additional goal of the program is to provide education to the investigators on best practices for conducting their human subject research study in compliance with their IRB-approved protocol, Chapman IRB policies and guidance, and federal regulations. The program is also designed to help investigators, their teams, and the University prepare for external audits by granting, regulatory, and accreditation agencies.

## Roles

The purpose of the IRB is to help researchers ensure that the rights and safety of human participants in research are protected and that research is conducted in compliance with relevant regulations. To achieve this, the IRB (1) advises investigators in the design of research projects that minimize potential harm to participants, (2) reviews all planned research involving human participants prior to initiation of the research, (3) approves research that meets established criteria for protection of human participants, and (4) monitors approved research to ascertain that participants are being protected. The IRB has the authority to approve, require modifications, disapprove, suspend, or terminate all human subject research activities at Chapman. The IRB may determine whether a post-approval monitoring visit is needed.

The Director of Research Integrity provides oversight and management of the post-
approval monitoring program and assures that the IRB and the Institutional Official receive reports or updates on items of concern.

As part of the post-approval monitoring program, the IRB Chair(s), in consultation with the Director of Research Integrity, may determine if a post-approval monitoring visit is needed. This is considered a “directed” visit. Additionally, the IRB Chair(s) review post-approval monitor reports in consultation with the Director of Research Integrity and/or the IRB Administrator to determine if additional follow-up is needed.

Post-approval monitoring will be conducted by designated Research Integrity staff. The designated monitor will meet with investigators and/or their teams and confirm by observation and documentation comparison that research activity is performed in accordance with approved IRB protocols. The monitor reviews study records, observes research activity, prepares reports, provides recommendations for maintaining compliance, provides training or information on training options when needed, and assists in execution of corrective and preventative actions.

**Protocol Selection**

All studies, even those determined to qualify for exempt status, are subject to monitoring. Studies chosen for monitoring visits are primarily randomly selected. However, emphasis may be placed on monitoring studies involving greater than minimal risk, vulnerable populations, deception, confidentiality concerns, waivers granted by the IRB (e.g., waiver of informed consent or waiver of documentation of informed consent), or studies conducted by investigators with past IRB concerns.

Monitoring visits may also be “directed” by the IRB, the Director of Research Integrity, or the IRB Chair(s) as needed (e.g., to assist in verification of findings in cases of potential noncompliance, to provide verification of implementation of corrective actions implemented in response to noncompliance, to assist the IRB in monitoring studies requiring more frequent review, etc.).

A principal investigator (PI) may also request an on-site review to help keep records and procedures 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, as the goal of post-approval monitoring is to assist investigators in conducting compliant research. During these PI-requested visits, the monitor focuses on areas of improvement and, if protocol deviations are found, counsels the PI on self-reporting the issue to the IRB, along with submitting a protocol modification if needed.

**Monitoring Process**

The monitor schedules the visit with PI(s) and their staff, making every attempt to accommodate schedules. “Directed” monitoring may or may not be scheduled.
During the post-approval monitoring visit, the monitor compares procedures being conducted in the laboratory or study area with those listed in the IRB-approved protocol and any approved modifications. This may include reviewing study records, visiting with the PI to review procedures being followed, observation of the consent process, etc. Documented discrepancies between observed and approved activities are brought to the attention of the PI.

The monitor reviews and assesses areas such as, but not limited to the following:

- Research team composition and training
- Recruitment procedures
- Screening procedures
- Consent process
- Study procedures
- Publications from the study
- Current enrollment and verification of informed consent
- Reports of adverse events
- Storage of study documents and data
- Privacy and confidentiality issues
- Subject payment
- Questions and concerns from the PI and research team

One of the primary goals of the post-approval monitoring program is education. The monitor is able to explain the IRB process, the importance of following the approved IRB protocol, and what is expected from investigators and their team. Additionally, the monitor is a resource for investigators, providing best practice ideas for conducting their human subjects research in compliance with IRB polices and educating the research team on IRB guidance documents, policies, and federal regulations.

The monitor also assists the principal investigator in identifying any protocol deviations and/or unanticipated problems, provides guidance for self-reporting any deviations or 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 modification of an existing protocol or reverting to procedures that were originally approved; however, protocol deviations and/or unanticipated problems are reported to the IRB.

**Information Sharing Process and Follow-Up**

Following completion of the post-approval monitoring visit, the monitor discusses observations with the PI and/or their staff prior to leaving the office/laboratory. If the PI is unavailable, a time is scheduled to discuss the results of the visit. Issues that pose an immediate threat to research participants or that may constitute serious noncompliance are
brought to the immediate attention of the Director of Research Integrity and IRB Chair(s).

A written report of the post-approval monitoring visit is prepared by the monitor. The goal of this report is to outline any discrepancies from the IRB-approved protocol and offer suggestions or recommendations for areas of improvement, including any suggested protocol modifications identified during the visit. A draft copy of the report will be shared with the PI for their comments and review. Following review by the PI, the report is finalized and a copy is shared with the PI for their records. The final report is then shared with the Director of Research Integrity and the IRB Chair(s) who review the report to determine whether additional follow-up is needed.

The Research Integrity staff assists investigators, 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.

**Appeal Process**

If a PI disagrees with the findings of the post-approval monitoring visit or required actions, they are invited to address these concerns with the monitor during the discussion at the end of the visit. If a satisfactory resolution has not been determined, the PI may then contact the Director of Research Integrity to discuss these issues within 30 days. Again, if no satisfactory resolution is agreed upon, the PI may address the IRB in writing within a second 30-day period.

**Recordkeeping**

A copy of the final post-approval monitoring visit report is kept with study files.