Ann & Robert H. Lurie Children's Hospital of Chicago

Institutional Review Board Post-Approval Monitoring (PAM) Program Overview & Timeline

"An IRB shall conduct continuing review of research covered by this policy [regulations] at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research."
45 CFR 46.109 (e), 21 CFR 56.109(f) [FDA]

The Lurie Children's Institutional Review Board (IRB) has the responsibility and authority to observe ongoing research projects and the consent process, conduct periodic reviews of research projects, as well as conduct audits of research records. The IRB will be implementing a Post-Approval Monitoring (PAM) program for the review of research records randomly, for cause, and based on the compliance records of the investigators.

Notification Procedure for Investigators:

Investigators will be notified via e-mail at least one week prior to the PAM visit. This email will contain pertinent information including the study being evaluated, the records that need to be available, the name of the person(s) who will conduct the review, the date and location of a review meeting if indicated, etc. Full cooperation by the Principal Investigator and/or research team is expected.

PAM Procedures:

The basic PAM procedures are described below but due to the high variability in research studies, it is anticipated that modifications will be made to tailor each PAM inspection to the specific study.

<u>The person(s) conducting the visit will typically:</u>

1. Review the IRB documentation and correspondence to identify approved elements to review, e.g., protocol eligibility criteria, informed consent procedures, interventions, security / confidentiality procedures.
2. Assemble PAM materials, e.g., specific PAM tool, interview forms.
3. Notify the PI of the PAM inspection visit and make meeting arrangements, e.g., scheduled time and location, names / titles of research team members, location of records, number of subjects enrolled.
4. Visit the research site(s) to review procedures and records:
    a. Informed consent obtained
    b. Confirmation of eligibility of subjects
    c. Confirmation of interventions / treatments used
    d. Unanticipated problems and adverse events reported to the IRB
    e. Security / confidentiality measures employed
5. Meet with researchers individually to obtain additional input, if necessary.

What to expect after the PAM is completed:

1. A report of findings is compiled and sent to the IRB Chair, ORIC Director, and/or the IRB to review.
2. If necessary, a follow-up meeting or discussion with PI is arranged to clarify any outstanding questions, discuss specific deficiencies found, and obtain input on possible corrective actions if necessary.

3. A final report is prepared which includes requirements for corrective actions and timeline for responding.
4. Once finalized; the report and suggested / required actions are sent to the PI for review and response.
5. If indicated, investigators should respond to the report within established timeframe.
6. The PI's response will be brought to the ORIC Director, the IRB Chair, and/or the convened IRB to determine if any further action is needed.

Procedures for Immediate Action:
If information is discovered at the time of the PAM inspection that indicates that research participants may be at risk, the person conducting the PAM inspection will promptly notify the IRB Chair regarding action to be taken.

At any time during the review process the IRB Chair or IRB may determine that it is necessary to act to protect subjects by suspending, modifying, or permanently closing the research study. If this occurs, the policy and procedures in Policy & Procedures Manual, Section 14.1 I "Suspension or Termination of IRB Approval" will be followed.

The PI is notified in writing of any exceptions or problems requiring corrective action. If possible non-compliance is discovered during the PAM inspection, the non-compliance policies and procedures will be followed. See Policy & Procedures Manual Section 14 "Non-Compliance and Research Subject Complaints".