Continuing Review (Renewals)

OVERVIEW
The IRB must conduct substantive and meaningful continuing review of research at intervals appropriate to the degree of risk. The IRB determines whether continuing review should occur at intervals greater than once per year. This review may take place through full committee IRB review or expedited IRB review, as applicable.

The purpose of IRB continuing review is to analyze the progress of the entire study and the risk/benefit ratio to ensure continuation of the research is acceptable.

PROCEDURES
Criteria for Conducting Continuing Review
FDA and DHHS regulations set forth the criteria to be satisfied if an IRB is to approve research. These criteria are the same for initial review and continuing review. The following information and materials must be provided at the time of continuing review to assess whether the study continues to meet the criteria for IRB approval:

- The number of research participants accrued including a summary of any withdrawals of research participants from the research;
- A summary of amendments approved over the last renewal period. (e.g. brief details of inclusion/exclusion criteria change, procedure change, risks change, dosage change, investigator changes, enrollment goal change, etc.)
- A summary of any unanticipated problems (in many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, consent document, and investigator’s brochure);
- A summary of complaints about the research since the last IRB review;
- A summary of any recent literature that may be relevant to the research and any amendments or modifications to the research since the last IRB review;
- Any relevant information, especially information about risks associated with the research (for example, DSMB reports);
- A copy of the current informed consent document and/or any newly proposed consent document; and
- A copy of the complete protocol.

Continuing Review Notifications
To aid researchers, the HRPP Office will send a courtesy reminder approximately 8 weeks prior to study expiration. Although this reminder is routinely sent out by the HRPP Office, it remains the responsibility of the Principal Investigator (PI) and his/her study personnel to ensure that study approval does not expire.

PI Responsibility
It is the responsibility of the PI and the research staff to complete the form and to submit all relevant materials to assure IRB review. Refer to Guidance: Materials Required for IRB Review and Approval for a general list of information and materials to be submitted with this application.

Lapses in Approval
A lapse in IRB approval of research occurs whenever continuing review information has not been provided to the IRB and, therefore, the IRB has not conducted continuing review and re-approval of the research by the expiration date.
When IRB approval of an ongoing research project lapses and the investigator wants to continue the project, the investigator must contact the HRPP Office immediately upon discovery of lapse.

In such circumstances, all research activities including intervening or interacting with subjects and obtaining or analyzing identifiable private information about human subjects must stop unless it is determined to be in the best interests of already enrolled subjects to continue participating in the research. Continuing participation of already enrolled subjects in a research project during the period when IRB approval has lapsed may be appropriate, for example, when the research interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to the subjects. Enrollment of new subjects cannot occur after the expiration of IRB approval.

The determination regarding whether it is in the best interest of already enrolled subjects to continue to participate in research after IRB approval has expired may be made initially by the investigator, BUT the investigator should submit a request for confirmation that the IRB agrees with this determination. The IRB determination may be made by the IRB Chair or by another IRB member designated by the IRB Chair, or at a convened meeting. If the IRB determined that it is not in the best interest of already enrolled subjects to continue to participate, investigators must stop all human subjects research activities.

Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred. Retrospective approval for work done after the expiration date cannot be granted.

When continuing review of a research project does not occur prior to the end of the approval period specified by the IRB, IRB approval automatically expires.

IRB Procedure for Conducting Continuing Review

Full Committee Review: The IRB will review each study at a convened meeting, unless the study qualifies for expedited review in accordance with DHHS and FDA regulations.

Expedited Review may be used for the continuing review of research previously approved through a convened IRB as follows:

- **Category 8**
  - a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; OR
  - b. Where no subjects have been enrolled and no additional risks have been identified; OR
  - c. Where the remaining research activities are limited to data analysis

OR

- **Category 9**
  - An expedited review process may also be used if the research is not conducted under an investigational new drug application (IND) or investigational device exemption (IDE) and where the research categories 2 through 8 do not apply but the IRB has determined and documented at a convened IRB meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Typically a research study that qualified for expedited review at initial review will qualify for an expedited review procedure at the time of continuing review. However, it is possible that a research study previously approved under categories 1 through 7 may need to undergo continuing
review by the IRB at a convened meeting if the research has changed, or will change, outside of the scope of research activities eligible for an expedited review procedure.

IRB Review Process
The IRB will determine if the study should be terminated, amended, or allowed to continue. The IRB may determine that significant new findings regarding the research might relate to research participants’ willingness to continue taking part in the research. In such cases the IRB has the authority to require communication of such information to research participants.

The IRB will consider the following during continuing review:
- Any unanticipated problems involving risks to research participants
- Any new information regarding the risks and benefits to the research participants
- Research progress
- Informed consent process and use of correct approved consent
- Changes in the risk/benefit ratio
- Investigator and institutional issues
- Whether the information contained in the consent document is accurate and complete

The IRB may approve renewal of research for a defined time period which will be no greater than two years (730 calendar days) depending on the governing regulations. Expiration date is the last date the protocol is approved, and is specified in the IRB determination correspondences. If additional risks to participants are identified, then the IRB may approve the renewal with additional restrictions (e.g. limiting number of research participants enrolled or requiring more frequent reporting to the IRB).

Extended Approval
Research excluded from the scope of the FWA (see guidance on Protections for Non-Federally Funded Human Research) may be reviewed using methods commensurate with those outlined by the federal regulations.

The extended approval commensurate review method allows nonexempt non-federally funded research projects, involving no greater than minimal risk, to qualify for continuing review by the IRB every two years. This method is acceptable provided that the study continues to meet the aforementioned standards. The IRB maintains the right to make exceptions to this process.

Exclusions from this commensurate review method include, but are not limited to, the following:
- Federally funded research;
- FDA regulated research;
- Research determined to be greater than minimal risk;
- Research with prisoners;
- Research involving clinical intervention; and
- Any other research as determined by the reviewing staff in the SJH Human Research Protection Program (HRPP).

REFERENCES
OHRP’s Guidance on IRB Continuing Review of Research
FDA’s Guidance on IRB Continuing Review after Clinical Investigation Approval