

	CONTINUING REVIEW			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	3.02	02.12.2020	3.02	02.07.2020

IRB review of approved protocols is on-going. Approval is granted for a set period of time as determined by the Board. This period of approval is granted for up to one year depending upon the nature of the study and the degree of risk to the subject. The expiration date is calculated as one year from the approval date minus one day. If the approval period is for less than one year, then it is always the number of months less one day. The purpose of IRB continuing review is to assure that (a) the risk/benefit of the research remains acceptable, (b) the informed consent process and documents are still appropriate and (c) the enrollment of subjects has been appropriate. The IRB may require information from outside sources to verify that no material changes have occurred since the previous IRB review. Investigators should notify the IRB of any premature closure or completion of a study.

Studies that are considered exempt at initial review do not require continuing re-approval. However, the investigator must submit a status report to the IRB every three years if they wish to continue the study. Further, investigators must notify the IRB of any changes to the protocol so that an evaluation may be made to determine whether the study remains exempt from IRB oversight.

Non-FDA regulated studies that were originally given expedited approval after implementation of the New Common Rule (January 21, 2019) do not require continuing re-approval. However, the investigator must submit a status report to the IRB every three years if they wish to continue the study. Further, investigators must notify the IRB of any changes to the protocol so that an evaluation may be made to determine whether the continuing re-approval is now necessary.

As a courtesy, a notification reminder requiring an application for continuation is forwarded by e-mail to the principal investigator 45 days, 30 days, and 15 days prior to the expiration of the current approval period. This form must be returned prior to the deadline listed. This continuation application must be completed in its entirety and, if initially required, accompanied by copies of the most recently-approved consent form and HIPAA Authorization document. Copies of the three most recently-completed informed consent documents, HIPAA authorization documents and Notice of Privacy Practices acknowledgement forms signed by subjects during the current approval period, with all identifiers redacted, must also be submitted with the re-approval application. Incomplete or late re-approval applications may result in suspension of all activities for that protocol. Investigators cannot enroll new subjects, continue participation of currently-enrolled subjects (unless medically indicated for safety), or continue data collection, etc. during any period not approved by the IRB. If the investigator does not receive a signed and approved Re-approval application form back from the IRB for any reason before the study's approval period expiration date, the study is considered to be administratively de-activated on the expiration date. The expiration date is the last date of the current protocol approval period. Investigators must refrain from enrolling any subjects until formal notice of continuation is received. It should be noted that under all circumstances the investigator is ultimately responsible for assuring that an application for continuation and all renewal materials are supplied to the Board in a timely manner. All materials must be received in the IRB offices prior to the deadline listed in the e-mailed notification to assure review at the pertinent meeting.

All applications for continuation of an on-going protocol are date-stamped when received in the IRB office. Applications are matched to study folders and the packet is provided to the Chair for consideration. All continuing review applications are evaluated by the Chair or designee to determine if they are eligible for expedited review and re-approval as defined at 45CFR46.110, 21CFR56.110 and the policies detailed in the present document. Studies that qualify for expedited continuing review include:

- Studies that were originally approved by expedited review before implementation of the New Common Rule (before January 21, 2019);
- FDA regulated studies that were originally approved by expedited review; or,
- Studies that were originally approved by the Full Board that are now closed to accrual and are either in survivor follow-up or data analysis only.

For studies receiving expedited re-approval, the continuation period will start on the day the Chair grants approval, but in no case will that period be for longer than one year. If not eligible for expedited review or if the status has changed, the application is forwarded to the Full Board for review.

Applications which are complete and require Full-Board review for continuation are placed on the agenda for the pertinent Full Board meeting.

If it is determined that the study must receive Full Board consideration for re-approval, the Chair assigns a primary reviewer for the evaluation of the continuation of the protocol in the same manner used for new applications. A comment checklist is provided for the reviewer's summary and recommendation.

For continuing review of research by a convened IRB, when they are scheduled to attend an IRB meeting, all members (including attending alternate members) are provided and review: the application (which represents the status report on the progress of the research) including a protocol summary containing the relevant information necessary to determine whether the proposed research continues to fulfill the criteria for approval; the currently-approved consent document. These are provided in each Board member's meeting book. During the meeting, the primary reviewer presents a summary and recommendation based on the review of the full protocol file kept in the IRB office. This material is available to all members prior to and during the meeting. Members are asked for comments, a motion is made and the Chair calls for a vote. The vote is recorded on the Chair's vote sheet. The IRB determines that the current consent document is still accurate and complete, and that any significant new findings that arise from the review process and that might relate to participants' willingness to continue participation will be provided to participants. Notification of the Board's decision is made to the principal investigator following the meeting. The approved re-approval application form indicates the new approval period. That approval period starts on the date of the meeting at which the application for continuation was considered and approved. In some cases, continuing approval will not be granted at the meeting and the application may be returned to the Full Board for review. If the IRB approves the research with conditions, the date of approval is the date the conditions are determined to be met. If the protocol approval period expires before the conditions are reviewed and approved, all research activities must stop until approval is obtained. The period of approval in all cases will be for no more than one year. In some cases, the approval period will be for less than one year.

The principal investigator receives the document indicating the new approval period. Any restrictions or additional requirements imposed by the Board are also communicated to the principal investigator in writing.

The IRB computer file record is updated to indicate the start date of the new approval period.

If, for any reason, a study that does not require continuing review is asked to conduct a continuing review, the IRB will document in the study record the rationale for that decision.

Continuing reviews are no longer required if a study is closed or if data analysis is still ongoing with only de-identified data. In order to further assure that projects are being conducted per the IRB-approved protocol, the IRB management staff in conjunction with the LSUHSC-NO Office of Compliance Programs

may conduct random “non-directed” audits of selected protocols. The HIPAA Privacy Officer examines study records for compliance with HIPAA Authorization requirements and an IRB Coordinator examines study records for compliance with all aspects of protocol and informed consent requirements. Any deficiencies are reported to the IRB Chair and procedures for handling issues of non-compliance are initiated.

Post-Approval Monitoring

In addition to continual review of projects when items for action are submitted for review by the IRB; e.g., SAEs, Unanticipated Problems, amendments, etc., and at the time of re-approval, the IRB and Office of Compliance Programs conduct a formal post-approval monitoring program to assure compliance with all aspects of the research study.

Study Self-Assessment

The IRB randomly selects studies each yearly quarter for which the study team must complete the LSUHSC-NO IRB Post-Approval Self-Assessment form. Based on the results of this process, studies may be selected for “non-directed” or “directed” (based on suspected non-compliance issues) audit by the IRB. These audits may be conducted in conjunction with the Office of Compliance Programs HIPAA. All study-related materials including, but not limited to, Case Report Forms, regulatory documents, communications with the Sponsor, signed informed consent documents, and source documents must be made available to the IRB for these on-site audits.

Audits conducted by the Office of Compliance Programs and HRPP

As time and resources permit, the Office of Compliance Programs and Privacy Officer conducts randomly-selected, non-directed audits of studies selected as described in the previous section that come under the aegis of the HIPAA Privacy Rule. Authorizations and acknowledgements of distribution of Notices of Privacy Practices are examined.

As described previously, during these same audits, staff of the HRPP examine the general conduct of studies, regulatory documents, and informed consent documents.

Directed For-Cause Audits

Based on any information received by the IRB that might suggest an issue of non-compliance, the IRB and/or Office of Compliance Programs may conduct audits of the conduct of a study including all related study documents. Such information may come from document review, reports from study subjects, reports from study team members, or anyone having knowledge of potential non-compliance. Procedures for dealing with issues of non-compliance are initiated upon receipt of any allegation of non-compliance.