

Renewal of Research Involving Human Participants

Purpose

- 1) The policy describes when continuing review or renewal of research must occur for research that underwent initial Chapman University Institutional Review Board (IRB) review and approval. In addition, this policy describes the requirements for conducting continuing review of research. Continuing review of research is not required for studies deemed exempt by the IRB or for minimal risk research that was approved by the IRB via expedited review procedures after January 21, 2019, unless the IRB provides a justification for requiring renewal at the time of initial approval. Throughout this document, the terms continuing review and renewal are used interchangeably.

Policy

- 1) The Chapman IRB conducts a review for renewal of human participants research at intervals appropriate to the degree of risk, but not less than once per year as follows:
 - a) Greater than minimal risk research approved by convened IRB.
 - b) Food and Drug Administration (FDA) regulated minimal risk research approved by expedited review procedures.
 - c) Minimal risk research approved by expedited review procedures prior to January 21, 2018.
 - d) Minimal risk research approved by expedited review procedures after January 21, 2018, when the IRB documents its decision along with its rationale and interval for annual review.
- 2) During the renewal process, the IRB determines that all regulatory requirements as set forth in [45 CFR 46.111](#) and [21 CFR 56.111](#) are met, or continue to be met, as a condition for approving research for continuation.
- 3) At the time of renewal, the IRB may determine which research studies require verification from sources other than the investigator to assure that no material changes in the research have occurred since the previous IRB review.
- 4) The Chapman IRB utilizes a reviewer checklist to ensure human participants will be protected while participating in research. The IRB continuing review checklist incorporates the regulatory criteria to review and approve research involving human participants. The checklist assures that the regulatory criteria have been fulfilled, and where applicable, also contains other requirements to approve research.

Research that Does Not Require Renewal ([Revised Common Rule FAQs](#))

- 1) Research that meets at least one of the following criteria does not require renewal but is still subject to IRB oversight:
 - a) Research was determined to be exempt (including exemption categories requiring limited IRB review).
 - b) Research reviewed in accordance with the limited IRB review procedure.
 - c) Non FDA regulated research eligible for initial review by the expedited review procedure after January 21, 2019.
 - d) The convened IRB (i.e., the full board) has determined the research presents no greater than minimal risk to participants. The research has progressed to the point that it involves identifiable data or de-identified data, for analysis only (per 45 CFR § 46. 109(f)(1)).
 - e) Accessing follow-up data from procedures that participants would undergo as part of clinical care.
- 2) The IRB may determine that research meeting the above criteria is required to undergo continuing review in the following circumstances:
 - a) The research sponsor is requesting continuing review as a condition of funding.
 - b) The research involves oversight that must be monitored, such as Conflicts of Interest for the researchers or institution.
 - c) The PI or other researchers have had serious non-compliance or a pattern of non-serious non-compliance in their research practice (these are reviewed on a case-by-case basis by the IRB).
- 3) When continuing review is required for research meeting the above-referenced criteria, the IRB will specifically document in Cayuse IRB that renewal is required for the research, including the frequency of such review as well as the justification for requiring the renewal.
- 4) Although a formal renewal submission might not be required, PIs continue to be responsible for submitting to the IRB any incident reports, serious or continuing non-compliance, and modifications to the approved research for the life of the research. PIs should also notify the IRB of the completion of the research.

Notification of Renewal

- 1) As a courtesy, the IRB will send email reminders to Principal Investigators (PI) before the research expires. An initial reminder will be sent via Cayuse IRB 75 days prior to study expiration and every 15 days thereafter until a renewal submission has been formally reviewed and approved by the IRB. However, it is ultimately the PI's responsibility to complete and submit the IRB renewal submission in time for IRB review and approval prior to the study's expiration of approval.
- 2) The IRB recommends investigators submit a renewal application at least 30 days prior to the expiration of research reviewed by expedited procedures and 60 days prior to the expiration for research requiring full board review. This will allow sufficient opportunity for the IRB to review the submission and make their determination prior to the expiration date.

Renewal of Research Using Expedited Procedures

- 1) The IRB will use expedited review procedures to conduct continuing review of:
 - a) Research previously approved via expedited review procedures that continues to be eligible for expedited review.
 - b) Research previously approved by the convened IRB where:
 - i) The research is permanently closed to the enrollment of new participants, all participants have completed all research-related interventions, and the research remains active only for long-term follow-up of participants; or
 - ii) Where no participants have been enrolled and no additional risks have been identified either at the local site or at any site if the research involves a multi-site study; or
 - iii) The remaining research activities are limited to data analysis.
 - c) Continuing review of research not conducted under an Investigational Device Exemption (IDE) ([21 CFR Part 812](#)) where expedited categories two (2) through eight (8) do not apply but the IRB determined and documented at a convened meeting, and in the meeting minutes, that the research is no greater than minimal risk and no additional risks have been identified ([Expedited Category 9](#)).

Renewal of Research Originally Reviewed by the Convened Board

- 1) As stated above, except when expedited review procedures are applied, the Chapman IRB must review research involving human participants at convened meetings, often referred to as full board reviews or full committee reviews. At the convened meetings, a quorum of the IRB must be present.
- 2) IRB will review research renewals in the same manner it reviews initial submissions, in accordance with the [Initial Review of Human Subjects Research](#) guidelines. In addition, the IRB will also consider:
 - a) Any unanticipated problems involving risks to research participants.
 - b) Any new information regarding the risks and benefits to the research participants.
 - c) Risks posed by the study procedures (e.g., interventions or interactions with participants).
 - d) The type of safety monitoring needed as determined during the initial review.
 - e) Changes in the risk to benefit ratio.

IRB Approval and Expiration Dates

- 1) When the IRB conducts the initial review, as well as at each renewal, it will determine the interval of continuing review. The IRB will evaluate the risks associated with the proposed research to make a determination of a review interval that corresponds with the degree of risk.
- 2) Research activities that the IRB has approved without explicit conditions have an effective approval starting on the day they are approved; that is, the date the IRB reviewed and approved the proposed research.
- 3) If the IRB has approved research activities with explicit conditions, that research will receive a final approval date that is effective on the day the IRB issued approval with the conditions (e.g., the date of the convened meeting).

- 4) Period of Approval. More than minimal risk studies, and any other studies designated by the IRB, require a renewal submission. The approval period expires based on the date the convened IRB approved the research. The approval period will not surpass 365 calendar days (366 calendar days if approval has been granted during a leap year) from the approval date. In certain instances, this review interval may be sooner than annually if the IRB determines more frequent review is necessary as noted below.
 - a) In some instances, shorter renewal intervals (e.g., semiannually, quarterly, or after a determined subject enrollment number) may be stipulated. The IRB meeting minutes will document and justify how the convened IRB has determined the review interval.
 - (1) The list that follows provides examples of instances when the IRB could require shorter continuing review intervals:
 - (a) There is a high degree of risk to participants.
 - (b) The stage of research is such that many of the risks are unknown.
 - (c) The proposed procedures have not been used in human participants.
 - (d) There have been confirmed instances of serious or continuing noncompliance.
 - (e) An IRB member believes more frequent review is required.
 - (f) Other reasons for which the IRB requests closer monitoring.
 - b) PIs will be notified in writing of approval and expiration dates for their research. Researchers are encouraged to review determination letters thoroughly and retrieve all newly approved study documents (e.g., informed consent documents, recruitment materials) from the electronic system.

Extensions of the Approval Period

- 1) There is no grace period extending the research beyond the expiration date of IRB approval. If the IRB has not reviewed a renewal submission and re-approved the research prior to the study expiration date, IRB approval automatically expires. If this should occur, the PI must stop all research activity, including but not limited to interactions and interventions with participants, as well as data analysis.
 - a) During the lapse of IRB approval, new participants cannot be enrolled, and prospective data cannot be collected until the renewal process has been completed.
 - b) Should an investigator wish to continue the research following the study expiration, a new application must be submitted in Cayuse IRB for IRB review and approval.

Criteria for Renewal of Research

- 1) The criteria for approval of research detailed at [45 CFR 46.111](#) and [21 CFR 56.111](#), and all applicable regulatory subparts, are reevaluated during the renewal process. In order to review the study, IRB members are provided and review the following documents:
 - a) Consent, parental permission, and assent document(s).

- b) Renewal application which includes a summary since the last IRB review of:
 - i) The number of enrolled participants
 - ii) Any significant new findings that may relate to the research participant's willingness to continue participation
 - iii) Adverse events and adverse outcomes experienced by participants
 - iv) Unanticipated problems involving risks to participants or others
 - v) Participant withdrawals
 - vi) The reasons for withdrawals
 - vii) Complaints about the research
 - viii) Modifications
 - ix) Any relevant recent literature
 - x) Any interim findings
 - xi) Any relevant multi-center trial reports
 - xii) The researcher's current risk to benefit assessment based on study results
- c) The IRB administrator assigns IRB members to serve as the primary and secondary reviewers for each renewal submission.

Possible IRB Determinations

- 1) The determinations outlined below are applicable to research reviewed by expedited procedures or the convened IRB.
- 2) The IRB determinations made during initial review or renewal of research comprise the following:
 - a) **Approved:** Approved by the IRB as written without explicit conditions. The research may proceed.
 - b) **Minor Stipulations:** The IRB has determined that research is approved with required minor changes.
 - i) Minor changes that are required will be clearly delineated so that the PIs understand the IRB's stipulations and can address them fully.
 - ii) The PI must address and complete the IRB's stipulations to obtain full IRB approval.
 - iii) For approvals with stipulations, the IRB Chairs or designated IRB reviewers may approve the proposed research on behalf of the IRB upon reviewing the PI's adequate response(s) to the conditions.
 - iv) When the IRB approves research with minor stipulations prior to the expiration date of the preceding IRB approval period, IRB approval does not lapse. Investigators have 30 calendar days following receipt of the stipulations to secure full approval.

- c) **Deferred:** The IRB requires additional substantive clarification(s) regarding the proposed research or the research lacks sufficient information and the IRB cannot establish whether it satisfies the criteria for IRB approval of research ([45 CFR 46.111](#); [21 CFR 56.111](#)). The research may not proceed until the convened IRB has approved a revised application incorporating all necessary information.
 - i) The IRB may invite PIs to the convened IRB meeting if the IRB has additional questions concerning the proposed research.
 - d) **Disapproved:** The IRB has determined that the proposed research cannot be conducted at Chapman University.
 - i) A disapproval determination may only be rendered at a fully convened IRB meeting.
 - (1) PIs may request that the IRB reconsider disapproved research by submitting a written response to the IRB.
 - (2) The IRB may reconsider its original review determination in light of new information the PI offers about the proposed research
- 3) The IRB meeting minutes record the determinations that the convened IRB makes, as well as the votes that support these determinations.

Modifications at Renewal

- 1) Researchers may submit modifications to the research (e.g., changes to personnel, informed consent forms, recruitment materials) simultaneously with renewal. These are two separate submissions in Cayuse IRB. Approval for the proposed changes must be secured prior to implementation.

Notification of IRB Determinations

- 1) The PI will be notified of the IRB determination.
- 2) For research reviewed at a convened meeting, the IRB will determine whether the PI's responses to minor stipulations must be reviewed by the convened IRB or may be reviewed for appropriateness and completeness by the IRB Chair or designated reviewers. Responses to clarifications that are directly relevant to regulatory criteria for approval of research must be reviewed by the convened IRB.
- 3) When the PI has responded appropriately and completely to all stipulations, a renewal is granted. The PI will be issued an approval letter indicating a new study expiration date and stating that the research can continue.
- 4) For deferred research, the PI will be notified of the reasons the research was deferred. The entire submission, with all required documents, will need to be resubmitted after revision for IRB review. If IRB approval expires during the deferral (prior to the IRB approving or approving with minor stipulations), all research activities must cease as outlined in the [Extensions of the Approval Period](#) section of this policy.
- 5) For research that is disapproved at renewal, the PI will receive a letter that delineates the reasons for disapproval. PIs may appeal the determination in writing to the IRB Chair.

Revision history:

- May 2023 - Minor editorial changes only
- 28Jun2022 - original publication date