CONJOINT HEALTH RESEARCH ETHICS BOARD (CHREB)
Research Services Office
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CHREB Annual Renewal Guidelines

The CHREB conducts continuing review of research taking place within our jurisdiction at intervals no less than once per year consistent with regulatory requirements (TCPS2(2022), ICH-GCP, US DHHS 45 CFR 46 , FDA 21 CFR 56).

Expiry Dates of Studies

A certificate of research ethics approval is valid for a one-year term. Approved studies must be re-reviewed on or before the one-year anniversary date of the previous REB review. Subsequent renewals of approval will expire on the one-year anniversary date of the previous REB review.

Amendments approved after the initial approval/renewal date also expire on the anniversary date.

Please note that the IRISS system sends out automated reminders 30 days, 15 days and 7 days ahead of the current approval's expiry date, as well as on the actual date of expiry. It is expected that the Principal Investigator will respond to this notice in a timely fashion and well ahead of the approval expiry date either by submitting an application for renewal or closure.

If an annual renewal requires full board approval the Investigator is responsible for ensuring that the application is submitted by the appropriate REB meeting deadline

Requests for Annual Renewal must be submitted by the Principal Investigator while the study is active (i.e., recruiting, undergoing study procedures, follow up with participants). See **Study Closure FAQ** to determine when a study may be submitted for closure.

Submission Criteria for Full Board or Delegated Approval

Delegated Approval

TCPS2(2022) Article 6.12 and 6.14 reiterate the principle of proportionate research ethics review (see also TCPS2(2022) Article 2.9) and stipulate that for both initial and ongoing research ethics review, the level of REB review (either Full Board or Delegated review) shall be determined in accordance with the level of risk to participants.

In practice, where there have been no significant changes to the research, and no increase in risk (or other ethical implications) for research participants, AND provided that the study Sponsor, Funding Agency or Regulatory Agency does not require that annual review be conducted by the convened REB, then the Chair (or designate) will review the request for approval under the category of 'Delegated Review'.

The Chair (or designate) can at any time put a request for annual renewal forward to the Full Board.

If the Annual Renewal does not qualify for delegated review (for example, if there has been a change in the risk to research participants) or if the granting agency, study sponsor or regulatory agency requires it, the application for annual renewal will be reviewed by the convened (full) REB.

If an annual renewal requires full board approval, the Principal Investigator is responsible for ensuring that the application is submitted by the REB meeting deadline. Refer to the links on the CHREB's homepage for the REB meeting schedule.

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Studies sponsored by the United States Department of Health and Human Services

Studies sponsored by the United States Department of Health and Human Services (DHHS) (e.g. NIH and its related Institutes, US Center for Disease Control, etc.) may require Full Board Review under 45 CFR 46.109 (e) and 45 CFR 46.110 (Code of Federal Regulations), unless they fall into one of the 9 categories recognized as eligible for expedited (i.e., delegated) review. Refer to Guidance on the Use of Expedited Review Procedures issued by the US Department of Health and Human Services for an interpretation of these categories, and particularly Section E that outlines when expedited review procedures may be used in the context of continuing review.

Generally, if a study subject to these regulations was initially reviewed by the Full Board, the annual renewal must also be conducted by the Full Board.

Studies sponsored by other United States federal agencies, or subject to the US Food & Drug Administration regulations

Studies that are funded by other American federal agencies (e.g. US Department of Defense) or that are subject to the US Food & Drug Administration Regulations may require Full Board Review under 21 CFR 56.110. Refer to FDA's Guidance entitled IRB Continuing Review after Clinical Investigation Approval for further information on expedited (i.e., delegated) continuing review for clinical investigations.

As with studies sponsored by DHHS, annual renewals of studies that are funded by other American federal agencies or that are subject to US Food & Drug Administration Regulations and that were initially approved by a convened board must generally also be conducted by the Full Board unless the research meets the criteria outlined in category (8) or (9). (See IRB Continuing Review after Clinical Investigation Approval, Section D).

Certificate of Annual Renewal

The approval date on the renewed certificate will be the one-year anniversary of the original approval/subsequent renewal date.

Industry sponsors/institutions that require renewal at a particular time before the expiry date must submit their application for renewal in good time **before** this required date.

The renewed certificate will **not** be backdated for any reason.

If the request for renewal is approved **after** the expiry date, the renewed certificate will be dated with the date on which the request for renewal was actually approved by the REB.

Failure to Comply with Requirements for Annual Renewal

If the study has expired (i.e., the renewal was not submitted on time), the Principal Investigator must provide an explanation for the late renewal and confirmation that NO study related actions took place during the time ethics approval lapsed. Principal Investigators are directed to submit a **"Request Chair Consideration"** in IRISS to re-open the application.

Failure to apply for annual renewal **before** the expiry date of the may result in the following actions being taken:

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- Notification of the investigator's Department Head regarding the failure to comply;
- Suspension of the financial account such that no further funds will be released until the expired status of the study has been addressed and all existing payroll expenses are irreversibly charged to the departmental account
- Discontinuation of the study's REB approval and formal closure of the study file 29 days post expiry.

REB Termination of Research Activities

The REB may also terminate approval if after 4 years no participants have been recruited. This is in consideration of the administrative burden that such reporting creates on the REB. As well, scientific standards and research ethics standards continually evolve. A dormant certification may not keep pace with such changes and participant safety might be best served by new applications. In cases where the research has not been initiated and no participants have been recruited, the REB must consider:

- The rationale provided by the researcher
- Changes in research ethics oversight standards
- Sponsor requirements