

CLINICAL TRIALS – RENEWALS & PI ANNUAL ASSURANCES

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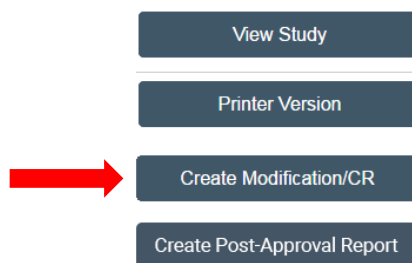
OVERVIEW – RENEWALS & PI ANNUAL ASSURANCES

- **Description:** To provide study maintenance guidance regarding how to submit renewals and PI assurances in [BruinIRB](#).
 - Local IRB (LIRB) studies will require a study renewal application in BruinIRB on an annual basis.
 - Central IRB (CIRB) studies will have a valid date range of 1 year (from the date it was submitted to the IRB).
 - *Formal renewal applications can be initiated and submitted via the Central IRB portal (please refer to the CIRB helpdesk for further inquires and guidance if needed)*
 - In addition, for CIRB renewals, a “PI annual assurance” is required within BruinIRB.
- **When to initiate:**
 - LIRB: You will receive a renewal notification via email from BruinIRB approximately 3 months prior to study expiration.
 - CIRB: You will receive a renewal notification via email from the CIRB to submit a study renewal application. Additionally, you will receive a notification via email from BruinIRB for PI to complete PI annual assurances.
 - BruinIRB will send out Annual PI Assurances reminders 90, 60, and 30 days before the anniversary date of the initial approval.
- **Timeline**
 - It is highly recommended that renewal applications should be submitted **at least 6 weeks in advance**.
 - PI annual assurances may take 1-2 business days.

ACTION ITEM – HOW TO SUBMIT RENEWALS for LIRB STUDIES

1. Identify where to access the IRB.
 - a. [BruinIRB](#): Utilized for FDA-regulated, multi-site, industry-sponsored clinical trials.

Next Steps



2. What materials are required for BruinIRB renewal applications?
 - a. Enrollment totals at site
 - b. Enrollment totals since the last study renewal (within the last calendar year)
 - c. Enrollment totals for the study across all site (verify with sponsor)
 - d. Summary of study progress to date
 - e. Brief description of study plans for upcoming year
 - f. [Deviation Log](#)

***Note: you can verify/reach out to study team (i.e. study coordinators) to confirm above information**

3. After you complete the application, submit and ask the PI to complete assurances. (PI assurances are required for the application to be submitted and reviewed by IRB for renewals.)

4. Upon receiving approval letter for renewal, send it to the (1) study team for filing, (2) Research Administrator for invoicing, and (3) sponsor for recordkeeping.

ACTION ITEM – HOW TO COMPLETE RENEWALS & PI ANNUAL ASSURANCES for CIRB studies

1. For the CIRB renewal applications, please visit the specific vendor's (Central IRB – such as Advarra, WCG, etc.) webpage for access.
2. In addition to CIRB renewal applications, PI annual assurances within BruinIRB are required. BruinIRB will send the below email to the PI and PI proxy at the first timepoint reminder (90 days) to complete PI assurances:

Please complete the PI Annual Assurances on the above-referenced study. Annual Assurances are required in place of annual continuing review and are required in order to maintain the active approval/exemption/external review accepted status for a study. The activity asks you to verify that nothing has changed in the study, and to remind you of the requirement to submit amendments if changes are proposed or closure reports when the study is complete.

If this activity is not completed by 6/28/2025 this study will be automatically closed by the UCLA OHRPP.

3. Upon receiving this reminder, forward the PI this email and ask the PI to complete assurances on the study page in BruinIRB portal.

CONTACT/RESOURCES

- BruinIRB: (310) 825-5344 | BruinIRB@research.ucla.edu
- [UCLA CTSI: researchgo@mednet.ucla.edu](mailto:researchgo@mednet.ucla.edu)
- UCLA DOM CTP: DOMCTP@mednet.ucla.edu