CLINICAL TRIALS – IRB AMENDMENTS

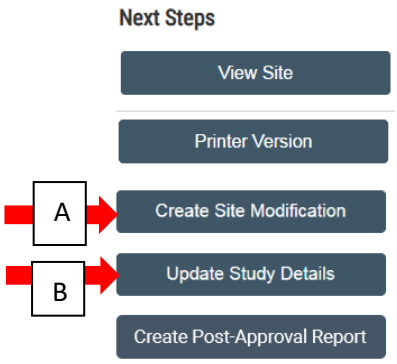
Revised May 14, 2025

OVERVIEW – IRB AMENDMENTS

- **Description:** To provide study maintenance guidance regarding how to prepare and submit amendments to BruinIRB.
  - Amendments can range from one change to many changes including: protocol, investigator brochure (IB), informed consent form (ICF), recruitment materials, etc.
- **When to initiate:**
  - Amendments may be sponsor-initiated or site/study team-initiated.
    - Sponsor-initiated
      - Sponsor will directly reach out asking you to submit an amendment for research site once an amendment has been released by sponsor.
    - Site/study team-initiated
      - PI conflict of interest (which typically includes financial disclosure)
      - PI change
- **Timeline**
  - Best practice is to submit an amendment within 3-5 business days of receipt of complete amendment package from sponsor (i.e. any document(s) that have been amended/changed).
  - Amendments may be processed and approved depending on the complexity of the amendment (i.e. anywhere from 1-2 business days to 3+ weeks).

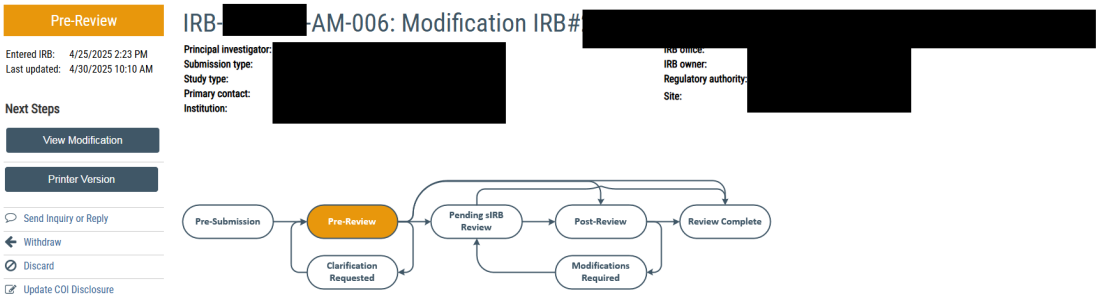
ACTION ITEM – HOW TO SUBMIT AN AMENDMENT IN BRUINIRB

1. Identify where to access the IRB.
   a. BruinIRB: Utilized for FDA-regulated, multi-site, industry-sponsored clinical trials.
      i. All study amendments must be submitted to BruinIRB – whether as a *formal modification* or *updating study details* (please reference #3 below).
   b. Central IRB: Utilized when sponsors have a central IRB of record for oversight of clinical trials (e.g. Advarra, WCG, etc.)
      i. Sponsor will submit the amendment to the CIRB portal on site's behalf.
         - Sponsor will notify site (typically, regulatory coordinator) via email that sponsor has submitted the package to CIRB.
         - Please note, this record does *not* need to be submitted to BruinIRB.
2. What materials are required for amendment submission?
   a. Always check with the sponsor for the changes involved as different materials may be required.
      i. Most amendments may include changes to protocol and ICF. Amendments may also include investigator brochure (IB) updates, changes to recruitment material, updated risk information, changes to the study schedule of events, etc.
         - (Note: this list is not an all-inclusive – there may be other changes involved, which is why it's recommended to always discuss the changes via email with the sponsor/CRA contact for study.)
3. Creating an amendment submission in BruinIRB
   a. Depending on the nature of the amendment, you will utilize one of two options: (a) *Create Site Modification* **or** (b) *Update Study Details*:

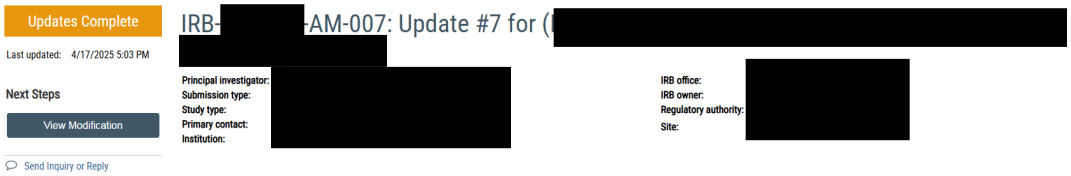


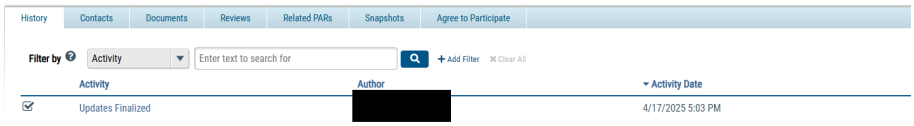
i. Amendment applications, using the '*Create Site Modification*' option, for studies where UCLA is relying on another IRB are accepted when:
   i. Change in PI and other study personnel
   ii. New or additional ancillary review required
   iii. New or changes in HIPAA determinations (made by UCLA)
   iv. New or changes in Conflict of Interest (COI)
   v. New or change in funding
   vi. New or change in UCLA site-specific consent language

ii. After submitting the amendment with the appropriate materials for a ***modification***, the study will move into pre-review:



iii. For all other instances, select the ***update study details*** option.
   i. After updating the study with appropriate materials, the study page will note "updates complete":





b. After submitting the amendment to BruinIRB, consider if the changes to the amendment may affect the budget. If so, email the Clinical Research Finance team *(and copy the research administrator)* at CoverageAnalysis@mednet.ucla.edu and ask them to consider revising the study budget based on the protocol amendment changes. Note: If you are not the budget negotiator for the budget amendment, please ensure to copy the appropriate budget negotiator on this email.
   i. Tip: in your email, ensure to include the redline/tracked changes protocol to assist Clinical Research Finance with this task.
   ii. Best practice is to provide the list of changes in the amendment to the study's financial Research Administrator.

c. In the event the amendment requires a change in the ancillary (e.g. extra visits are added; CT added/removed at "X" timepoint; etc), best practice is to notify the individual ancillary group(s) affected so that an updated quote can be made available in OnCore.
    i. This will trigger an updated email notification "Budget Out" from OnCore.

CONTACT/RESOURCES

- BruinIRB: (310) 825-5344 | BruinIRB@research.ucla.edu
- Clinical Research Finance: CoverageAnalysis@mednet.ucla.edu
- UCLA CTSI: researchgo@mednet.ucla.edu
- UCLA DOM CTP: DOMCTP@mednet.ucla.edu