CLINICAL TRIALS – INSTITUTIONAL REVIEW BOARD APPLICATION (IRB) WITH INFORMED CONSENT FORM (ICF)

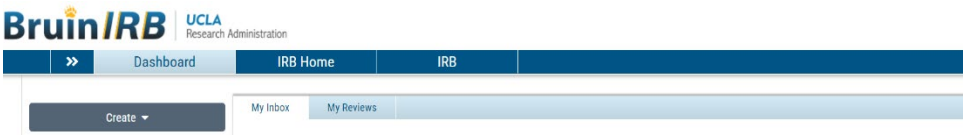
Revised July 30, 2024

OVERVIEW – IRB APPLICATION AND ICF EDITS

- **Description:** To provide guidance regarding various IRB start-up tasks, deadlines, and responsibilities. The UCLA IRB, which exists to ensure the safety and welfare of research participants in human research conducted at UCLA, has the authority to approve and disapprove research. Submitting a new application to the IRB serves as an intention from the study team to conduct the clinical trial research at UCLA following IRB guidelines.
- **When to initiate working on IRB application:**
  - As soon as you receive the required materials for new study IRB submission [refer to *Regulatory Document Request Form* for further guidance, if necessary].
- **Timeline**
  - IRB approval can take approximately 4-6 weeks to obtain.
  - One can inquire about the status of the IRB application after 3 weeks of initial IRB submission date.
    - Please use the "send study inquiry" tab located on the study's IRB page.
    - Applications are reviewed on a rolling basis.

ACTION ITEMS

1. How to create an IRB account?
   a. PI submits an email request (user cannot submit request on their own behalf)
   b. To request an IRB account set-up for a new user, the PI emails the IRB office (BruinIRB@research.ucla.edu), Ccing the appropriate Division Chief, the information below:
      i. Staff member name
      ii. UCLA logon username ID
      iii. University ID number (UID)
      iv. UCLA email address
2. Where to access the IRB
   a. BruinIRB: Utilized for FDA-regulated, multi-site, industry-sponsored clinical trials.
   b. Central IRB: Utilized when sponsors have a central IRB of record for oversight of clinical trials (e.g. Advarra, WCG, etc.)
      i. Please visit the specific vendor's (Central IRB) webpage for access
3. What materials are required for submission?
   a. Regulatory Document Request Form
   b. Initial IRB submissions may be completed by a designated staff member, but final submission must be submitted by the PI.
      a. PI must complete PI assurances.
      b. PI can assign a designated PI proxy (up to two).
         i. To assign someone the PI proxy role: PI logs into the IRB study page > locate the PI proxy option > click "update" to add staff into this role.
4. Creating a New Study in IRB system
   a. Access the IRB portal (BruinIRB):
   b. After you login, on the main page, locate "create":



   c. Reference Protocol/Study Material to answer IRB study specific questions.
5. Informed Consent Forms (ICF) Template and Edits:
   a. Utilize this ICF template checklist for reliance studies that are submitted and processed through BruinIRB.
      - This checklist contains required/mandatory UCLA language that is incorporated into each study's ICF template.
      - All content listed in the checklist is non-negotiable, required boilerplate language per UCLA IRB compliance.
   b. Insert the required language from the UCLA ICF language template checklist into sponsor's ICF template.
   c. Send to Sponsor/CRO for negotiation/approval.

CONTACT/RESOURCES

- BruinIRB: (310) 825-5344 | BruinIRB@research.ucla.edu
- UCLA DOM CTP: DOMCTP@mednet.ucla.edu