Procedures to Obtain Clinical Trial/Clinical Study Approval at the Lundquist Institute at Harbor-UCLA Medical Center

1. Bookmark helpful contact information emails and phone numbers of Lundquist Institute Administration on your computer, found (as of Winter 2025) at https://lundquist.org/functional-directory.

   A user friendly update to the Lundquist Institute website (https://lundquist.org) is anticipated to be launched in late Summer 2025.

   Note that personnel at the Lundquist Institute change over time, so refer back to the Lundquist Institute websites above if the below emails or sites do not work.

2. Contact Lisa Palacio (lpalacio@lundquist.org) to become a Lundquist Investigator (most often can be expedited by your Divisional Administrative Office.

3. Obtain a DHS or Lundquist email address
   a. DHS email addresses are assigned automatically when individual is assigned a **E**(mployee) or **C**(ontractor) number
   b. PI/Supervisor will need to request a Lundquist email address for new employee by submitting a Lundquist IT ticket by emailing: ITSupport@lundquist.org.

4. Complete the required CITI training modules as directed by Lundquist Research Compliance.

   http://citiprogram.desk.com/customer/portal/articles/1231781-new-learner-account-registration-
   a. Add "**Lundquist Institute for Biomedical Innovation at Harbor-UCLA Medical Center** " as your Organization Affiliation.
   b. If you are a user of **iRIS** (also known as **iMedRIS**), the IRB (Institutional Review Board) Electronic Submission System, use the same email address you use for your iRIS account. Otherwise, you must use a DHS or Lundquist email address. Personal email addresses are not acceptable.
   c. Currently Required courses (subject to change):
      a) Biomedical Researchers
      b) CITI Good Clinical Practice Course
      c) Biomedical Responsible Conduct of Research
      d) Research & Administrative Team Members (IPS)
      e) Conflicts of Interest
      f) CITI Export Controls Course

5. Contact Ernestina Yiadom (eyiadom@lundquist.org) at the Lunquist IRB (Compliance Office) once training is complete to request a new iRIS (also known as iMedRis) account. Provide

the individual's full name and email address used for the CITI account. Once approved, you will receive an email with log in instructions. General Compliance Office (IRB) questions can be directed via email to irb@lundquist.org.

6. Complete Conflict of Interest form

   Please login to iRIS at https://imedris.lundquist.org to complete and submit your Annual COI (Conflict of Interest) Disclosure Form. Once you log in to iRIS, click the Annual Financial Interests Disclosure Form box at the top of the page and then click Add a New Form. Be sure to click Save Section after each section is complete. You can also access this form from your home page task bar. After completing the form, you will need to approve the form by entering in your user ID and password.

7. For multi-center studies in which Lundquist/Harbor-UCLA is one of many study sites, send the study protocol and sponsor-proposed budget to the Office of Research Administration's (**ORA**) current pre-award officer at ORA@lundquist.org. Strongly consider cc'ing the individuals in the ORA office who are, as of 2/25: Jessica Kim (jessica.kim@lundquist.org), and Celine Castellano (celine.castellano@lundquist.org). Ask them to assign the clinical trial a Protocol number, begin negotiations with the study sponsor, and to add the study protocol visits into Lundquist Clinical Trial Conductor.

8. If you need use of nursing services, phlebotomy services, and/or rooms for patient visits, contact Loritta (Rita) Manai (lmanai@lundquist.org) and Jocelyn Campos (jocelyn.campos@lundquist.org) at **CTRC** (Clinical Trials Research Center) of the Lundquist Institute /Harbor-UCLA **CTSI** (Clinical Trials and Science Institute) to request a proposed study budget. General email for CTSI is ctsinavigation@lundquist.org.

9. The Lundquist/Harbor-UCLA CTSI and CTRU also has select other services, such as dietary services, bone densitometry, informatics, biostatistics, regulatory support, community partners for community partnered research, career development and training, among other services. Information on CTSI and CTRU services can be found at the Lundquist/Harbor-UCLA's website: Lundquist.org/CTSI (to be launched in Winter 2025).

10. Submit DHS Research Project Request Form (Harbor) to Harbor-UCLA Chief Medical Officer (CMO). The DHS (Department of Health Services, the LA County health care system of which Harbor-UCLA is a Medical Center) Research Project Request Form can be found at: https://research.lundquist.org/redcap/surveys/index.php?s=HE7LR8XXP3. Jessica Kim and Celine Castellano in ORA will perform a MediCare analysis of the study so that the Research Order (RO) Form can be attached to the CMO (Chief Medical Officer) application. Once CMO acknowledgment is received, iMedRIS application can begin.

11. Begin new iMedRIS study application (https://imedris.lundquist.org/). IMedRIS is the IRB system for Lundquist, although iMedRIS also is required for a few non-IRB related study matters.

    If the study requires a is local IRB only, this is the only study application that you will complete.

    If the study oversight is through a central IRB (i.e., WIRB, Advarra), this is the first step to obtain oversight waiver from The Lundquist Institute to have the investigator be part of a multi-center study. If you have spoken with Loritta (Rita) Manai and/or Jocelyn Campos or had any consultation from the Lundquist/Harbor-UCLA CTSI (Clinical Trials and Science Institute) or the CTSI's **CTRC** (Clinical Trials Research Center), **make sure that when you put in your IRB application that you noted that are using the CTSI (Clinical Trials and Science Institute) services. We strongly encourage you to check off use of CTSI/CTRC services even if you are not sure you will use these service as to allow you the *choice* to use CTSI services, if needed.** There is no cost or obligation of CSTI use if you check off CTSI/CTRC use. Additionally, CTSI/CTRC needs to track use of services via IRB applications in order to keep its resources available for campus investigators in the future.

12. **If you are using a central IRB for your study** (i.e., WIRB, Advara, many others), you still must go through the Lundquist IRB (aka the Compliance Office) to make them aware of the research study.

    a. If so, modify the sponsor-provided informed consent forms to include California-required PHI, Institutional injury language, 24 hour emergency phone number found on the iMedRIS website under the Help section "?", Section 2.0, Informed Consent Form Template (https://imedris.lundquist.org/System_Help_Win.jsp?s=101010101&action=helpwindow), and patient compensation amount (once study budget has been approved). Please send your draft proposed informed consent to the Director of Research Compliance at the Lundquist IRB, Liz Burrola (lburrola@lundquist.org) for review, prior to submitting the central IRB application.

    b. Once informed consent forms have been reviewed and deemed acceptable by Liz Burrola, please send to study sponsor for in-house legal review. There may be some back and forth between the sponsor and the Lundquist IRB given they don't always see eye to eye.

    c. Once the study sponsor in-house legal review has been completed, please re-send informed consent forms to the Director of Research Compliance at the Lundquist IRB, Liz Burrola. Once budget has been negotiated and informed consent forms

have been reviewed and deemed acceptable by Liz Burrola, you may begin either local or central IRB study application.

d. Once central IRB study application has been completed, please **SAVE**, but do **NOT SUBMIT**. Attach the draft central IRB study application to the iMedRIS study application so that Compliance Office may review.

e. Once the DRAFT central IRB study application has been approved by Liz Burrola and waiver of oversight to central IRB has been granted to the IRB (Compliance Office), submit the central IRB application for review.

f. Once sponsor signs off on the central IRB application, it will be reviewed by central IRB. This approval, along with the final CMO approval need to be attached to the local iMedRIS study application for review and approval.

g. If central IRB has approved the study and IRB (Compliance Office) has approved the study, Clinical Trial Agreement (CTA) has been executed between study sponsor and the Institute, and site initiation visit has been completed, the study team may begin to screen and recruit subjects for the clinical study.