1) Do your CITI training
Go to https://www.citiprogram.org and create an account (use the same email address you use/will use for your iRIS account).
Use Lundquist Institute as your organization affiliation
We must do: HIPAA, Biomedical researcher – basic/refresher, Good clinical practices - basic/refresher (repeat each every 3 yrs), and Conflict of interest (repeat every 4 yrs)
Forewarned: this will take a long time – 6 hours approximately
EVERYONE who will be on your study, enrolling patients, needs to complete CITI training
If you submit an IRB application with an investigator on it who is not yet CITI trained, it will slow down your IRB approval
When you complete each module, download a copy of the certificate for your files
If you have already done this for another institution, your credit IS transferable, but you must assign it in the CITI system to Lundquist Institute
For questions contact Tina Yiadom at eyiadom@lundquist.org, 222-3624

2) Complete the patent/copyright agreement form (this only needs to be completed once).
Bring this with you and turn it in during Step 5
(Not yet available online, but available from Luz Garcia)

3) Get an iRIS account (https://imedris.lundquist.org) – everyone who will be an investigator
Contact Tina Yiadom (eyiadom@lundquist.org, x 3624) to request an iRIS account.
Submit your Conflict of Interest / Financial disclosure through iRIS – this has to be re-done annually.
The above steps are done once, at the time of your first submission, not for subsequent studies

4) Determine the classification of your project
a) Not Human Research (Worksheet HRP-310) – you don't need to apply to the IRB!
b) Exempt (Worksheet HRP-312) and see below)
c) Expedited Review (Worksheet HRP-313)
d) Full IRB Review
These worksheets are available on iRIS under My Assistant -> Operating Procedures -> 1.2 Human Research – Worksheets

5) Use the Investigator Protocol template to write a research plan, and if your study requires consent, the Template Consent and Template PHI to create consent & PHI consent documents
Use HRP-503 Protocol Template and make sure to keep the table of contents with clickable links to each section as this is a requirement
The consent/PHI and protocol templates are available on iRIS under My Assistant -> Operating Procedures
For the research plan, if a section is inapplicable to your project, mark it "N/A"
HRP 317 Long vs Short form consents
If your study meets the requirements for Exempt (see below), you may use an abbreviated / verbal consent process. You must provide the following information through an information sheet or written script:
a) The subject is being asked to participate in a research study
b) A description of the procedure(s) the participant will be asked to complete
c) Participation is voluntary; and
d) The investigator's name and contact information

Three approvals will be needed: DHS, Research Committee, IRB Compliance (items 6-8)
You can seek these approvals simultaneously, although the IRB submission does ask that you upload your DHS approval (although you can submit and upload DHS approval later). You can start your IRB submission on Imedris without a study number yet.

6) If utilizing DHS resources = most studies (medical records, nursing, pharmacy etc)
Fill out and submit DHS Research Project Request form (https://harbor.click/research-request) and submit to your Dept. Chair, who will submit to CMO for approval

7) Request project number from the Office of Research Administration (ORA) in RB-1 (Walter P. Martin Research Center) for categories b, c, d
- Fill out Institutional Research Project Application Form (regular or abbreviated version) and submit along with form from #5 (don't have to get individual signatures anymore on Institutional Research Project Application Form if have DHS form from #5 AND bring email from Dept Chair and HUMC CMO showing DHS approval).
Abbreviated form: for projects that would fall under the Institutional Review Board's (Human Subjects Committee's) Expedited, Exempt categories, or Not Human Research determination.
- You will need to include a copy of your study protocol (the HRP-503 you did above in #4)
- Luz Garcia for government/non-profit funded projects, including CTSI activities and institutional/internal projects (lgarcia@lundquist.org, x3621)
- Barbara Lee for industry funded projects (blee@lundquist.org, x3621)
Additionally, a PRACC form must be filled out if the research is externally funded
Obtain and submit this form to Luz Garcia 310-222-3621

8) Submit an IRB Application on iRIS (HRP-211)
Go to Study Assistant, Add a New Study, and select "IRB Application." Fill out each section. Use Worksheet HRP-314 Criteria for Approval to improve the chances your project will be approved. As part of your submission, you will need a lay summary of your project, CVs of all the study investigators (unless their CV is already in the system as part of their Iris profile), data collection forms to be used, any recruitment materials (eg flyers) you wish to use (although can say you intend to use a flyer but don't have it yet, and can submit it to IRB later).
If you don't have a paper Data Collection Form (eg you are using Redcap), submit a data dictionary with all the headers of what you're collecting (you can download that from Redcap)
Note: you can find the IRB committee 1 & 2 rosters and meeting dates on iRIS under My Assistant -> Operating Procedures -> 3. Human Research – Commonly Needed Information

9) Await IRB Approval
Do not begin human research activities until you have the final IRB approval letter
If you receive a request for modifications to secure approval, make the requested modifications and submit them to the IRB using the iRIS generated response form "Modifications Required to Secure Approval"

10) Starting your study
Once your project is approved, you must download Stamped forms and *use only those* (consent, data collection, etc) downloaded from iRIS. Do not use unstamped forms and do not use forms beyond their expiration date. Doing either of these things will trigger an audit.
If you need **consent forms translated into Spanish**, you can request that through the compliance office (this will cost $), or request translation through official DHS translator. Do NOT translate your consents until the English version is fully approved and stamped by the IRB.

Also, once your project is approved, if it involves a clinical patient care unit, you must **submit it to Nursing**. They will review it and keep it in a binder in the ED for nurses to review.

Write cover letter briefly describing your study and nursing's role (if any), and submit it along with a copy of the protocol, consents, IRB approval letter, to Joy Lagrone jlagrone@dhs.lacounty.gov and Dawna Wilsey DWilsey@dhs.lacounty.gov.

Notes about obtaining consent

Long form consent documents:

- Subject or legally authorized representative (LAR) signs & dates consent
- Witness (neutral adult not affiliated with the study) signs & dates consent
- Individual obtaining consent signs and dates consent (must be a study investigator)
- If subject hospitalized, clinician physician responsible signs the consent
- Copy of signed/dated consent and Human Subject's Bill of Rights given to subject
- Within **fourteen days** the Principal Investigator must sign the consent document

Short form consent documents:

- Subject of LAR signs and dates short form consent
- Individual obtaining consent signs and dates the summary
- Witness to oral presentation signs and dates short form consent and summary
- Copies of signed/dated consent, summary, and Human Subject's Bill of Rights given to subject

Exempt Categories

1) Commonly accepted educational settings and practices, not adversely affecting students' opportunity to learn nor assessment of instructors; not conducted by supervisors with employment decisions, not unproven educational techniques
2) Only involves interactions (not interventions) of educational tests, surveys, interviews, observation of public behavior (including video/audio recording) and one of:
   a) De-identified data recorded
   b) Any data disclosure would not harm subject (finances, employability, reputation, etc)
   c) Data not de-identified but limited IRB review done
   Children only if investigators don't participate in the activities being observed.
3) Benign (brief, harmless, painless, not offensive, not deceiving the subject unless subject authorizes) behavioral interventions with collection of information (written or verbal responses or audiovisual recording) from an *adult* subject, if subject prospectively agrees, AND at least one of:
   a) De-identified data recorded
   b) Any data disclosure would not harm subject (finances, employability, reputation, etc)
   c) Data not de-identified but limited IRB review done
4) Secondary research of identifiable private information or biospecimens (re-use of data / specimens from prior research study or from collection for non-research purposes) if at least one of:
   a) Publicly available data
   b) De-identified data recorded
   c) "health care operations" or "public health activities" data as per 45 CFR 160, 164
   d) research by a Federal agency
   Children data/specimens allowed. No contact between investigator and subject allowed.
5) Federal department or agency research
6) Taste and food quality evaluation and consumer acceptance studies

Note:
RB1 = Walter P. Martin Research Center
RB2 = St. John's Cardiovascular Research Center
RB3 = Liu Research Center