Using IREx when another IRB is the IRB of record.

Many institutions choose to use IREx to set up and maintain reliances. IREx is hosted by Vanderbilt University, but many IRBs are eligible to use the site. More information on IREx and its inception can be found here: https://www.irbexchange.org/p/ There are many resources on how to use IREx. We recommend the training videos.

Directions:

1. The reviewing IRB or study team should send you instructions on the reliance process. If they have not, ask them for this. This is important because the reviewing IRB may not use all the features in IREx, so please read them carefully. The instructions below are used when the reviewing IRB uses ***all*** of the reliance features in IREx.
2. Using the Ask Andy form request access to your study in IREx by providing the study title and names of people who need to access IREx. Usually, this is the PI and the CRC. Attach the instructions from the reviewing IRB.
3. The IRB will respond when they have provided you with access.
4. The PI will need to fill out the PI Survey in IREx
5. The UCSF study will need to submit in iRIS.
6. In section 6.0 of the IRB application mark "yes" to the question that asks about using an external IRB.
7. Mark "Smart" for the reliance agreement.
8. Type in "IREx" when it asks for a registration number.
9. Fill out the rest of the application as you normally would.
10. Attach the protocol if there is one, and any ancillary committee reviews.
11. Attach the localized consent(s) and assent(s) if UCSF is enrolling.
12. Note that at this this stage the consent form has not been approved by any IRB. You are submitting to the UCSF IRB to make sure that the consent(s) have the proper UCSF language ***before*** the other IRB reviews it/them.
13. Use this checklist to help you add the UCSF required language: https://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/checklist%20non%20ucsf%20checklist.pdf
14. For some studies additional require language may be needed such as radiation risk language or genomic data sharing language. Use the language found in our template here: https://irb.ucsf.edu/consent-and-assent-form-templates
15. Once the PI survey has been completed and all documents are in order in iRIS, the UCSF IRB will complete their surveys in IREx, upload the consent forms in IREx, and accept the reliance. They will also send you a stipulation that explains this. At this time you should contact the reviewing IRB or study team and let them know you are ready for IRB review. Follow their instructions for this process.
16. When the reviewing IRB approves UCSF they will update IREx. The UCSF study should then respond in iRIS with the approved consent form(s) and the approval letter showing that UCSF has been added as a site.
17. UCSF will issue an acknowledgement letter after confirming all materials. This letter will acknowledge the reliance and state the HIPAA determinations as applicable to your study.
18. Post approval reviewing IRB: Follow the reviewing IRB instructions for submitting to them.
19. Post approval submissions to the UCSF IRB: Continue to submit all changes to personnel, funding, and changes to the reliance application such as amending chart review dates or adding CRS services.
20. The reviewing IRB should ask you to report or check with the UCSF IRB if an amendment is made that may be impacted my UCSF policy or California law, or if there has been a determination of serious non-compliance or serious and continuing non-compliance. For questions about this use the Ask Andy form.