Reviewing		**The site that is performing the IRB review and will serve as the IRB of Record. This can include the IRB itself or the study team at that site. This will be specified below.**
Relying		The site that is using someone else's IRB to review and approve the site's participation in the study. This can include the IRB or the study team at that site. This will be specified below.

Setting up a UC Reliance	
Step 1	• Check with relying IRB to see if relying PI and study is eligible for a UC reliance. Be sure the relying campus is engaged in human subjects research. See guidance here: http://irb.ucsf.edu/not-human-subjects-research. • The reliance registry is for University of California sites only. Please contact your local IRB to set up reliances with sites outside the UC system. For example VA sites cannot use the registry. • If you are the relying site, you can begin number #9 to have it ready to submit while the other steps are underway. • Many UCs will not allow for exempt reliances. Please ask your local IRB before you start the reliance process. • Links for new users expire after a while. If this happens, go directly to the website to login • If you are the relying site, you can begin number #9 to have it ready to submit while the other steps are underway.
Step 2	**Reviewing** coordinator initiates reliance in the reliance registry (fills out data in registry).
Step 3	**Reviewing** coordinator invites reviewing PI, relying PI, and relying coordinator(s).
Step 4	**Reviewing** PI creates profile if needed and goes through assurance signing process.
Step 5	***Relying*** PI creates profile if needed and goes through assurance signing process (fills out data in registry specifying any activities that happen specifically at relying site that might differ from the reviewing site).
Step 6	**Reviewing** study team submits either initial study or modification to add reliance (all items such as procedures, consent, sample size, recruitment should have headers with site name where a specific site differs from the reviewing campus; decide if you will have one consent with all site names and procedures or separate consents to accommodate differences such as radiation risk language; submit communication plan). Attach a PDF of the registry information by using the print button. The PDF status should indicate that both PI's have signed off and that the next step is pending Reviewing IRB approval.
Step 7	**Reviewing** IRB approves the reliance or declines the reliance in the registry.
Step 8	If declined, "***relying***" site must get local IRB approval.
Step 9	If approved, the ***relying*** site must submit a truncated application/"shadow file" to its local IRB. Each UC has different requirements, so the relying study team should check their IRB website for details. At UCSF we have a truncated application in iRIS that should be submitted with all local ancillary approvals and communication plan. Attach a PDF of the registry information that indicates the Reviewing IRB has approved the reliance and is waiting for the Relying IRB to accept the reliance.
Step 10	***Relying*** IRB receives a truncated application/"shadow file" and either accepts or declines to rely in the registry.
Step 11	If the ***relying*** IRB declines to rely in the registry, ***relying*** site must get local approval. **Reviewing** campus must remove this site from their IRB application and all related documents by submitting another modification.

Step 12	If the ***relying*** IRB accepts to rely, they will update the registry with this information. Once the registry is updated, the ***relying*** site can begin research provided all ancillary committee requirements have been met.

Maintaining a Reliance
Reviewing study team and PI are responsible for reporting and distributing all study materials including but not limited to: • AE (Adverse Event) reports • continuing reviews (with data from all sites) • modifications • amendments, ***etc.*** • **approval letters** • **IRB approved study materials**
Relying study team and PI are responsible for communicating the following to the reviewing study team who will then submit to the IRB on their behalf. • AE (Adverse Event) • continuing reviews • modifications • amendments etc.
All ancillary committee changes should be submitted at the local level. Check with individual IRBs for details. At UCSF this includes: • personnel change • adding funding • Conflict of Interest change • data extraction change • other ancillary committee changes such as Radiation Safety Committee At UCSF you will not receive approval letters for relying sites, but it will be acknowledged in the system; therefore, the study team will need to check the Submission History in iRIS to find out when the submission has been processed to completion.
Reviewing study team should alert relying sites of reporting requirements. Here are some links to UCSF guidance: http://irb.ucsf.edu/adverse-event, http://irb.ucsf.edu/protocol-violation-or-incident
All sites should follow a communication plan of regular check-ins with the reviewing study team. These calls should ensures that all IRB materials are being reported to the reviewing IRB; and they should ensure that all relying sites have up to date approved study material.
Some AEs must be reported to both the reviewing and the relying IRB such as: • continuing non-compliance • serious and continuing non-compliance Please contact your Quality Improvement Unit or your IRB Reliance analyst if you have questions.
Each reliance is as unique as the study it involves; if you are not sure or have a question about the process, email your IRB analyst.