

USING THE UC IRB RELIANCE REGISTRY IF YOU ARE...

RELYING CAMPUS PRINCIPAL INVESTIGATOR (ReLPI) or RESEARCH COORDINATOR* (RC)

REGISTERING/LOGING IN

- As a Relying PI or Research Coordinator, you will first receive an email invitation to register/log in to the UC IRB Reliance Registry after the Reviewing Campus PI (RevPI) had already entered the basic information about your multi-site study, and identified you as a PI or RC on a Relying campus (the campus of the IRB that, according to the 2009 /2011 UC MOU, will rely on the IRB review that was conducted on the Reviewing PI's campus). Please follow the instructions provided to you in the initial email, after you receive it.
- You will be required to go to the <http://irbreliance.ucop.edu>
- To start using the UC IRB Reliance Registry (the Registry), you will only have to register once in the system, regardless of whether you are on a relying, or a reviewing campus for a particular study. Please note that the first-time registration is a two step process:
- If you don't already have a user profile, you can create it by clicking "Register", and filling out the "User Registration" form in the Registry
- The Registry will verify your user email account by automatically emailing you a temporary password. You will need to return to the Registry using that password within the timeframe specified in the verification email. The Registry will prompt you to create a new, safe password.
- **You are now ready to use UC IRB Reliance Registry!**

ACKNOWLEDGING YOUR PARTICIPATION AS A RELYING PI/RC IN THE NEWLY REGISTERED STUDY

- Be prepared to answer all the questions marked with the red asterisk (funding, enter contacts of relying campus PIs, paste in the study abstract...) **You won't need to upload any documents!** Note that you can complete the form in few sessions but make sure you save each entry!
- Only after all the invited ReLPis registered their participation, the RevPI will be able to sign the Request form, convert it to a PDF and submit, along with the research protocol, to the Reviewing Campus IRB, so any delay to respond to the email invitation to register your participation will further delay the IRB review. Please note that although your campus IRB will likely accept to rely on the Reviewing Campus IRB review, this acceptance, and your ability to commence the study, will be conditioned upon the approvals from all necessary ancillary committees' (such as stem cell or radiation safety committee) reviews on your campus that you will need to obtain prior to conducting the research on your site.
- Once the Reviewing campus IRB approves the study, they will enter the study approval's expiration date in the Registry, and will upload the approved protocol, and consent form, if applicable. You, and your campus IRB will receive an automated email sent by the Registry, informing you of the IRB approval. Your campus IRB will then be able to review all the uploaded documents and decide whether they accept or deny to rely on the Reviewing Campus IRB review. Should they choose to accept to rely, they can upload the letter and a reliance will be completed.

ANNUAL RENEWAL , SUBMITTING AMENDMENTS & REPORTING ADVERSE AND UN-ANTICIPATED EVENTS

- As a Relying PI/RC, you are required to promptly inform the RevPI/RC of any need for amendments, and to report any adverse or un-anticipated events on your site. The RevPI's responsibility is to communicate your notifications to the reviewing campus IRB, using the regular IRB channels on their campus, not using the Registry. Any decision, change in the protocol etc., will be reported and uploaded into the Registry by the Reviewing Campus IRB.
- Annual IRB renewals are the RevPI's responsibility. If they do not obtain the timely renewals from their IRB, none of the relying sites will be allowed to continue with the research. Once the renewals are approved, the RevIRB will make a note in the Registry.

MANAGING YOUR STUDIES AND YOUR TO DO LIST

- While the Registry will send you an email to alert you each time about a new reliance activity related to the studies that you are involved in, you can also use the Dashboard tab in the Registry to monitor your next steps, and to get a clear picture of the pending actions by others on your studies. You will be able to access all uploaded documents for any research that you are associated with, either as a reviewing or as a Relying PI/RC.

RESEARCH COORDINATORS* (RC): when using the UC IRB Reliance Registry, Research Coordinators have all the same authorities as the PI on the study (for instance: create a Reliance Request, add other PIs and Research Coordinators participating in the study on the Relying Campuses, fill out all the fields describing the study in the Registry) **EXCEPT ONE: sign and submit the Reliance Request form. This can only be done by the RevPI, whose agreement to the listed assurances is understood as the PI's signature and will have to be submitted from their account.**