RAP IRB - RCS COLLABORATIONS FLOWCHART

(also see Collaborations and Reliance Arrangements website)

Will anyone external to the UO be <u>engaged</u> in human subject research activities? (e.g., interact or intervene with participants, obtain consent and/or obtain identifiable participant information/specimens for research purposes).



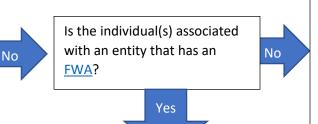
Indicate the study is Single Site on the Basic Study Info Page, Question 4 and ensure your IRB materials explain why this collaborator is not engaged in human subjects research.



- 1. Indicate the study is multi-site/collaborative on the Basic Study Info Page.
- 2. Include a description in your materials about the role of external individuals and/or institutions in this research and how they are engaged.
- 3. Follow steps below for each type of arrangement:
 - Individual investigator agreements (IIA)
 - Reliance Arrangement
 - Multiple IRB Reviews*
 - Permission

Is the collaboration with an individual that is either a) not affiliated with an institution or b) are working on this project independent of any institutional affiliation? (Independent investigator)

Yes



Permission

No, permission from the entity may be necessary. Inquire and attach any approval to Basic Study Info section.

Each person from the group will need to complete the steps for an **individual investigator**.

Individual Investigator

Upload the following under Local Study Team Members, Question 2:

- List the individual(s) on the
 External Research Personnel Form
 and upload the form under the
 Local Study Team Members
 question 2.
- An Individual Investigator Agreement (IIA) needs to be executed for this person.
- Training needs to be obtained and uploaded.

IRB Oversight Needs to be Addressed:

- Reliance Arrangement (add each relying site as a pSite).
 - Check 'Yes' under Basic Study Info Page, Question 6.
 - Add each relying site as a pSite. If adding at time of Modification, IRB may need to issue a contingency for the pSite approval before the site engages.
 - Needs an IAA executed and uploaded into pSite record and a site approval letter before engaging.

OR

- Multiple IRB Approvals* are needed:
 - Upload doc of approval under Basic Study Info Page, Question 9.

*NOTE: Federally funded research mandates sIRB unless justified by the IRB and/or an exception is approved by the funding agency. Document the rationale for multiple IRB reviews in place of sIRB and IRB's approval using the review checklists and prereview activity.