

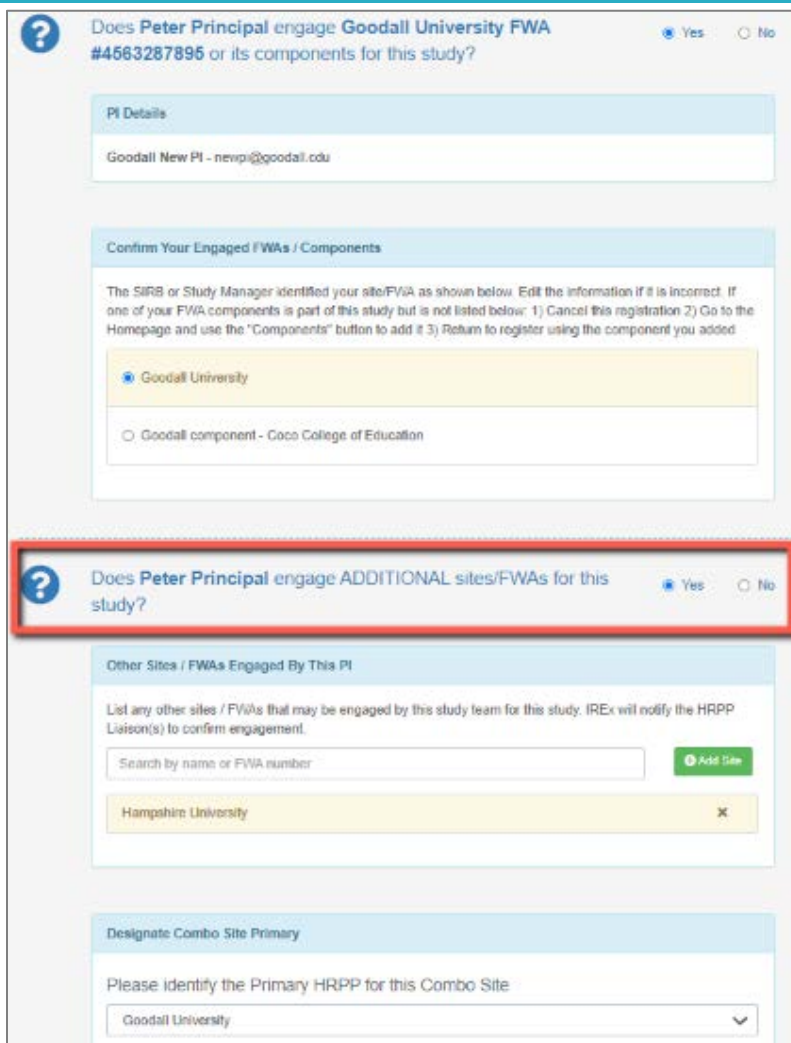
WHAT ARE COMBO SITES?

Combo Sites occur when **one investigator** engages **multiple Federalwide Assurances (FWAs)** for a given study. In these cases, each FWA must document reliance and local considerations for the Reviewing IRB. IREx now includes functionality to appropriately identify and group Combo Sites together to indicate a shared single study PI or study team. Though sites share a PI and/or study team, they are still able to proceed with reliance documentation and sIRB review and approval individually, as they are ready.

***Note:** The sIRB may review and issue approval of the study at each FWA separately. The Relying Site HRPP should communicate with the research team if they should not begin the study activities until multiple or all FWAs engaged by the team have completed the process.

WHO INDICATES THAT AN INVESTIGATOR IS PART OF A COMBO IN IREX?

When a **Participating Site HRPP** registers for a study, they can indicate that additional FWAs are engaged by the investigator for the study.



Does Peter Principal engage Goodall University FWA #4563287896 or its components for this study? Yes No

PI Details

Goodall New PI - newpi@goodall.edu

Confirm Your Engaged FWAs / Components

The sIRB or Study Manager identified your site/FWA as shown below. Edit the information if it is incorrect. If one of your FWA components is part of this study but is not listed below: 1) Cancel this registration 2) Go to the Homepage and use the "Components" button to add it 3) Return to register using the component you added

Goodall University

Goodall component - Coco College of Education

Does Peter Principal engage ADDITIONAL sites/FWAs for this study? Yes No

Other Sites / FWAs Engaged By This PI

List any other sites / FWAs that may be engaged by this study team for this study. IREx will notify the HRPP Liaison(s) to confirm engagement.

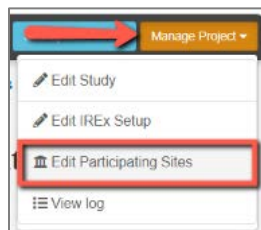
Search by name or FWA number

Hampshire University

Designate Combo Site Primary

Please identify the Primary HRPP for this Combo Site

Goodall University



If a Study Manager learns a PI engages an additional FWA after the Relying HRPP has registered, the Study Manager can add the additional site through the 'Edit Participating Sites' dialog. Simply add the new site and use the same PI name and email address. Do not check the box that the PI engages another site. IREx will automatically make them a Combo Site.

HOW ARE COMBO SITES DISPLAYED IN IREX?

Combo Sites are displayed with a link icon on the Status Summary tab. The site completing the actions is in black with the related site in light blue.

Site	Reliance Agreement	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Anderson Medical Center Baylor College Med	SMART 2	✓	Started 10/1/2021	0 / 3 Surveys Complete	Not Approved
Baylor College of Medicine Anderson Med Ctr	SMART 2	✓	Contacted 10/1/2021		

WHAT ARE THE DOCUMENTATION REQUIREMENTS FOR COMBO SITES?

Documentation requirements are the same for each site in the combo as they are for single sites. That is, the HRPP of each site must document reliance, complete the HRP Survey and verify the PI Survey for their FWA. Furthermore, the PI engaging multiple sites must complete one PI survey per site engaged.

DOCUMENTATION	PRIMARY HRPP	NON-PRIMARY HRPP(S)
Reliance Decision	X	X
Institutional Profile	X	X
HRP Survey	X	X <i>Option to defer to Primary HRPP's responses</i>
PI Survey	X <i>Can copy and edit one survey to the other</i>	X <i>Can copy and edit one survey to the other</i>
Approval Documents from sIRB	Two sets of sIRB approval documents	

Because the information provided for one FWA may be applicable to the other, the information in the HRP and PI Surveys can be copied and edited from one site to another. However, a signature is required for each survey submitted.

HRP Survey – Copy / Edit Option

Goodall | GUMC

The sIRB needs **local considerations/reviews for Goodall University Medical Center - FWA#78899657**.

As a non-primary HRPP for this combo site, please indicate how you would like to proceed:

Complete the survey from scratch.

Copy & edit responses from Goodall

PI Survey – Copy / Edit Option

Anderson Med Ctr | Baylor College Med

The sIRB needs a PI Survey for **Baylor College of Medicine**.

You have already completed a PI survey for this combo site. Please indicate how you would like to proceed:

Complete the survey from scratch.

Copy & edit responses from Anderson Med Ctr

HOW ARE APPROVAL DOCUMENTS DISPLAYED FOR SITES IN A COMBO?

Approvals are now listed separately in the Site-Specific Approvals tab for each site in the Combo. This helps to capture any differing documents (i.e., consent forms) between sites and allows site approvals to be uploaded as they are issued by the sIRB, without holding up all sites in the combo.

Study-wide IRB Approvals
Site-specific IRB Approvals
Status Summary

Protocol Version: 1

Anderson Medical Center

▼ Initial Study: Full Board (exp. 9/1/2022) Current

Baylor College of Medicine

▼ Initial Study: Full Board (exp. 9/1/2022) Current

Anderson Medical Center and Baylor College of Medicine are Combo Sites