

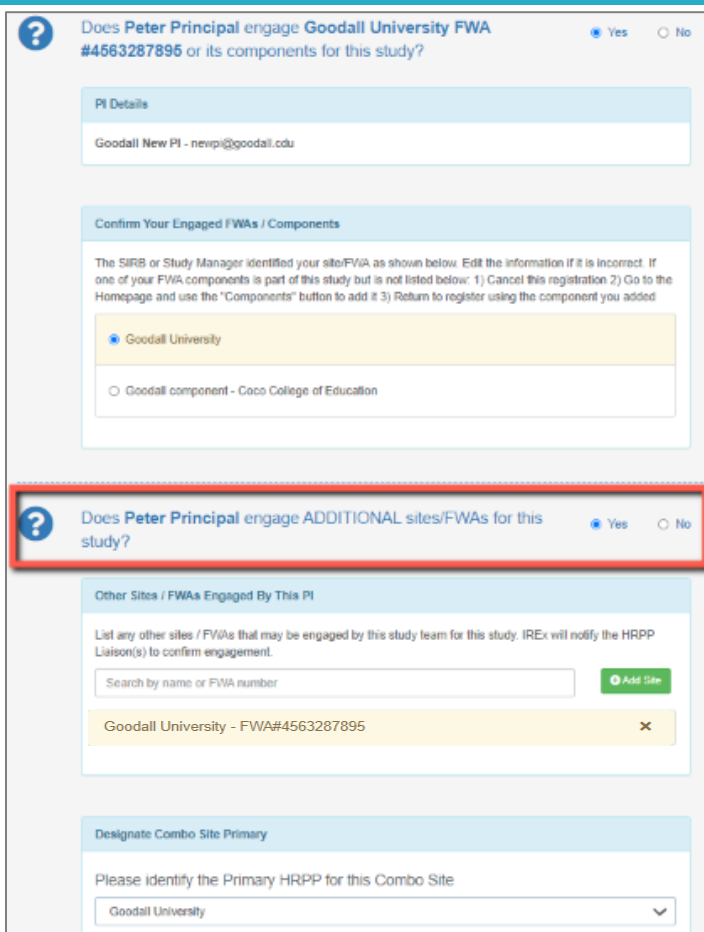
## WHAT ARE COMBO SITES?

Combo Sites occur when **one investigator** engages **multiple sites with unique Federal Wide Assurances (FWAs)** for a given study. In these cases, each site/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. 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 **Relying 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 #4563287895 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.

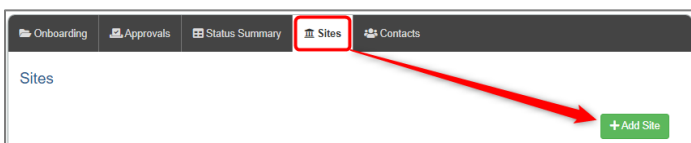
Search by name or FWA number

Goodall University - FWA#4563287895

Designate Combo Site Primary

Please identify the Primary HRPP for this Combo Site

Goodall University



Onboarding Approvals Status Summary **Sites** Contacts

Sites

If an existing PI on the study engages an additional FWA, the Study Manager can add the additional site by clicking '+Add Site' button on the **Sites** tab. Add the new site, use the same PI name and email address, and save. IREx will automatically

link them into a Combo Site. **Do not** check the box that the PI engages another site if that site is already listed on the study.

## 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	Agreements	Reliance Decision	Local Considerations	Approval Status
Anderson Medical Center Baylor College Med	2 / 2 Agreements Complete	Contacted 5/21/2024		
Baylor College of Medicine Anderson Med Ctr	2 / 2 Agreements Complete	Contacted 5/21/2024		
Goodall University GUMC	2 / 2 Agreements Complete	Started 5/21/2024	0 / 3 Surveys Complete	
Goodall University Medical Center Goodall	2 / 2 Agreements Complete	Started 5/21/2024	0 / 3 Surveys Complete	

## MANAGING COMBO SITES

To manage Combo Sites, navigate to the **Sites** tab and click the trash icon next to the Combo Sites you wish to edit.

**Sites**

[+ Add Site](#)

Institution	Granted Access	PI (required)	Study Team Member	Actions
Baylor College of Medicine #00045678	✓	Bayl Orpi	Coordinator Baylor	Contacts Email
<a href="#">Carnegie University #32322829</a> <a href="#">Boston Children's Hospital</a> <a href="#">Carnegie University Medical Center #12345678</a>	✓	PI 2 Carnegie	John Carr	Contacts Email
Case Western Reserve University #00000161	✓	Case PI	Case Coordinator	Contacts Email

The Manage Combo Sites dialog box will appear. To delete a site from an existing Combo, select the site you wish to delete and save. To add an additional site to an existing Combo, click **+ Add Site**, find the site you wish to add, and save.

Manage Combo Sites

Select Sites you want to **remove** from the combo. If you want to remove a Site that's locked , you must create a [Site Closure](#).

- Boston Children's Hospital
- Carnegie University - FWA#32322829
- Carnegie University Medical Center - FWA#12345678

[+ Add Site](#)

## 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 their Institutional Profile for their site/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

The sIRB needs **local considerations/reviews for Goodall University Medical Center**.

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

The sIRB needs a PI Survey for **Goodall University Medical Center**.

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 Goodall

## HOW ARE APPROVAL DOCUMENTS DISPLAYED FOR SITES IN A COMBO?

Approvals are now listed separately in the **Approvals** tab, under **Approval History**, 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. (1) Under **View As**, (2) choose the appropriate site, and view the (3) Global (i.e., Study-Wide) Documents and the (4) Site-Specific Approval documents for that site.