IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

IREX COMBO SITES OVERVIEW

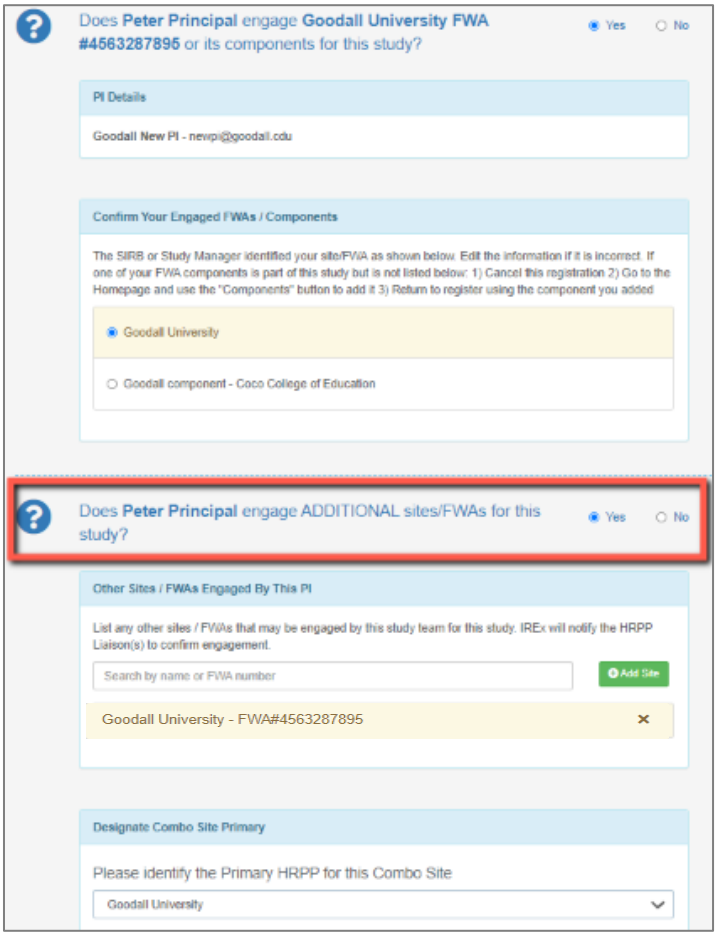
WHAT ARE COMBO SITES?

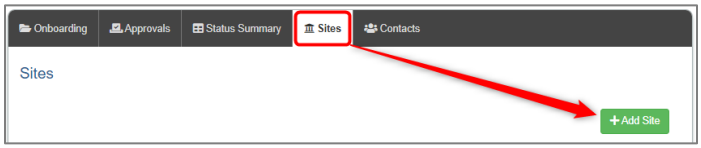
Combo Sites occur when **one investigator** engages **multiple sites with unique Federal Wide Assurances (FWAs)** for a given study. In these cases, each site/FWA must document reliance and local considerations for the Reviewing IRB. IREx now includes functionality to appropriately identify, and group 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.

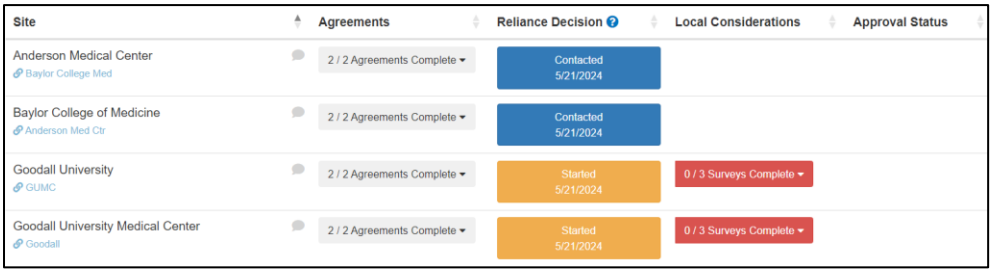




If an existing PI on the study engages an additional FWA, the Study Manager can add the additional site by clicking '**+Add Site**' button on the **Sites** tab. Add the new site, use the same PI name and email address, and save. IREx will automatically link them into a Combo Site. **Do not** check the box that the PI engages another site if that site is already listed on the study.

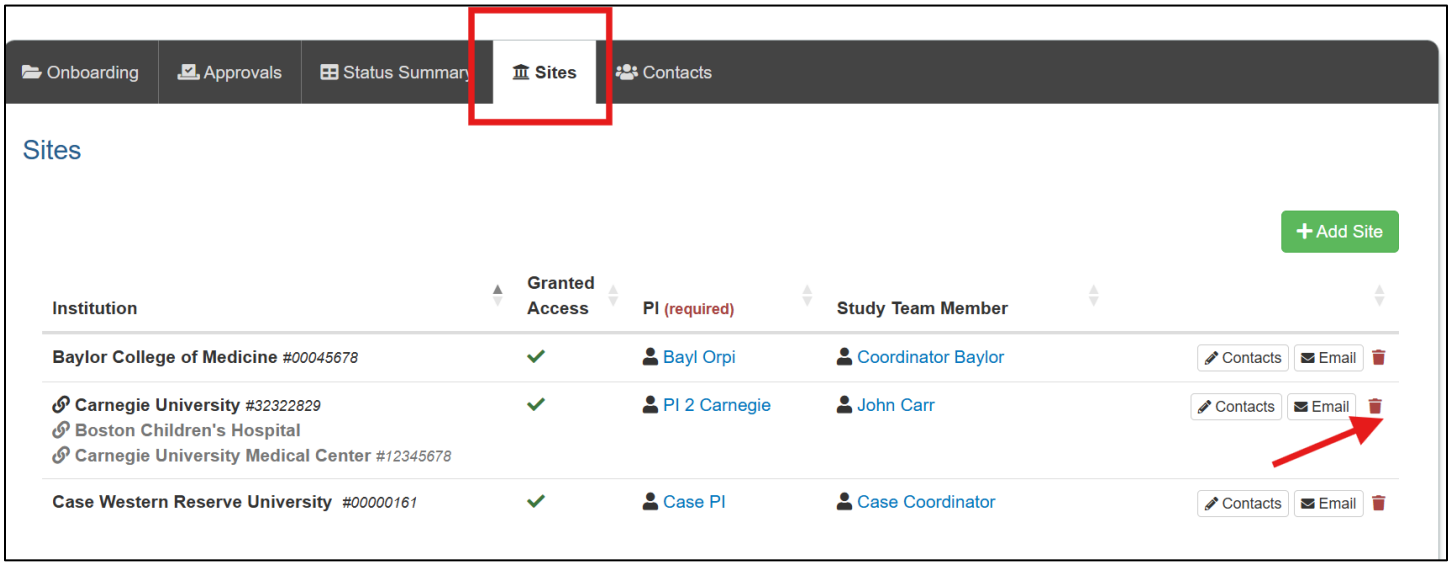
HOW ARE COMBO SITES DISPLAYED IN IREX?

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.

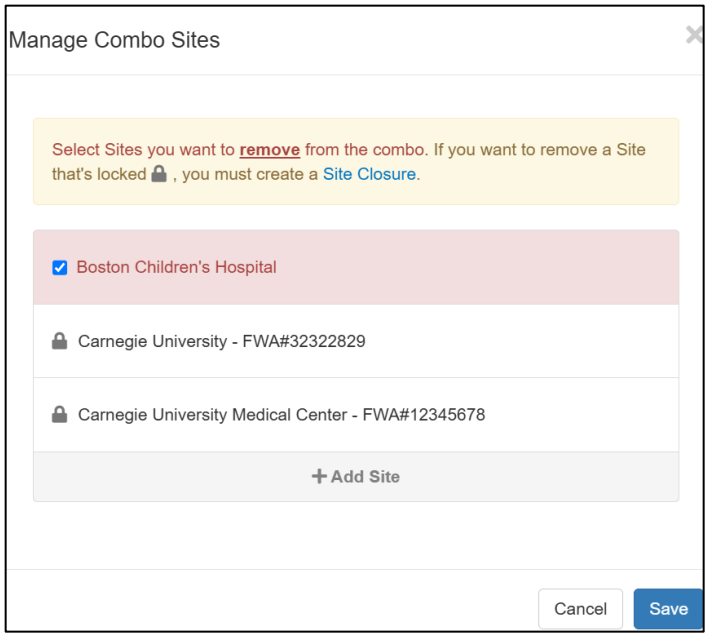


MANAGING COMBO SITES

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



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.



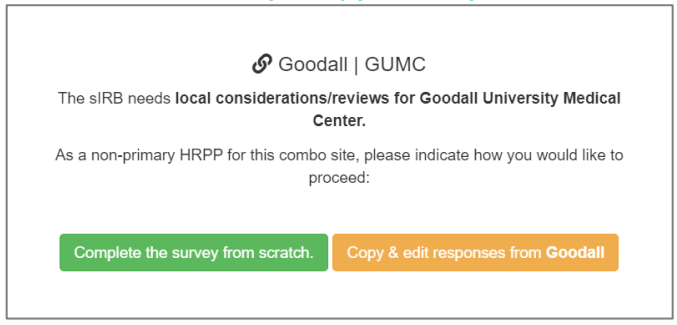
WHAT ARE THE DOCUMENTATION REQUIREMENTS FOR COMBO SITES?

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.

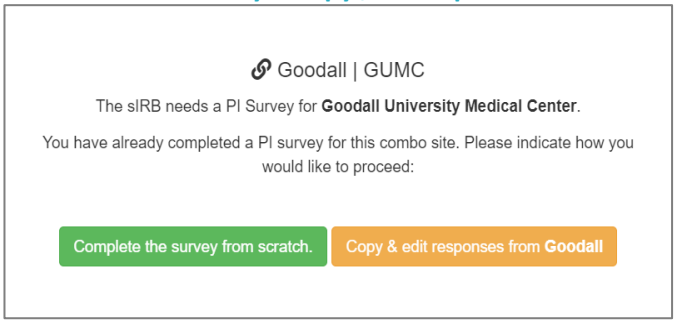
DOCUMENTATION	PRIMARY HRPP	NON-PRIMARY HRPP(S)
Reliance Decision	**X**	**X**
Institutional Profile	**X**	**X**
HRP Survey	**X**	***X*** *Option to defer to Primary HRPP's responses*
PI Survey	**X** *Can copy and edit one survey to the other*	***X*** *Can copy and edit one survey to the other*
Approval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

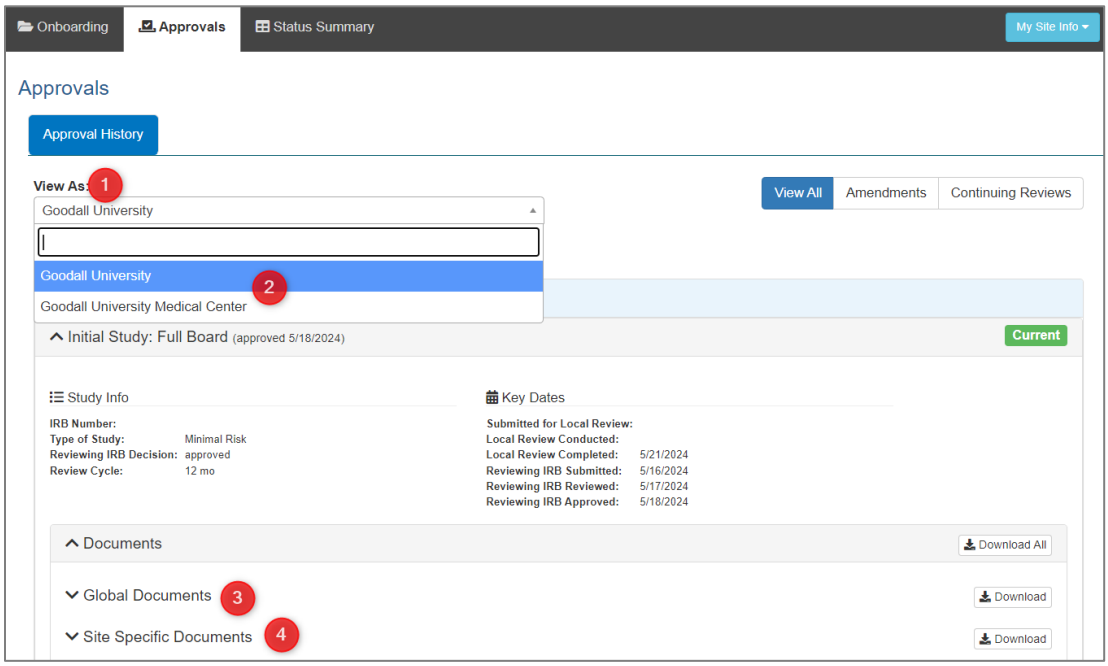
Because the information provided for one FWA may be applicable to the other, the information in the HRP and PI Surveys can be copied and edited from one site to another. However, a signature is required for each survey submitted.

HRP Survey – Copy / Edit Option



PI Survey – Copy / Edit Option



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.