

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 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.

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.

- The HRP of each site must document reliance, complete the HRP Survey and verify their Institutional Profile for their site/FWA.
- PI engaging multiple sites must complete one PI survey per site engaged.

Information in the HRP and PI Surveys can be copied and edited from one site to another because information provided for one FWA may be applicable for the other. A signature is still required for each survey submitted.

PI Survey – Copy / Edit Option

 Goodall | GUMC

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

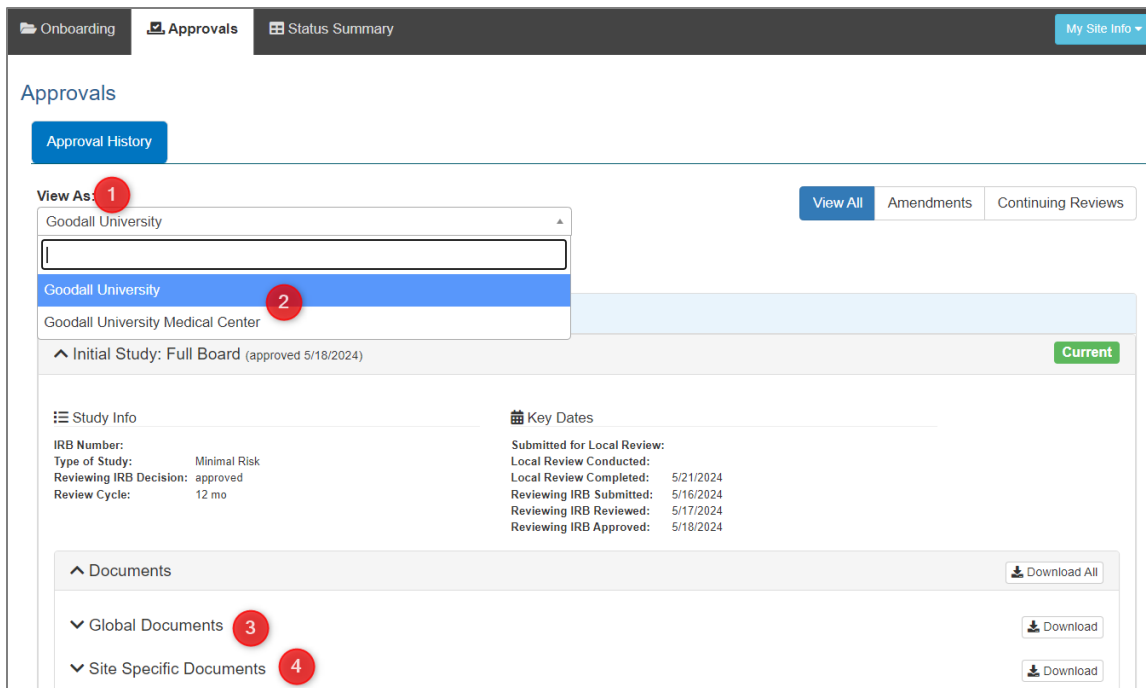
You have already completed a PI survey for this combo site. Please indicate how you would like to proceed:

Complete the survey from scratch.

Copy & edit responses from Goodall

HOW ARE APPROVAL DOCUMENTS DISPLAYED FOR SITES IN A COMBO?

Approvals are listed in the **Approvals** tab, under **Approval History**, for each site 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.



The screenshot displays the 'Approvals' tab in the IREx system. The 'Approval History' section is active, showing a 'View As' dropdown (1) set to 'Goodall University'. Below this, a list of sites (2) includes 'Goodall University' and 'Goodall University Medical Center'. The 'Initial Study: Full Board (approved 5/18/2024)' is marked as 'Current'. The 'Study Info' section shows the IRB Number, Type of Study (Minimal Risk), Reviewing IRB Decision (approved), and Review Cycle (12 mo). The 'Key Dates' section lists dates for submission, local review, and approval. The 'Documents' section at the bottom shows 'Global Documents' (3) and 'Site Specific Documents' (4), each with a 'Download' button.