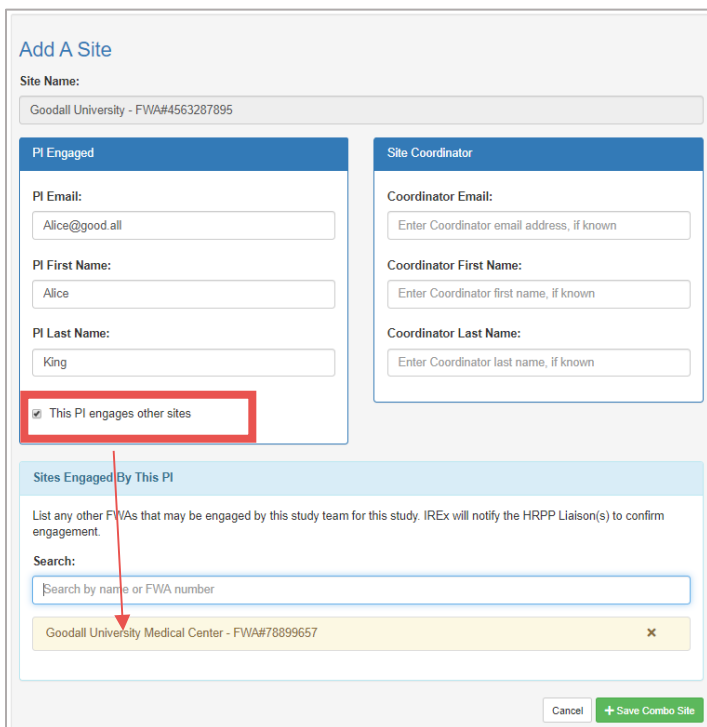


WHAT ARE COMBO SITES?

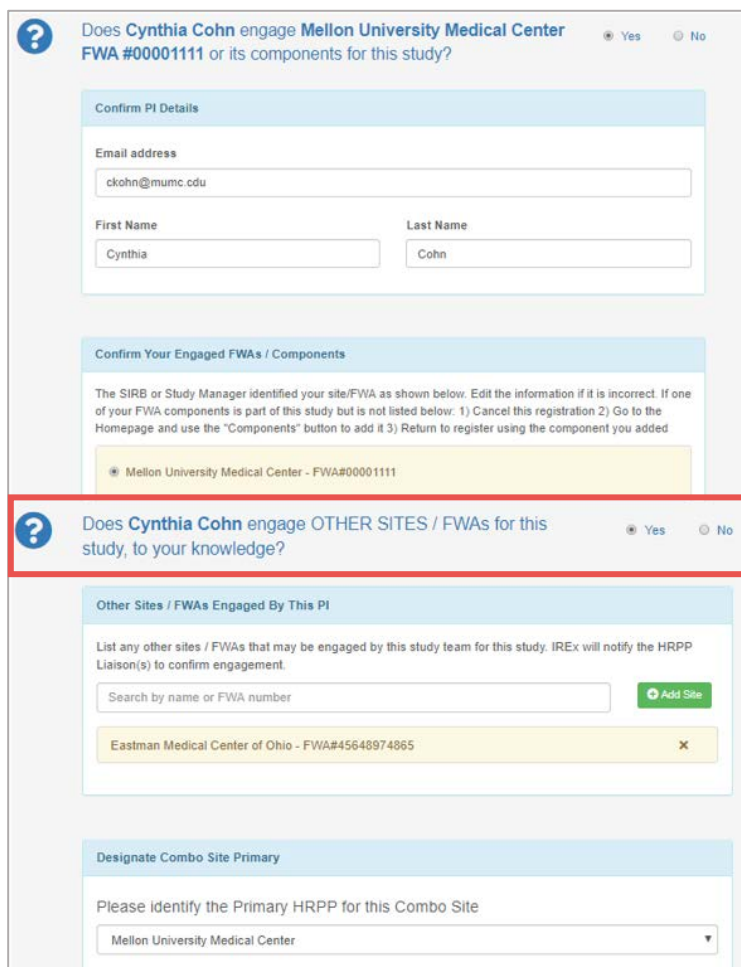
Combo Sites occur when **one investigator** engages **multiple Federalwide Assurances (FWAs)** for a given study. In these cases, each FWA must document reliance and local considerations for the Reviewing IRB. IREx now includes functionality to appropriately identify and group Combo Sites together so Study Managers know when documentation is complete, and the Combo Site can be submitted for review to the Reviewing IRB.

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

The **IREx Study Manager or Reviewing IRB** may identify Combo Sites when adding Participating Sites to the study.



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



Although Combo Sites may be identified by a Study Manager, **determining site engagement in research remains the responsibility of the Participating Site(s)**. The Participating Site HRPP may determine that the site is not engaged in research and can indicate this on the IREx registration page.

HOW ARE COMBO SITES DISPLAYED IN IREX?



Combo Sites are displayed with a link icon. Additionally, each Combo Site has a designated “Primary HRPP”, selected by one of the FWAs in the Combo Site. The Combo Sites is always displayed with the Primary listed first.

WHAT ARE THE DOCUMENTATION REQUIREMENTS FOR COMBO SITES?

Each Combo Site has a self-identified “Primary HRPP”, which is confirmed by the first site to register for the Combo.

The Primary HRPP is the main point of contact and final sign off before the Combo Site can be reviewed by the Reviewing IRB.

As shown in the table below, each FWA in a Combo Site completes an Institutional Profile and indicates reliance on the Reviewing IRB. If local considerations are captured in IREx, the Combo Site’s “Primary HRPP” must complete the HRP Survey and validate the PI Survey.

DOCUMENTATION	PRIMARY HRPP	NON-PRIMARY HRPP(S)
Reliance Decision	X	X
Institutional Profile	X	X
HRP Survey	X	Option to defer to Primary HRPP’s responses
PI Survey <i>(only one PI Survey is required per Combo Site)</i>	Must validate PI Survey responses	Can view, but not edit, PI Survey responses

Non-primary HRPPs can defer to the Primary HRPP’s answers on the HRP survey or complete their own HRP Survey separately for their FWA.

Additionally, non-primary HRPPs can view, but not edit, the PI Survey. Only one PI Survey is completed for the Combo Site since there is only one study team.