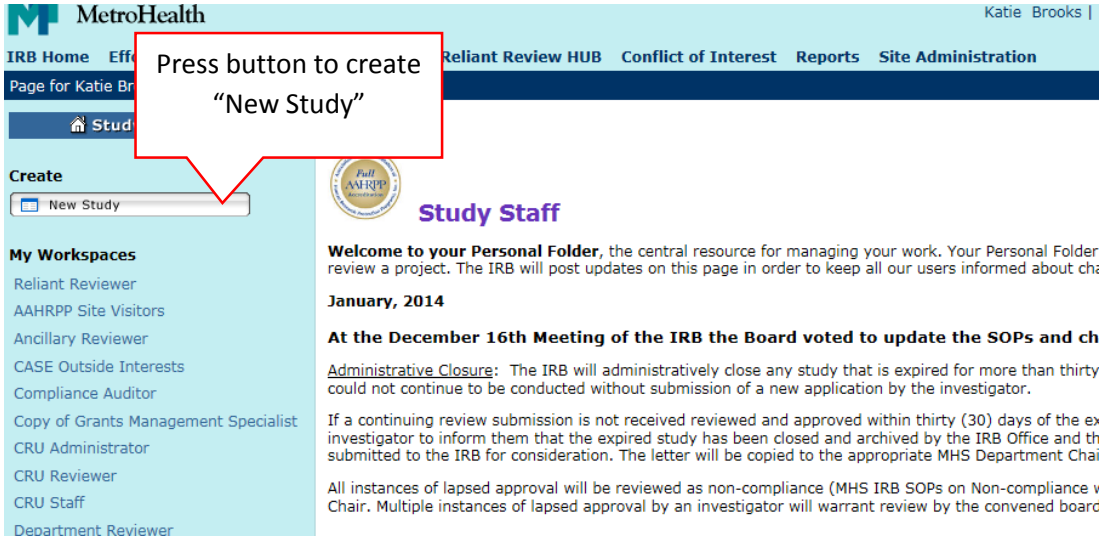
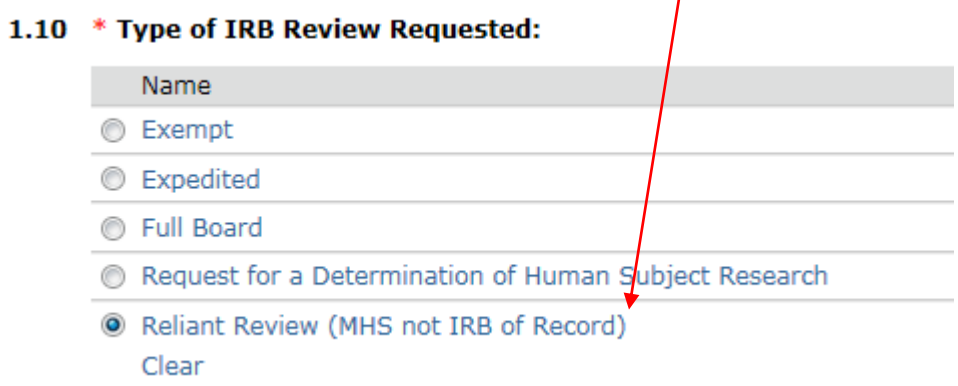
How to Create New Shell Study:

1)



2) Fill out the first page of the application to match the protocol in the Hub.
3) Add ALL relevant MHS study staff and List MHS PI (1.4 and 1.3, respectively)
4) On the second page of the application, at eIRB 1.10 for Type of Review Requested, select "Reliant Review (MHS not IRB of Record)"



5) On the next page in the application, complete all the relevant Reliant Review information: (see next page of instructions for more details):

1.10 Reliant Review Application:

1.10.1 **Reliant Review Catagory:**

Name
◉ Reliant Review HUB (CTSC)
○ NCI IRB

Clear

Select "Reliant Review HUB (CTSC)"

1.10.2 **FOR IRB STAFF AND CANCER CARE STAFF (NCI) ONLY:**

Protocol and Additional Documents (HIPPA & Consent Forms):

Ignore this section.

Add

Name	Version
There are no items to display	

1.10.3 **IRB of Record:**

Name
◉ Case Western Reserve University
○ Cincinnati Children's Hospital Medical Center
○ Cleveland Clinic Foundation
○ Nationwide Children's Hospital
○ NCI CIRB
○ The MetroHealth System
○ The Ohio State University
○ University Hospitals Case Medical Center
○ University of Cincinnati

Clear

Indicate which IRB is the IRB of record.

Approval Date as Set by IRB of Record(i.e.CIRB): * 1/1/1999

Expiration Date as Set by IRB of Record(i.e.CIRB): * 1/1/1999

Enter "1/1/1999" for both dates, IRB admin will update to match the IRB approval letter.

****Note This must be updated annually by the research staff at MetroHealth.**

1.10.4 **Attach IRB of Record Approval Letters (Initial Approval and Continuing Review Approval letters and Investigator Checklist):**

Ignore this section, unless you have these documents already.

Add

Name	Version
There are no items to display	

1.10.5 * **How is this Reliant Review Study being Funded?**

Funded through CTSA grant

Indicate funding source for study.

1.10.6 **Is Clinical Research Unit (CRU) Used?** ○ Yes ◉ No Clear

Select whether or not CRU resources are needed.

NOTE: If you selected CRU yes, make sure you have spoken with Noreen Roman.

6) Enter NCT number if study is registered on ClinicalTrials.gov, **if not write N/A**
7) CLEARLY indicate the Data security and data transfer plans related to the study.
    - How you will *secure* the data
    - How you will *transfer/share* data
8) Press “Continue” and then “Finish” or hit “Save” at bottom of the screen.
9) Notify your IRB administrator. **DO NOT PRESS SUBMIT. IRB STAFF WILL SUBMIT ON YOUR BEHALF AFTER REVIEWING YOUR WORK.**

Note: Once the Shell is complete and Reliance is accepted for the study, you will receive an automatic eIRB notification/Letter.