

How to Create New Shell Study:

1)

Press button to create "New Study"

MetroHealth Katie Brooks |

IRB Home Eff Reliant Review HUB Conflict of Interest Reports Site Administration

Page for Katie Br

Stud

Create

New Study

Study Staff

Welcome to your Personal Folder, the central resource for managing your work. Your Personal Folder review a project. The IRB will post updates on this page in order to keep all our users informed about ch

January, 2014

At the December 16th Meeting of the IRB the Board voted to update the SOPs and ch

Administrative Closure: The IRB will administratively close any study that is expired for more than thirty could not continue to be conducted without submission of a new application by the investigator.

If a continuing review submission is not received reviewed and approved within thirty (30) days of the ex investigator to inform them that the expired study has been closed and archived by the IRB Office and th submitted to the IRB for consideration. The letter will be copied to the appropriate MHS Department Chai

All instances of lapsed approval will be reviewed as non-compliance (MHS IRB SOPs on Non-compliance v Chair. Multiple instances of lapsed approval by an investigator will warrant review by the convened board

My Workspaces

- Reliant Reviewer
- AAHRPP Site Visitors
- Ancillary Reviewer
- CASE Outside Interests
- Compliance Auditor
- Copy of Grants Management Specialist
- CRU Administrator
- CRU Reviewer
- CRU Staff
- Department Reviewer

- 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)"

1.10 * Type of IRB Review Requested:

Name
<input type="radio"/> Exempt
<input type="radio"/> Expedited
<input type="radio"/> Full Board
<input type="radio"/> Request for a Determination of Human Subject Research
<input checked="" type="radio"/> Reliant Review (MHS not IRB of Record)
Clear

- 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 Category:

Name
<input checked="" type="radio"/> Reliant Review HUB (CTSC)
<input type="radio"/> 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):

[Add](#)

Name	Version
There are no items to display	

Ignore this section.

1.10.3

IRB of Record:

Name
<input checked="" type="radio"/> Case Western Reserve University
<input type="radio"/> Cincinnati Children's Hospital Medical Center
<input type="radio"/> Cleveland Clinic Foundation
<input type="radio"/> Nationwide Children's Hospital
<input type="radio"/> NCI CIRB
<input type="radio"/> The MetroHealth System
<input type="radio"/> The Ohio State University
<input type="radio"/> University Hospitals Case Medical Center
<input type="radio"/> University of Cincinnati

[Clear](#)

Indicate which IRB is the IRB of record.

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

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

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

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

1.10.4

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

[Add](#)

Name	Version
There are no items to display	

Ignore this section, unless you have these documents already.

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.