Facilitated Review Instructions

What is Facilitated Review? Facilitated Review relies on IRB Authorization Agreements (IAA). These are written agreements between two institutions that allows Institution A to act as the “IRB of Record” for Institution B (the “Named IRB”).

The bulk of the human subject protection considerations are made by the IRB of Record, with secondary review being done by the Named IRB using the information obtained from the IRB of Record. The Named IRB retains the ability to accept or reject the initial review, or subsequent reviews, and may require secondary IRB review through the regular means.

Overview of the Facilitated Review Process

First, it is important to understand the following terms:

- **IRB of Record** - The IRB that has reviewed and approved the protocol
- **Named IRB** - The IRB from which you are requesting a Facilitated Review

Before a study can even be considered for Facilitated Review at the Named IRB, the IRB of Record must complete its review and approve the study according to all applicable regulatory standards (federal, state, and local) using its usual process.

Next, an investigator from the institution of the IRB of Record submits an abbreviated application to the Facilitated Review HUB. This notifies both the IRB of Record and the Named IRB study of intent to involve patients, staff, resources, etc. from the Named IRB in the study.

This application gives the Named IRB access to information from the IRB of Record. This includes the IRB of Record’s completed application with protocol, other information utilized in their review, and their final determination documentation (i.e., approval letters and other determination letters). It may also include the IRB of Record’s grants and contract information as applicable. Minutes (if applicable) from the IRB of Record’s review of the study will be given to the Named IRB by the IRB of Record.

The Facilitated Review application also contains information specifically required by the Named IRB including:

- Consent Documents to be used at the Named IRB. These must use the Named IRB’s consent templates, elements and required language.* They will receive a local context review.
- How recruitment will be done at the Named IRB
- What procedures will take place at the Named IRB and where
• How many subjects are expected to be enrolled from the Named IRB

• Who at the Named IRB is responsible for the conduct of the research

• The Principal Investigator’s plan to communicate to the Named IRB all amendments, continuing reviews, adverse events, unanticipated problems, significant findings, suspensions, non-compliance matters and other information as appropriate.

*Samples of these consent forms can be found on the Facilitated Review landing page (See page 3, Entering the Facilitated Review HUB.)

The Named IRB will review all applications for Facilitated Review and determine if they meet institutional criteria for Facilitated Review. In addition to reviewing the information listed above, the Named IRB will also consider things including but not limited to:

• Completeness of the application; all questions must be answered and all requested documents attached.

• Credentials of Investigators (CREC, COI)

• Required Regulatory determinations by the IRB of Record

• Applicable Institutional Policies e.g. pharmacy, nursing, or radiation safety.

If the Facilitated Review meets its institutional criteria the Named IRB grants approval for Facilitated Review and it advances to the next stage of review.

If it does not meet the criteria for Facilitated Review, the Named IRB notifies the IRB of Record and investigators of the decision and the investigators may request an IRB approval from the Named IRB through the usual process.

In the next stage of review, the Named IRB performs a local context review meaning further consideration of its specific institutional requirements and its specific population of potential subjects. Finally, the Chair (or sub-committee) of the Named IRB determines whether to accept the approval of the IRB of Record:

- If yes, the Named IRB grants approval of the study and notifies the investigators.
- If no, the Named IRB notifies the IRB of Record and investigators of the decision and the investigators may request an IRB approval from the Named IRB through the usual process.

Please note that at any point during this process the IRB of Record or the Named IRB may request changes or ask for additional information from the investigators.
Instructions for Completing and Submitting a Facilitated Review

Before you can start completing the application, you will need to:

- Have an approved protocol at one of the following institutions: MetroHealth, University Hospitals CASE Medical Center, Cleveland Clinic, or Case Western Reserve. Likewise, only these institutions can grant a Facilitated Review for your study.

- Register with the MetroHealth IRB website if you are not already registered. It is hosting the Facilitated Review HUB. To register go to https://mhirb.metrohealth.org. Click on the word “Registration” in red and complete the form that appears. You will be sent an ID and Password within 24 business hours. If you have questions about registration call Ginger Pomiecko at 216-778-7741. Please instruct anyone else who will be on your study to do this as well if they are not already registered with the MetroHealth IRB website.

Entering the Facilitated Review HUB

Once you get your ID and Password go to https://mhirb.metrohealth.org. Click on “Login” in the upper right of the screen and you will be taken to your home page.

Your Home Page will look like this:
To enter the Facilitated Review HUB click on the link, “Facilitated Reviews” in the top left.

Above is the Facilitated Review Home Page. From this page you will be able to create and manage all of your Facilitated Reviews. This page also contains documents and information for all the IRBs participating in the Facilitated Review HUB. For example if UH is the IRB of Record and you want to request a Facilitated Review from MetroHealth, click on the grey tab Documents for MetroHealth. Here you will find consent form templates and other information for non-MetroHealth investigators such as requirements for accessing PHI and MetroHealth medical records.

The Review tab lists any Facilitated Reviews you are currently working on and the Approved tab lists your currently approved Facilitated Reviews. The Archived tab lists and former Facilitated Reviews that are now closed or withdrawn. Click on the name of a study to open it. This will take you to its main page.
Creating a Facilitated Review Submission

To create a new Facilitated Review, go to the Facilitated Review HUB and click the “New Facilitated Review” button in the left side bar.
The first page of your application will open.

First, notice that the top and bottom of each page are set up as follows:

Continue - To go forward a page

Back – Takes you back to your previous page. Click, “Save” in toward the middle of the green header before doing this or you will lose any changes you made to that page.

Save- Save any changes on your current page. You do not need to click this if you are going to hit the Continue button.

Exit- Returns to the main page of the study. If you have made changes on your current page, make sure to hit Save first.

Jump to: - Use this drop-down to jump from page to page within the application. Again, click, “Save” before doing this to save your work.

Below is a page-by-page example of a Facilitated Review Application. In this example an investigator from UH is requesting a Facilitated Review to do a study at MetroHealth. The application has two universal pages that must be answered for all Facilitated Reviews and then the application branches depending on the institution from which you are requesting a Facilitated Review. Each institution has its own brief application forms. You can also request CRU review at the Named IRB.
All applications start with the same two universal pages.

**Universal Page One**

As you are answering questions note that all questions with an * asterisk have to be answered or you will not be allowed to advance to the next page.

Enter the name of the Principal Investigator at the IRB of Record

Enter Short Title [must be consistent with the title of the protocol approved by the IRB of Record; if that institution does not have a short title and a long title, use the long title here.]

Enter Long Title [must be consistent with the title of the protocol approved by the IRB of Record]

Select IRB of Record

Select the Named IRB
### FACILITATING REVIEW: REQUIRED INFORMATION FROM ALL INVESTIGATORS

The questions on this page are required by all participating institutions.

#### IRB of Record Risk Determination:

**Degree of Risk as determined by the IRB of Record?**  
- [ ] Low  
- [ ] Test Greater Than Minimal Risk  

**IRB of Record Review Type:**  
- [ ] Expedited  
- [ ] Full Board

#### What Resources will you require of the Network IRB Site (NIRB):

- [ ]

#### Projected Enrollment:  
*Please use the Tab key to go from box to box when answering this question*

<table>
<thead>
<tr>
<th>Question</th>
<th>Normal IRB</th>
<th>IRB of Record</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Projected enrolled subjects (maximum)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Projected evaluable subjects (maximum)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Principal Investigator Documents:

Please add the following documents (as applicable): Current Approved Protocol, all associated documents (e.g., data collection forms, surveys, psychological tests, Questionnaires, Investigator Brochure, all currently approved consent forms, any Approval letters from IRB of Record [initial approval letter and Continuing Review Approval Letter(s)].

- [ ]

### Principal Investigator Documents:

Please add the following documents (as applicable): Current Approved Protocol, all associated documents (e.g., data collection forms, surveys, psychological tests, Questionnaires, Investigator Brochure, all currently approved consent forms, any Approval letters from IRB of Record [initial approval letter and Continuing Review Approval Letter(s)].

- [ ]

If you are choosing to recruit subjects at the Network site, you will need to submit consent forms on our approved templates. These templates can be found on the next page. Please copy the appropriate template to your desk top to create your consent form(s). When you are done attach all your consent forms below. If you have recruitment materials please attach them below so they can be reviewed and stamped as well.

#### 450 Current Forms: Recruitment Materials and all other documents that have to be stamped:

<table>
<thead>
<tr>
<th>Name</th>
<th>Version</th>
<th>Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

Use of CINA Resources:

- [ ] Will you be using the Clinical Research Unit (CRU)?  
  - [ ] Yes  
  - [ ] No  
  - [ ] Clear  
- [ ] Are you using CRU at University Hospital?  
  - [ ] Yes  
  - [ ] No  
  - [ ] Clear  
- [ ] Will you be using RedCap?  
  - [ ] Yes  
  - [ ] No  
  - [ ] Clear  
- [ ] If Yes, Identify which RedCap you will be using, i.e., CASS, CCF, MHIS.
- [ ] Will you be using Research Match?  
  - [ ] Yes  
  - [ ] No  
  - [ ] Clear

Learn more about Research Match at: [https://www.researchmatch.org](https://www.researchmatch.org)
Select the risk as set by the IRB of Record

Select the type of review received by the IRB of Record

Write up a list of resources that you will require from the Named IRB

Enter the study enrollment numbers. Use the tab button to go from box to box to enter the numbers.

Attach Principal Investigator documents

Attach **ANY** consent forms or other document that will need to be reviewed and stamped by the Named IRB

Use of CTSA Resources

Will you be using the CRU?

Are you using the CRU at IRB of Record?

Will you be using RedCap?

If yes, which RedCap?

Will you be using Research Match?

This is the end of the universal pages. When you click continue you will now go to the supplemental application pages for the Named IRB. Depending on the institution this portion of the application will be 4-6 pages long.
Following our example here are the pages for the MetroHealth application:
2.0 MetroHealth Questions II

2.1 Is this an Investigator Initiated Study? Yes/No/Not Clear
2.2 Has this protocol had a science review? (other than the IRB review) Yes/No/Not Clear
2.3 Are there any Conflicts of Interest (financial) you or your study staff (Co-Investigator, Coordinators, Other Study Staff) may have on this study? Yes/No/Not Clear
2.4 If you answered “Yes” to Question 2.3, please explain:
2.5 Please attach your plan for informing the MetroHealth IRB of all new Amendments, new Continuing Reviews, and Unanticipated problems:

3.0 MetroHealth Questions III

3.1 PHI Questions:

Are you collecting PHI? Yes/No/Not Clear

If the answer is Yes to 3.1 and will be collecting PHI:
Select Data Identification Type(s):
- Anonymized: No identifying information will be collected from the subject(s).
- Anonymized/Confidential: Data will be linked to subjects via a code or indirect identifier (i.e., study ID or numbers).
- Identifiable: Data will be linked to subjects via direct identifier (e.g., medical records numbers, etc.)

Is any PHI going to be stored as paper files? Yes/No/Not Clear

If any PHI going to be stored in an electronic format? Yes/No/Not Clear

3.2 Is your data being stored on a laptop computer? Yes/No/Not Clear

3.3 Are you planning to store your data using a storage device? (i.e., jump drive, external hard drive, CD, etc.) Yes/No/Not Clear

3.4 Where will data be stored?

Answer yes or no.
Subject Recruitment: Answer all questions by selecting the most appropriate answers.

4.1 What are the characteristics of your study population?
- Vulnerable Populations
  - Poor / Unemployed
  - Minor - Children under 18
  - Terminally ill patients
- Alcohol
- Psychiatric Patients
- Postpartum/Fetal Tissue
- IRCs
- Traumatized/Comatose Patients
  - Employed
  - Visually/Motor Impaired
  - Students
  - Prisoner/Parolee/Court
  - Limited or Non-Reader
  - Pregnant Women
  - Aborton
  - Non-English Speaking
  - Minor
  - Cognitively Impaired
  - Developmentally Impaired
  - Institutionalized Patients
  - Children in Foster Care
  - Children who are Ward
  - Other

If you checked "Other" in question 4.1 please explain:

4.2 Subject Age Range:
- 0 - 6
- 7 - 11
- 12 - 17
- 18 - 24
- 25 - 39
- 40 -

4.3 Subjects Characteristics:
- Subject Population Categories
  - Normal/Healthy Volunteers
  - Inpatients
  - Outpatients
  - Household Patient
  - Patients with the "disease in question"
  - Relatives of patients with the "disease in question"
  - Other

If you checked "Other" in question 4.3 please explain:

4.4 Recruitment Methods/Sources:
- Name
- Internet/World/MetroHealth Internet
- Telephone Survey
- Advertising/Advertisements/Magazines, Television, Radio
- Newspapers/Posters/Fliers
- Letters
- None
- Research Match
- Epic Alerts
### 5.0 MetroHealth Questions V

#### 5.1 Did you receive a Waiver of Consent for the IRB of Record?
- [ ] Yes
- [x] No

#### 5.2 Did you receive a Partial Waiver for Recruitment from the IRB of Record Site?
- [ ] Yes
- [x] No

#### 5.3 What type of Informed Consent will be used in this study? (Check all that apply.)
- [ ] Consent Type
- [ ] Informed Consent Form
- [ ] Verbal Consent
- [ ] Written Consent by Subject
- [ ] Written Consent by Legally Authorized Representative
- [ ] Written/Signed Consent by Parent/Guardian
- [ ] Written/Consent by Minor
- [ ] Health Care Surrogate Appointment Form
- [ ] Video/Audio Consent Form
- [ ] Short Form Consent
- [ ] Other
- [ ] None

If you selected "Other" or "None" in response to question 5.3 please explain:

#### 5.4 Is there a Data Safety Monitoring Plan? [ ] Yes [ ] No [ ] Clear

#### 5.5 Is there a DSMB or ORC? [ ] Yes [ ] No

#### 5.6 Will Human Biological Materials be collected as part of this study? (i.e., blood, tissue, fluids and substances etc.) [ ] Yes [ ] No [ ] Clear

#### 5.7 Does this research involve human cell lines and/or products that are made from human biological materials?
- [ ] Yes
- [ ] No

### 6.0 Research Procedures and Risks VI

#### 6.1 Type of Research:
- [ ] Database/Registry
- [ ] Retrospective Chart Review
- [ ] Quality Assurance Study (QAI-Exempt Review, if you are going to publish in a research journal-Expected)
- [ ] Clinical Drug Trial
- [ ] Clinical Device Trial
- [ ] Emergency Use of a Device or Drug
- [ ] Pharmacologic Research
- [ ] Other

If you selected "Other" research type in response to question 6.1 please explain:

#### 6.3 What Procedures will you be doing with MetroHealth Subjects? (Select from the following lists.)

Will this research involve any of the following Social Behavioral Procedures:
- [ ] Behavioral Observations
- [ ] Behavioral Interventions
- [ ] Interview/Focus Groups
- [ ] Population Based Field Study
- [ ] Psychological Testing
- [ ] Surveys/Questionnaires
- [ ] None of the above Social Behavioral Procedures Apply to this Study

#### 6.4 Medical Procedures:
Submitting a completed Facilitated Review

When you are done answering all questions and attaching all documents, go to the main page for your study and click the **Submit Complete Protocol File** button.

The Facilitated Review then goes to the state **IRBR Review** and the IRB of Record Administrator will ensure that the file is complete and attach any documents needed from their IRB, e.g., copies of minutes.

The IRB of Record Administrator can either approve your submission or request changes or clarifications.

If the IRB of Record Administrator Approves your application it will go to the Named IRB and you will be sent an email notification. The application will now be in the state, **Awaiting Acceptance**.

The Named IRB Administrator will review the Facilitated Review and either accept or reject it for Facilitated Review. If it is rejected you will receive an email with further explanation. If it is accepted, your Facilitated Review Application it will move to the state **Under Review**.

Again the Named IRB Administrator will review and can ask questions or request clarification or additional documents using reviewer notes.

### How-to Work With Reviewer Notes

**ALL** requests for changes are done with reviewer notes. There are two ways to see your reviewer notes. First, from the main page of your Facilitated Review submission (The page should state, "**SUMMARY VIEW OF PROTOCOL INFORMATION AND STATUS**"), click the gray Reviewer Notes Tab.

To go to the page with a particular note, click the blue link after, "Jump to:" in that note. It will take you to the page with the note so you can make your corrections and respond to the note. The second method of viewing notes is to click, "Edit Facilitated Review" in the left side bar. This is how one re-enters the application. If you do not see a note on the top of the first page, click the, “Next” button in the yellow area at the top. It will take you to the next note. There is also a “Previous” button to skip back to a previous note. Make sure to click “Save” before using these buttons if you made any changes.

Responding to reviewer notes is a two-step process. First, make the change or clarifications in the actual application itself, i.e., change your answer. Second, click the blue link in the note that says, “Click here to respond.” Answer the note by indicating you have made the requested change, e.g. OK, done, or complete. Please remember, reviewer note answers are not part of the official submission. If information is important, put it in an answer to one of the application questions.

Once you complete the requested changes, hit, “Exit” toward the middle of the top of the page to return to the main page of your study. Finally, click, "Submit Changes" in the left side bar. If you do not answer all reviewer notes you will get an error message when you try to submit your changes. Try again once you have responded to all reviewer notes.

A Facilitated Review may go back and forth several times before the Named IRB Administrator feels it is ready for a **Facilitated Review** by the Chair of the Named IRB. Once the Named IRB Administrator sends it to the Chair for review he/she can approve it, disapprove it, ask questions or require changes, or require a regular expedited or full board review instead of a facilitated one.
If the Chair approves the Facilitated Review the Named IRB Administrator will stamp all consent forms, surveys, recruitment materials and other documents to be used at the Named IRB with the proper approval and expiration dates.* The expiration date will be the same expiration date issued by the IRB of Record. Lastly, you will receive an email containing a link to your approval letter. This approval letter will remain accessible on the main page of your study through a link in your history log titled, “View Correspondence.”

* NOTE: Only the stamped consent forms and recruitment materials can be used to consent subjects at the Named IRB institution.

Required Notifications to the Named IRB

Once your Facilitated Review has been Approved you must submit to the Named IRB copies of all amendments, continuing reviews, adverse events, unanticipated problems, significant findings, suspensions, DSMB reports, non-compliance matters and other information as appropriate.

When you submit a new continuing review approval from the IRB of Record, the Named IRB will re-stamp your approved documents with the new expiration date issued by the IRB of Record. You must submit your continuing review approvals to the Named IRB before the expiration date or your study will expire at the Named IRB. If it expires, you must cease research activities at the Named IRB.

How do you submit all of the above documents?

Open the main page of your study. Click the Upload Supporting Documents button in the left side bar and select a file to upload. You may have multiple documents. The Named IRB will receive a notification and will review and acknowledge these documents.

Closing a Facilitated Review

To close a Facilitated Review click the Submit a Request to Close Study button and attach your final report to the IRB of Record. The Named IRB will then close and archive your Facilitated Review.
**Questions?**

For questions on using the Facilitated Review HUB please call Ginger Pomiecko at 216-778-7741 or email gpomiecko@metrohealth.org. You may also contact Kathy Lawry at 216-778-2077 or email klawry@metrohealth.org.

For questions specific to the questions being asked in the application, call the IRB Administrator at your Named IRB.

For questions about a particular reviewer note, contact the IRB Administrator who created the reviewer note.

**IRB Administrators**

<table>
<thead>
<tr>
<th>MetroHealth</th>
<th>University Hospitals Case Medical Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ginger Pomiecko</td>
<td>Karya Ottey</td>
</tr>
<tr>
<td>216-778-7741</td>
<td>216-286-2278</td>
</tr>
<tr>
<td><a href="mailto:gpomiecko@metrohealth.org">gpomiecko@metrohealth.org</a></td>
<td><a href="mailto:Karya.ottey@uhhospitals.org">Karya.ottey@uhhospitals.org</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Case Western Reserve University</th>
<th>Cleveland Clinic Foundation</th>
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</thead>
<tbody>
<tr>
<td>(Note, this is not the UH IRB)</td>
<td></td>
</tr>
<tr>
<td>Isabel Sanchez-Cummings</td>
<td>Dan Beyer</td>
</tr>
<tr>
<td>216-368-6993</td>
<td>216-444-5848</td>
</tr>
<tr>
<td><a href="mailto:Isabel.sanchez@case.edu">Isabel.sanchez@case.edu</a></td>
<td><a href="mailto:beyerd@ccf.org">beyerd@ccf.org</a></td>
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