U-M HRPP CoC Application Instructions

Step 1: Actions to Complete Prior to Submitting to the U-M HRPP

1. Include the IRB MED or IRB-HSBS CoC text in the informed consent/assent documents for IRB review. If using assent documents, the CoC text may be modified as necessary, and as approved by the IRB, for the age and reading level of the children.

2. You must obtain IRB full approval, or contingent approval where applying for the CoC is the only contingency.

Step 2: Submitting the Application Package to the U-M HRPP

1. Prepare the following materials and scan as a single document:
   a. a copy of your IRB approval/contingent approval letter (you will find this in the Posted Correspondence space of your eResearch application)
   b. a copy of your consent/assent documents, if obtaining consent/assent
   c. a copy of the Key Personnel Listing template (see pp. 4-5)
      Typically, the key personnel listing should be consistent with the individuals appearing on the eResearch application who will have substantive interaction with the human participants. This includes having access to directly identifiable data or access to data that could be re-identified via codes/links.
   d. copies of any Drug Enforcement Certification of Registration forms, as applicable

2. In an email to HRPPCoCgroup@umich.edu use the following text for your message (inserting the applicable information, as indicated by the brackets):
   a. This is a CoC application for [name of PI].
   b. The study is a [single site/multi-site] project.
   c. The person to contact with any questions is [name].
   d. The PI confirms that no application has yet been submitted to the NIH.

Attach the single scanned document and send to the HRPP.

3. Upon receipt of your materials, you will receive an acknowledgement email with additional information about the review process and next steps
Step 3: U-M HRPP Administrative Review

CoC applications will undergo an administrative review by the CoC Coordinator. The administrative review is conducted to ensure that:

- the consent document(s) include text about the CoC (consult with IRB for requirements)
- the IRB approval is current (SCR or AME approval, as applies)
- the Key Personnel listing is consistent with the study team listed in your eResearch application

When the administrative review is completed, the PI will be instructed to go to the NIH CoC website to create and submit the application. **PIs should not create the NIH application until instructed to do so by the U-M HRPP.**

Step 4: Submitting your NIH CoC Application in the NIH CoC System

After receiving the go-ahead from the HRPP, you will create your application in the NIH CoC system.

The NIH CoC system does not allow the PI to save their application, nor does it allow the U-M HRPP to send the application back to the PI to make corrections. The application is relatively short and most of the information you will provide is straightforward and brief. Be sure to enter the information into the NIH application as accurately as possible. Should errors exist in the application, the only recourse available for correction is to complete a whole new application.

When completing the online NIH application, **enter the following data** as shown below:

**ITEM 1, Funding:** If you have no funding at all, select No Federal Funding

**ITEM 6** - Is a waiver or alteration of informed consent under 45 CFR 46 to be used? The answer to this question should be 'No' unless you have a waiver of consent form for the entire study. If you have a waiver of consent for screening purposes only (and you are required to obtain consent for the study) then answer No.

If you are using a waiver or alteration, answer Yes and another question appears: If yes, has the waiver or alteration been approved by the IRB in accordance with 45 CFR 46? Clicking Yes on this question is consistent with eligibility for a CoC. Clicking Yes means the waiver or alteration of informed consent has been approved by the reviewing Institutional Review Board (IRB).

**ITEM 7, Research Project Title:** Insert your IRB HUM number immediately before the title. For example, HUM00123456_Research Title

**ITEM 8 – Project Start Date**
This date must be in the future. If the research has already begun, enter today's date plus one business day.

**ITEM 12, Institutional Address:**
North Campus Research Complex 2800
Plymouth Rd, Bldg 520, Rm 2170

Last Updated: 02/14/2024
ITEM 13, Institutional Official
Sana Shakour, Ph.D., Associate HRPP Director
ITEM 14: sanashak@umich.edu
ITEM 15: 734-936-6288
ITEM 16, Performance Site: University of Michigan
ITEM 17: Provide your address (or other U-M address), as applies
ITEM 23, Other Key Personnel: You will be asked to enter your Key Personnel. This information should be consistent with what you submitted to the HRPP in the Key Personnel Listing document.

Step 5: Confirmation Process

Upon submission of your NIH CoC application, the U-M Deputy Institutional Official (DIO) will receive an email notification from the NIH with a link to your application. If the application is accurate and there are no questions, the DIO will formally agree to the CoC Assurances and issue the confirmation in the system. After the DIO has issued the confirmation, the NIH will typically issue the CoC in 1-3 days, on average.

When you receive the CoC from the NIH, upload a copy of the CoC to section 11-2 of your eResearch application. Once you have completed this step, the IRB will issue full approval for your application and you may begin your research.
If you have questions regarding these instructions, email hrppcocgroup@umich.edu.

1. The information you list should be consistent with what is listed in the IRB application in eResearch for the study team and only as it relates to current U-M faculty, staff, and students.

2. By HRPP policy, non-funded U-M collaborators will not fall under the U-M CoC coverage and should not be listed. These individuals should discuss obtaining their own CoC with their IRB or Institutional Official. Study team members where U-M will formally serve as the IRB-of-record may be listed as key personnel. **NOTE: final determination of coverage is always left to the Deputy Institutional Official’s (DIO) discretion.**

3. Refer to the sample listing on the next page. To create your listing, copy and paste the sample information into your document and then modify it with the correct information for your study team. Include KEY PERSONNEL LISTING as the title header for the document.

4. Start the listing with the PI who is named on the IRB application in eResearch. Follow the general format below for all study team members:

   **PI/Co-I/Study Coordinator/Research Staff**
   
   First Name:
   
   Last Name:
   
   Phone:
   
   Email:
   
   Degree:
   
   Current U-M Position: [Include “U-M” in the Position Title]
   
   Current Position (if not U-M affiliate): [Include name of their institution in the Position Title]*

* **IMPORTANT**! Only include a non-UM affiliate if they are unfunded and you are requesting that they be allowed to roll up under the U-M CoC. A determination will be made by the DIO.
KEY PERSONNEL LISTING

PI
First name: Mary
Last name: Jones
Phone: xxx-xxx-xxxx
Email: mjones@umich.edu
Degree: PhD Epidemiology
Current U-M Position: Professor, U-M School of Public Health

Co-I
First name: Joseph
Last name: Doe
Email: jdoe@umich.edu
Degree: PhD Biomedical Engineering
Current U-M Position: Assistant Professor and Director of Research, U-M College of Engineering

Study Coordinator/Project Manager
First name: Jane
Last name: Smith
Email: jsmith@umich.edu
Degree: PhD Social Psychology
Current U-M Position: Associate Professor, U-M Department of Sociology; Survey Manager, U-M Institute for Social Research

Research Staff
First name: Tom
Last name: Brown
Email: brownt@umich.edu
Degree: MA
Current U-M Position: Doctoral Student/Candidate, U-M Department of Sociology

Research Staff
First name: Sara
Last name: Wilson
Email: wilsons@harvard.edu
Degree: PhD
Current Position: Biostatistician and Data Manager, Harvard University Department of Sociology

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