HUMAN RESEARCH PROTECTION PROGRAM
UNIVERSITY OF MICHIGAN

***PIs must submit CoC application materials to the U-M HRPP
prior to submitting to the NIH***

Actions to Complete Prior to Submitting to the U-M HRPP

1. Include the required or optional IRBMED or IRB-HSBS CoC text in 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.

Submitting to the U-M HRPP

1. Prepare the following materials and SCAN AS <u>ONE DOCUMENT</u>:
   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. 5-6)
      Typically, the key personnel listing should be consistent with the individuals appearing on the eResearch application who will have substantive interaction with human subjects. 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):

   > This is a CoC application for [name of PI].
   > The study is a [single site/multi-site] project.
   > The person to contact with any questions is [name].
   > The PI confirms that no application has yet been submitted to the NIH.

   Attach the <u>single</u> scanned document (item 1) 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.

v.03 March 2024

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.***

Submitting your NIH CoC Application

The new NIH 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. Therefore, PIs want to 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.

After receiving the go-ahead from the HRPP, you will create your application in the NIH system. The application is relatively short and most of the information you will provide is straight-forward and brief. However, it is important that you complete the following items as described:

ITEM 1 – Select Funding Source(s) / Select Federal Agency
If you have no funding at all, select No Federal Funding
Do NOT use the Online Certificate of Confidentiality System if your research is funded by the NIH

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 – Institution Address
North Campus Research Complex 2800
Plymouth Rd, Bldg 520, Rm 2170

Ann Arbor
USA
Michigan
48109

ITEM 13 – Name of Institutional Official
Sana Shakour, Ph.D., Associate HRPP Director

ITEM 14: sanashak@umich.edu

ITEM 15: 734-936-6288

ITEM 16: University of Michigan

ITEM 17: Provide your address (or other U-M address), as applies

ITEM 23 – Other Person to Receive CoC Communications and Certificate
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.

Confirmation Process

Upon submission of your NIH CoC application, the U-M Delegate 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 Confirmation has been Issued

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, you must do the following:

- Send an email to hrppcocgroup@umich.edu to alert us that you have received the CoC. We will add your information to the HRPP CoC database.
- Upload a copy of the CoC to section 11-2 of your eResearch application and submit the change to the IRB – this may require an amendment. Once you have completed this step, the IRB will issue full approval for your application and you may begin your research.

You have a CoC – *Now What? Stay Compliant!*

- ***For researchers that obtain a CoC via direct application to the NIH:*** The CoC is "active" as long as you are enrolling or collecting identifiable data or biospecimens from participants. You no longer have to apply for a new CoC based on an expiration date stipulated by the NIH.

  However, if you reach the data analysis stage and then later propose to enroll more subjects or collect new data, a new CoC may be required. Contact the U-M HRPP CoC Coordinator to discuss this further.

- ***For researchers that have a CoC via NIH (or other CoC-granting agency) funding:*** Researchers who are still enrolling or collecting identifiable data or biospecimens from participants must plan to apply for a CoC should your funding expire and no new funding is expected.

  The U-M HRPP will send a reminder 3 months prior to the funding expiration date to allow

adequate time to apply to the NIH for a new CoC, should one be necessary. The notice is copied to the IRB since a failure to maintain an active CoC may pose increased risk to participants and result in a compliance issue.

You will follow the same application process that is outlined in this document.

- ***For all researchers holding a CoC:*** Although your CoC protects the data in perpetuity,the risk to subjects may be elevated if you do not maintain an appropriately active CoC. Plan ahead and stay in contact with your IRB or the CoC Coordinator for guidance.

Changes that could affect your CoC – *Stay Compliant!*

Please contact the U-M HRPP CoC Coordinator if:

- You become the direct or sub-recipient of an NIH, CDC, FDA, SAMHSA, or HRSA grant for a project that was issued a CoC by direct application.

  These grants come with a CoC as a term and condition of the award, or require that you applyto the agency for a CoC. The CoC Coordinator can guide you in next appropriate steps and help ensure that you remain compliant with institutional and IRB requirements.

- The PI leaves the U-M and the research will continue at U-M.

  A new CoC will be required under the new U-M PI's name. The departing PI must obtain their own new CoC through their institution if the research will be on-going at the new institution.

KEY PERSONNEL LISTING INSTRUCTION PAGE

**Instructions – Please read and contact Mary Donnelly, U-M HRPP CoC Coordinator
(hrppcocgroup@umich.edu) if you have any questions:**

1. The information you list should be consistent with what is listed in the eResearch application for the study team and only as it relates to current U-M faculty/staff/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 for 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 Delegate Institutional Official's (DIO) discretion.***

3. Refer to page 2 for a sample listing. 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 eResearch application. 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 PositionTitle]*

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

v.03 March 2024

HUMAN RESEARCH PROTECTION PROGRAM
UNIVERSITY OF MICHIGAN

KEY PERSONNEL LISTING

PI
First name:
Last name:
Phone:
Email:
Degree:
Current U-M Position:

Co-I
First name:
Last name:
Email:
Degree:
Current U-M Position:

Study Coordinator/Project Manager
First name:
Last name:
Email:
Degree:
Current U-M Position:

Research Staff
First name:
Last name:
Email:
Degree:
Current U-M Position:

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