Document Title: Managing Engaged External Collaborators

A. Introduction

This guidance is intended to help the research community recognize when external collaborating study team members are conducting Human Subjects Research, how the external collaborator(s) should be managed in the IRB application, and how to make a formal request for U-M to be the IRB of Record for the external collaborator(s). For the purpose of this guidance the Institution is applying the Engagement of Institutions in Human Subjects Research (2008) guidance to the assessment of individuals as well. This guidance document has been prepared jointly by the IRB-HSBS and IRBMED to summarize harmonized procedures established between the two departments.

For the purpose of this document, both IRBs are referred to as University of Michigan IRBs [U-M IRBs].

Definition of External Collaborator: Study team member(s) who are not affiliated with U-M but are conducting U-M human subject research.

Special Note: Generally, Active Emeritus Faculty, Adjunct Faculty, Visiting Faculty, Visiting Scholars, Visiting Graduate Students, International Visiting Scholars and Volunteers vetted through Volunteer services, count as affiliated with U-M during the term of their sponsorship/appointment. These individuals are to still be listed as "other" on the application but require no IRB agreement. Contact your IRB office for confirmation.

External collaborating study team members who are engaged in U-M's research must have IRB oversight, either via an IRB agreement or via IRB approval from their own institution. If the external collaborator's human subject research activity is already covered by another IRB approval, there is no need to list them in the U-M IRB application.

IRB Agreement types

IRB Authorization Agreement (IAA) – an agreement between U-M and another institution that holds an FWA.
Individual Investigator Agreement (IIA) – an agreement between U-M and an individual collaborator who is not affiliated with an FWA institution.
Collaborating Institutional Agreement (CIA) – an agreement between U-M and an institution/organization that does not have an FWA.

Non-Exempt Research

Is your collaborator performing any of the following activities:	● Obtaining informed consent, ● Interacting with subjects, ● Conducting study-specific intervention, or ● Accessing, using, obtaining identifiable data (including coded data with access to link) - NOTE: Before moving to the steps below, if the collaborator is only partaking in activities associated with identifiable data, could those activities be completed without access to the identifiers? If Yes - then share only de-identified data.
If "**No**":	Your collaborator(s) is **_not engaged_**. Don't list them on the study team and an IRB agreement isn't necessary. ● Please note, an UFA/DUA may be required for data access or sharing unless it is covered by a subcontract with the external institution. Please contact ORSP and Data Office (IRBMED studies only) with questions on a DUA.
If "**Yes**":	Your collaborator(s) **_is engaged_**. *The steps below must be taken by the U-M study team and the collaborator must also reach out to their local IRB to find out local requirements.* 1. If the external collaborator will recruit and/or consent subjects **at their own site**, and they will use **site-specific materials**, contact the U-M IRB office before moving forward.

Agreement Request:

2. Submit a request in MiCores to initiate the IRB agreement process (see pages 3-5)
    a. If the PI is a student, the request should be made in the FA's name
    b. See the "About our core" page in MiCore for information on what request form to submit.
    c. These requests can run parallel to your IRB application review, but it is ideal to wait for sIRB staff to confirm via review of the request that the external collaborator is engaged in research and that U-M is willing to provide IRB oversight before moving forward with the eResearch steps.

eResearch Steps:

3. List collaborator on the study team as **"other"**
    a. They will need to obtain a Friends Account (if they do not have an active level-1 login)
    b. Current CV must be provided
    c. If there is more than one collaborator from the same external institution, list only the lead person* as "other".
4. Documented human subjects research training –
    a. If affiliated with an institution that has an IRB, their institution is responsible for tracking their education – PEERRS is not required to be answered as "yes".
    b. If affiliated with an institution that does not have an IRB. The PEERRS answer must be answered as "yes". If not using PEERRS, documentation of their equivalent training must be submitted as outlined on the PEERRS website.
5. List the external institution in 3-1 (Performance Sites) – not applicable for collaborators not affiliated with an institution.
6. Describe their role in Section 05 Study Team Expertise, add a heading "EXTERNAL STUDY TEAM MEMBERS" (specifically how are they engaged – obtaining consent, interacting with participants, or using identifiable data)
7. When applicable, external collaborator and/or their institution's role in the research and/or access to data should be described in the consent form, including their retention and future use of data. For IRBMED, in most scenarios the IRBMED standard informed consent template already covers this requirement.
8. If the external collaborator will access or obtain identifiable information as part of this research, the procedures for this must be included in Section 11 or in the Data Management Plan. Please note, an UFA/DUA may be required for data access or sharing unless it is covered by a subcontract with the external institution. Please contact ORSP and Data Office (IRBMED studies only) with questions on a DUA.

Engaged collaborators may not begin research activities until the IRB review and agreement are complete

Exempt Research

- Generally, we do not execute agreements with external collaborators on exempt studies
- External collaborators from other academic or other institutions **with IRBs** *do not* get listed on our application but their role should be described in Question 1.8 Project Summary. They must get an exemption or other determination from their own IRB.
- Engaged, external collaborators *without an IRB*:
    o If the collaborator is an individual not affiliated with an organization - list as "other" in the application. This individual will also need to satisfy research training requirements with either PEERRS or study-specific training depending on the nature of the project/partners.
    o If the collaborator is affiliated with an organization/company/community group - list only the lead at the organization as "other". Research training requirements will still need to be satisfied for **all** collaborators*.
    o The role of the external collaborator should be described in Question 1.8 "Project Summary".

The PI and site lead are responsible for tracking the other engaged individuals and ensuring that they are trained using either PEERRS or study specific training

RESOURCES:

- U-M Human Research Protection Program
  - o Operations Manual Part 5
  - o Authorization Agreements Process
  - o Single IRB-of-Record (sIRB) Process
- OHRP regulations 45CFR46.109(a) and (d)).
- OHRP guidance "Engagement of Institutions in Human Subjects Research (2008)"
- OHRP guidance "Extending an FWA to Cover Collaborating Investigators (2005)"
- FDA guidance "IRB Responsibilities for Reviewing the Qualifications of Investigators,…. (2013)"
- ITS eResearch Regulatory Management Training Resources and Reference Materials
  - o "Adding a Study Team Member"
  - o "Obtaining a Friends Account"
- Engaged Collaborator Tracking Sheet.
- MiCores Request – Key Information: See pages 4-5

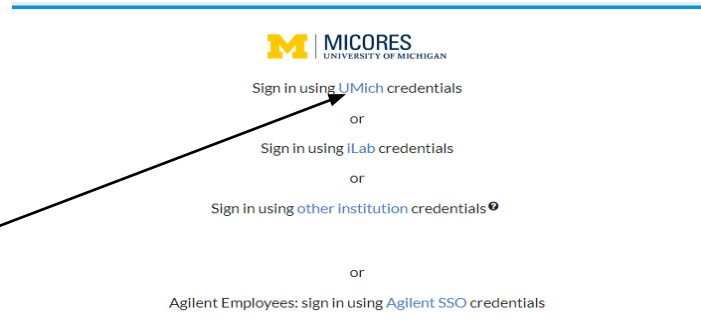| File Name: CSP_PG.202_Managing.Engaged.Ext.Coll_2023_June	Target Audience: Research Community
Author/Responsible Unit: Coordinated Services and Practices (CSP) unit	Date Released: 03.01.2024
Date Modified: 4.17.2024	

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MiCores Request – Key Information

⚠ **Requests must be initiated by a U-M member of the study team**

⚠ **If the PI is a student, the request must be made in the name of the faculty advisor (FA) –** see step 1 under Starting the Form

⚠ **If the PI/FA does not have an account in MiCores, please contact** ilab-support@agilent.com

1. Start the request here:

   https://umich.corefacilities.org/service_center/show_external/5567/umich_irbmed

2. Click on the **blue Sign In button**

MICORES
UNIVERSITY OF MICHIGAN

Sign in using UMich credentials
or
Sign in using iLab credentials
or
Sign in using other institution credentials ❓
or
Agilent Employees: sign in using Agilent SSO credentials

• Click the "UMich" link and you will be asked to log in with your unique name and Level-1 (Kerberos) password

If you use this link you should find yourself on the UMICH Single IRB Review page. If not, click on the

menu ☰ *icon; select Core Facilities, then UMICH Single IRB Review*
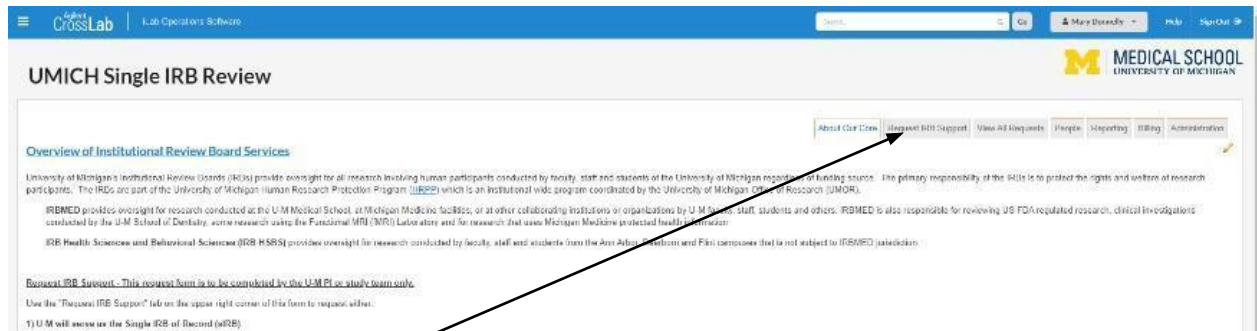
3. Select "**Request IRB Support**"

4. Select "Initiate Request" next to the appropriate form – more details about the forms and their purposes are available on the "About our core" page.

External Collaborator Support (IRB Authorization Agreement: IAA) (Ext. Coll IAA)   ➡ initiate request

External Collaborator Support (Individual Investigator Agreement (IIA) or Collaborating Institution Agreement (CIA)) (Ext. Coll IIA/CIA)   ➡ initiate request

Contact for help:

    IRBMED - Nicole Robson (niduffy@med.umich.edu)

File Name: CSP_PG.202_Managing.Engaged.Ext.Coll_2023_June	Target Audience: Research Community
Author/Responsible Unit: Coordinated Services and Practices (CSP) unit	Date Released: 03.01.2024
Date Modified: 4.17.2024	

5. Search for the PI/FA's name here

If you can't find their name, **stop, and contact** iLab-support@agilent.com.
They will help you either find the account or create a new one.

- Once you find their name, click [→ Proceed] and you will be taken to the form.

6. Here is an example of the form:

7. If the PI is a student (and the form was initiated under the FA's name), you can put the student PI's name/info in Q 2.

8. If you have external collaborators from multiple institutions engaged in your research, you can add more by selecting "yes" here.

9. Once you are finished filling out the form, hit "submit" and the request will route to the IRB staff.