

## External Collaborator Statement of Practice

---

**External Collaborator:** Study team member(s) who are not affiliated with University of Michigan (U-M) but are conducting non-exempt human subject research on behalf of the U-M. Their institution or organization is not otherwise a performance site.

### I. Statement

Institutional Review Boards (IRB) have a role in assessing an investigator's (or, a study team member's) qualification in conducting the human subject research activities proposed in a protocol or an IRB application. U-M IRB review and approval process includes evaluating study team members' qualifications and appropriate U-M affiliation(s). For study team members that are not affiliated with U-M, appropriate IRB oversight must be established prior to conducting any human subject research activities. The U-M IRB may choose to extend its oversight to study team members not otherwise affiliated with an institution having an IRB or whose institution is not otherwise a performance site in the research.

### II. Human Subjects Research Engagement

External collaborators are [engaged](#) in U-M Human Subjects research if the collaborator(s) are participating in one or more of the following research activities.

- Obtaining informed consent,
- Interacting with subjects,
- Conducting study-specific intervention, or
- Accessing, using, obtaining identifiable data (including coded data with access to link)

### III. IRB Application Requirements

External collaborator(s) are only added to the local study team on the IRB application if the external collaborator(s) are engaged and U-M is providing IRB oversight of the research activities that the collaborator(s) are performing.

Name: CSP_SP.202.00_External.Collaborator_2024.01.24	Target Audience: Research Community
Author/Responsible Unit: Coordinated Services and Practices	Date Released: 1.24.2024
Date Modified: N/A	

For more information and guidance, see [Managing Engaged External Collaborators](#).

In the event that an External Collaborator(s) that is not categorized as engaged in Human Subjects Research is added to the IRB application, these collaborator(s) should be removed. This change will not be applied to applications that were previously approved before the effective date.

#### **IV. Resources**

- [Managing Engaged External Collaborators Guidance](#)
- U-M [Human Research Protection Program](#)
  - [Operations Manual Part 5](#)
  - [Authorization Agreements Process](#)

Name: CSP_SP.202.00_External.Collaborator_2024.01.24	Target Audience: Research Community
Author/Responsible Unit: Coordinated Services and Practices	Date Released: 1.24.2024
Date Modified: N/A	