

Policy on IBC Applications for Managed Cores serving Researchers at U-M

Approved at the 5/17/19 IBC meeting.

Effective date: January 1, 2020.

Definition

For the purpose of this policy, a “managed research core” is defined as:

- A fee-for-service staffed facility at U-M supporting basic or clinical research (e.g., the Vector Core, cores listed on [MiCores](#)), or a
- A U-M space in which specialty equipment or services are offered in support of basic or clinical research and which is under the responsibility of a specific PI or program
 - May or may not be staffed, but an individual is taking responsibility
 - May or may not charge fees for services

Applicability

This policy applies to cores that 1) meet the above definition, **and** 2) where personnel of the core directly handle one or more of the following for the purpose of basic or clinical research (i.e., not patient care):

- Recombinant or synthetic nucleic acid molecules;
- Infectious agents, e.g., Bacteria, Viruses, Parasitic or Fungal agents, Prions;
- Biological toxins;
- Human-derived substances;
- Certain animal-derived substances, i.e., from non-human primates, ruminants, swine, chickens/fowl, wild vertebrate animals;
- Transgenic animals (vertebrate or invertebrate); or
- Administration of the above biological substances to animals.

Purpose

To ensure the personnel of managed research cores are fully prepared for safe handling of potentially hazardous biological materials within the core.

Policy

- 1) Managed research cores that conduct work requiring BSL2 containment are subject to EHS-Biosafety requirements for laboratory inspections and training.
- 2) Managed research cores that **handle biological substances subject to IBC approval** must complete an IBC Application regarding the work that occurs in the core with those biological substances.

Best practice:

- IBC Applications for managed research cores should be completed under the name of the staff person who serves as the manager of the core.
 - The faculty member serving as director of the core should be listed as a co-PI. This will allow the faculty member to maintain a separate IBC Application for their own research.
- 3) In addition to having an IBC Application for the work in the core itself, managed research cores should request verification of a **basic research** PI’s IBC Application if the core:
 - Accepts from PIs biological substances subject to IBC approval for processing, analysis, or other work, or
 - Provides to PIs biological substances subject to IBC approval for use in their own laboratory.

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Guidance on completing the IBC Application for a managed research core

- The faculty director/leadership of a managed research core should maintain their own separate IBC application for their own research projects.
- The core manager (e.g., someone in a staff position) should be listed as “Principal Investigator” on the IBC application.
- The faculty director of the core should be listed as “Co-Principal Investigator” in the Lab Personnel and Lab Spaces section.
- If the core has multiple locations, include all of these in the Lab Spaces section.
- In the Research Goals text box (included under each type of work selected), clearly state the **name of the core** for which the IBC application is being completed. This will allow the IBC to identify this as a managed research core application.
- Answer IBC application questions about the work conducted in the core as completely as possible considering the different types of samples likely to be received and handled.

This policy will be reviewed by the IBC every three years.
Initial approval: 5/17/19. Reviewed: _____