IBC Core Facility Guidelines

(Adopted 5/27/10 -- Updated 8/13/2013)

Core Facilities are designed to consolidate expensive technologies, provide access to state-of-the-art tools for research, coordinate shared resources, and expand the base of sponsored research by providing a strong research infrastructure that would be otherwise cost prohibitive to duplicate in multiple, individual laboratories. Research Resources' Core Facilities are affiliated with the Office of Research to develop policy and strategic direction. Core Facilities are accessible to all investigators at the University. Some facilities are accessible to researchers outside the University at fee levels equal to full costs of analyses.

The MU Institutional Biosafety Committee (IBC) and the Office of Research worked together to establish clear guidance for MU Core Facilities. Some Core Facilities require MU IBC review because biological material being used on their premises and because of potential exposure of staff and others to biohazardous material during laboratory procedures. The Core Facility Director must contact the MU Biosafety Office with information about the Core Facility to assist in determining if the facility requires completion of an IBC protocol document. A document meant to provide a standard format to submit information on planned core facility activities/services to allow the MU Biosafety Professional a method to assess if a Core Facilities activities/services will require MU IBC review and approval is the MU IBC Core Facility Review. The Core Facility Principal Investigator can complete the MU IBC Core Facility Review and send the completed document to the MU IBC at biosafety@missouri.edu. If you have questions about the guidance document or review document, contact the MU Biosafety staff at 882-7018.

Facilities that will require IBC review include (but are not limited to) the following:

- research involving work with or storage of recombinant or synthetic nucleic acid molecules, bacteria, toxins , human blood, tissue, or cell lines.
- generation of transgenic animals or plants
- material containing Lentiviral or Retroviral systems
- nature of materials on their premise

The MU IBC has identified five areas of focus regarding research conducted in MU Core Facilities:

1. appropriate training of core personnel
2. core staff should have information on type of sample and hazards associated with its use
3. biosafety inspection
4. database management and upgrade of record keeping
5. generation of transgenic animals or plants

<u>Training personnel</u>

- All core staff and users must complete MU Biosafety Training (EHS201 & EHS202), MU Bloodborne Pathogen (EHS220) training (if applicable), or other approved training course(s).
- If hazardous chemicals are used in the core, staff and users must also complete MU Chemical Safety for Laboratory Workers (EHS301-EHS305) training, or other approved training course.
- If research in the core involves a radioactive isotope, the Core Director must contact the MU EHS Radiation Safety Office to assure the Core Facility and equipment may be used for testing material containing radioactive isotopes. Equipment containing Class II or IV lasers must also be approved for use by the Manager of the MU Laboratory Safety Program.
- Training core staff and users on specialized pieces of equipment.

Knowledge of Material/Hazards

- The Core Director/Manager must document an initial interview with the Principal Investigator/staff planning to use the Core Facility. During this interview the Core Director/Manager will gain an understanding of the material the researcher and/or his/her staff will bring into the Core Facility. Additional contacts between the Core Director and Principal Investigator are necessary if changes in the type of testing material or assays are planned. Special attention must be given to the type of laboratory procedure performed and the type of material: to assess risk of aerosolization, required PPE, and transportation requirements for the material to and from the Core Facility.

Biosafety Inspection

- MU Biosafety staff will conduct an initial and periodic inspections of the core facility. Biosafety staff will review the material/hazards in the core facility, laboratory manipulations, assign a biosafety level, and use the *Biosafety in Microbiological in Biomedical Laboratories 5th Edition* to assess laboratory requirements. During these inspections the facility physical barriers, laboratory equipment, laboratory procedures, personal protective equipment, storage, and standard operating procedures for the lab will be assessed.

Database management and record keeping

- The Core Facility must maintain detailed records of all materials received that are used in protocols requiring review and approval according to *NIH Guidelines*. In addition, maintain detailed records of all materials received from outside core users. If possible, IBC protocol approval identification numbers should be included in these records.

- The Core Facility must maintain an auditable database of samples received and processed.
- MU researchers must list Core Facilities they intend to use on IBC protocol applications.
- The IBC will assign a specific ID number to each MU Core Facility and include the information in its protocol database to allow for quick retrieval of Core Facility information.

Generation of Transgenic Animals (Requires IBC application)

- NIH guideline Section III-E-3 "covers experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic rodents). Only experiments that require BL1 containment are covered under this section."
- NIH guidelines Section III-D-4-a covers experiments involving the creation of transgenic animals other than rodents "Recombinant or synthetic nucleic acid molecules, or DNA or RNA molecules derived thereform, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BL1 or BL1-N and appropriate to the organism under study."

Generation of Transgenic Plants (Requires IBC application)

- NIH guidelines Section III-E-2 covers "Experiments involving nucleic acid molecule-modified whole plants, and/or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants, except for those that fall under Section III-A, III-B, III-D, or III-F. It should be emphasized that knowledge of the organisms and judgment based on

accepted scientific practices should be used in all cases in selecting the appropriate level of containment."

The IBC views Core Facility Directors as the Principal Investigator for the facility with primary responsibility for a Core Facility's operation, staff, and equipment. If an IBC application is required, the Core Facility Director will be asked to sign the final page of the IBC application document's "Statement of Agreement". The "Statement of Agreement" can be viewed at the end of the IBC application form at: http://ehs.missouri.edu/files/doc/bio-material.doc .

Additional Information

- Contact the Office of Research for guidance on:
- MU Core Facility requirements
- Contract assistance
- Guidance concerning billing procedures
- Assistance with liability rules for non-MU or MU researchers/staff

NOTE: Non-MU researchers using the Core Facility may be required to obtain courtesy appointments if their use of the facility will involve multiple visits.