Requirements for Biomaker Spaces

Scope/Summary: This policy outlines the requirements for the establishment and operation of a biomaker space at MIT.

Background: The CAB/ESCRO is responsible for establishing policies that promote the safe and responsible conduct of biological research at MIT. The CAB/ESCRO reviews all procedures using biological materials to ensure safe practices and procedures, use of an appropriate laboratory space, and that the risks inherent in the proposed laboratory projects do not exceed the research experience and expertise of the participants.

I. Establishing a new biomaker space:

- To create a new biomaker space at MIT, a DLC or group of DLCs must first sponsor the biomaker space.
- A Principal Investigator must be designated for the space and assumes responsibility for the activities and personnel/participants of the biomaker space.
- A biological research registration (BRR) must be submitted to the MIT EHS Biosafety Program, reviewed and approved by the CAB/ESCRO.

II. Access to the biomaker space:

- The Principal Investigator is responsible for everyone in the biomaker space.
- Access to the biomaker space is restricted and controlled. The laboratory must be locked when not occupied.
- Only approved individuals who have completed all the established prerequisites may enter and work in the biomaker space.
- Work in the biomaker space must be supervised at all time by project supervisors.
- Defined hours of operation, and if relevant, the process for access after-hours should be listed in the biological research registration.

III. Project supervisors:

- Supervisors must be clearly defined in the biological research registration and the Principal Investigator is responsible for ensuring that supervisors are proficient in the techniques used in the biomaker space.
- Supervisors must complete the EHS trainings required for all approved projects.
- Supervisors should undergo a training/verification period to ensure they are familiar with experimental procedures as well as emergency response procedures.
- Approved supervisors should be experienced graduate students, postdocs, teaching instructors or Principal Investigators. Undergraduate students with exceptional experience and qualifications can serve as supervisors.

IV. Biomaker space participants:

- Participants must complete all the required EHS trainings, laboratory specific trainings, and department clearance prior to entering the biomaker space. Supervisors and ultimately the Principal Investigator are responsible for ensuring that training records are up-to-date.
- Usage of the MIT biomaker spaces is limited to the MIT community. DLCs may add additional restrictions for participation.
- Participants are required to affiliate with the responsible Principal Investigator in the MIT Learning Center.
- New participants should undergo a training/verification period to learn relevant techniques and achieve proficiency. Supervisors and the Principal Investigator should have a process in place to determine whether participants have the basic skills required to work safely in the biomaker space. Equipment specific and technical training may be required before granting access to participants. Internal trainings and clearance should be documented.

V. Inventory of materials and procedures:

- Lists of available material (i.e. plasmids, cells, microorganisms) must be available and kept current in the biological research registration and in the laboratory.
- The list of projects and procedures approved in the biological research registration should be available in the biomaker space.

VI. Summary of the biological research registration process:

- Work requiring BL2+ containment is not allowed in a biomaker space. Only experiments that can be safely performed at BL1 or BL2 can be approved.
- New biological research registrations need to receive the approval of the CAB/ESCRO before initiating any work.
- Only projects listed in the approved biological research registration can be performed.
- Biological research registrations can be amended to add new experiments or biological materials. Projects described in amendments can't start before receiving written approval on behalf of the CAB/ESCRO.
- Amendments that fall **outside** the purview of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) or that fall under section IIIE or IIIF of the NIH Guidelines, may be given administrative approval at the discretion of the Institutional Biosafety Officer. All amendments that fall under section III-A, B, C, or D of the NIH Guidelines cannot be administratively approved and must wait for the next duly constituted CAB/ESCRO meeting for approval prior to initiation of the work outlined in the amendment. All administratively approved amendments are reviewed at the next CAB/ESCRO meeting. If any questions or concerns arise at that time, the PI must respond to all committee concerns.
- For more information on the biological research registration process, please contact the MIT Biosafety Program.

Revision History:

Approved 6/22/2017