Title/Subject: **INSTITUTIONAL BIOSAFETY PROGRAM**

Applies to: ☒ faculty ☒ staff ☒ students ☒ student employees ☒ visitors ☒ contractors

Effective Date of This Revision: August 28, 2017

Contact for More Information: Office of Research Compliance

☐ Board Policy ☒ Administrative Policy ☒ Procedure ☐ Guideline

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BACKGROUND:

Central Michigan University (CMU) recognizes the importance of conducting a broad spectrum of original problem-solving activities that have the purposes of creating new knowledge and of designing new products and technologies. Cognizant that these activities may be accompanied by some risks, the university requires that activities covered by this policy be reviewed and only be conducted under the auspices of the Institutional Biosafety Committee (IBC).

PURPOSE:

This policy is established to ensure compliance with applicable federal and state laws and regulations, including the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), The Federal Select Agent Program (7 C.F.R. Part 331, 9 C.F.R. Part 21 and 42 C.F.R. part 73) and The United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and consistent with the guidance found in the Centers for Disease Control's Biosafety in Microbiological and Biomedical Laboratories (BMBL). Adherence to this policy shall not exempt the research from compliance with other applicable laws, regulations or policies (e.g., those governing research with human subjects or research with animals).

DEFINITIONS:

In the context of this policy, recombinant and/or synthetic nucleic acid molecules are defined as either:

1. molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate or are expressed in a living cell, i.e., recombinant nucleic acids;
2. nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
3. molecules that result from the replication of those described in (1) or (2) above.

Synthetic nucleic acid segments likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or pharmacologically active agent) shall be considered as equivalent to their natural counterpart. If the synthetic nucleic acid segment is not expressed or does not alter expression *in vivo* as a biologically active polynucleotide or polypeptide product, it is exempt from this policy.

Authority: Michael A. Gealt, Executive Vice President/Provost
History: None-New Policy
Indexed as: Biosafety; Research Compliance

Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to this policy unless the transposon itself contains recombinant DNA.

Select Agent:
Pursuant to 42 USC 262a and 7 USC 8401, select agents and toxins are a subset of biological agents and toxins that the Departments of Health and Human Services (HHS) and Agriculture (USDA) have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products. The current list of select agents and toxins can be found at 42 CFR §§ 73.3, 73.4, 9 CFR §§ 121.3, 121.4, and 7 CFR § 331.3.

Zoonotic:
Diseases and infections that are naturally transmitted between vertebrate animals and humans. A zoonotic agent may be a bacterium, a virus, a fungus or other communicable disease agent.

Pathogenic:
Causing or capable of causing disease.

Dual Use Research of Concern:
Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products or technology that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security.

POLICY:

This policy is applicable to all recombinant and/or synthetic nucleic acid molecule research which is conducted at or sponsored by or under the aegis of Central Michigan University. No activity involving the construction or handling of recombinant or synthetic nucleic acid molecules or organisms and viruses containing recombinant or synthetic nucleic acid molecules shall be initiated without prior notification, and if necessary review and approval, of the Institutional Biosafety Committee unless specifically exempt as described in Section E-6 of the NIH Guidelines.

In addition to recombinant or synthetic nucleic acid technology this policy extends similar oversight authority to the Institutional Biosafety Committee for research projects involving:

1. Agents infectious to humans and other animals;
2. Use of human tissues, fluids, or cell lines or primate tissues, fluids or cell lines;
3. Lab or field work on animals for which a documented and reasonable potential for transmission of zoonotic agents exists, e.g., wild-trapped rodents, birds, amphibians;
4. Lab or field work with the intent to isolate or culture pathogens;
5. Research on biological agents that produce harmful toxins, where there is significant potential for human exposure.
6. Research involving nanotechnology or other emerging technology that presents a potential hazard/biohazard.

PROCEDURE:

CMU's Vice President for Research will have overall responsibility under this Policy for the Institutional Biosafety Program. Those responsibilities are as follows:

1. Be responsible for establishing, implementing and compliance with all CMU Policies and all applicable regulations governing research with biohazards.
2. Provide support to the Institutional Biosafety Program within the means of CMU.

3. Establish a BSL3 subcommittee of the IBC to review proposals for research that would require the use of BSL3 containment facilities at CMU, including research with federally regulated select agents.
4. Designate the Responsible Official (who may also serve as the Biological Safety Officer) to serve on the BSL3 Subcommittee and have institutional responsibility to authorize and register, as appropriate with the Centers for Disease Control (CDC) and regulated Select Agents or other specifically designated agents, and to handle the transfer of such agents into and out of the University.
5. Be required to provide final explicit approval or disapproval, following BSL3 Subcommittee approval, to any investigator performing research with a Select Agent, for the commissioning of new BSL3 facilities, for the use of a Select Agent not previously existing on campus or for research assessed to have Dual Use Research of Concern potential.

In the performance of these duties, the Vice President for Research has the authority to delegate such activities as may be necessary in order to fulfill these duties.

To conduct its responsibility effectively, CMU maintains an Institutional Biosafety Committee (IBC) to review research protocols involving the biohazards specified in this policy. The IBC is an autonomous body established to ensure compliance with NIH guidelines and all other applicable federal state and local laws and regulations governing potentially biohazardous research conducted under CMU auspices.

Each Institutional Biosafety Committee is composed of a minimum of 5 voting members nominated by the Vice President for Research. : Three (or more) members of the university faculty and/or staff, at least two unaffiliated/non-university members (who may not be part of the immediate family of a person who is affiliated with Central Michigan University), and at least one person from the Office of Research Compliance who will serve as a non-voting member.

Official business of the IBC shall be conducted only when a quorum of the committee is present. A quorum shall consist of a majority of the members of the committee and will include at least one unaffiliated member.

CMU shall appoint a Biological Safety Officer who shall also be a member of the IBC if any investigator conducts research at Biosafety Level 3 or 4 (BSL3 or BSL4) as defined by the NIH Guidelines and BMBL, or engages in large scale (greater than 10 liters) research. The BSO will be a member of the BSL3 Subcommittee appointed by the Vice President for Research.

CMU shall appoint at least one individual with expertise in plant, plant pathogen, or plant pest containment principles, one animal containment expert and one expert in human gene transfer as appropriate.

The IBC has the following authority:

1. To approve, require modifications to secure approval, defer, or reject all research activities overseen and conducted by CMU, regardless of the location of these activities;

2. To suspend or terminate approval of research not being conducted in accordance with the IBC's requirements or that has been associated with unexpected serious harm or poses immediate threat of harm to the University community or the general public.

The BSL3 Subcommittee has the following authority:

1. To review proposals for research that would require the use of BSL3 containment facilities at CMU, including research with federally regulated select agents.

2. The BSL3 Subcommittee is further designated as the standing Institutional Review Entity required for identification and review of Dual Use Research of Concern, as specific in the US Government Policy on Oversight of Life Sciences Dual Use Research of Concern. Deans and department chairs in units hosting the research will be included in the review process.

All IBC-approved research studies are subject to ongoing IBC review, which must be conducted periodically. If IBC approval lapses, all research activity must stop. The IBC has jurisdiction over all biosafety research as described in this

policy and conducted under the auspices of CMU, regardless of funding source or performance site. Research conducted under the auspices of CMU includes research:

1. Conducted at CMU

2. Conducted by or under the direction of any CMU employee or agent (including students) in connection with his or her institutional responsibilities;

3. Conducted by or under the direction of any CMU employee or agent (including students) using any property or facility of CMU; or

4. Involving the use of any CMU non-public information.

No research involving potential biohazards may commence until all institutional approvals (including from the IBC) are obtained. CMU may review any research protocol and reserves the right to terminate the implementation of a research protocol that has been approved by the IBC, if in the opinion of CMU said research protocol would place the University or community at undue risk. CMU may not, however, approve the implementation of any research protocol that has been rejected by the IBC, nor may CMU override the decision of the IBC not to approve a research protocol.

The Vice President for Research and the IBC shall adopt a series of guidelines to implement this Policy. These Guidelines shall serve as the governing procedures for the conduct of CMU's Institutional Biosafety Program.