Name of Policy: Use of biohazardous materials, recombinant and synthetic nucleic acids, stem cells, and toxins in research. **Policy Number**: 3364-70-06 **Approving Officer**: President **Responsible Agent**: Vice President for Research **Scope**: All University of Toledo Campuses	**Review/revision date:** March 17, 2022 **Original effective date**: March 25, 2008

☐	New policy proposal	☒	Minor/technical revision of existing policy
☐	Major revision of existing policy	☐	Reaffirmation of existing policy

(A) Policy Statement

The University of Toledo (UToledo) assumes responsibility for reviewing research involving biohazardous or infectious materials, recombinant and synthetic nucleic acids, select agents and toxins, and stem cells. UToledo has a responsibility to comply with applicable state and federal laws and regulations, including the Department of Health and Human Services (HHS) select agent regulations (42 C.F.R. 73), the National Institutes of Health (NIH), National Research Council and Centers for Disease Control (CDC) guidelines (e.g. Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, the National Institutes of Health Guidelines on Human Stem Cell Research, Guidelines for Human Embryonic Stem Cell Research, Biosafety in Microbiological and Biomedical Laboratories, and United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern) and UT Policy 3364-70-29 (Dual Use Research of Concern) for microbiological practices, stem cell research, laboratory facilities, and safety equipment for select agents and toxins.

(B) Purpose of Policy

This policy summarizes UToledo requirements for conducting research involving the use of biohazardous or infectious materials, recombinant and synthetic nucleic acids, select agents and toxins, and stem cells conducted at the institution.

(C) Scope:

This policy applies to all UToledo faculty, students, and staff using recombinant and synthetic nucleic acids, biohazardous or infectious agents, select agents, and stem cells in research.

(D) Definitions

(1) Human Stem Cells (HSC): Cells characterized by the ability to renew themselves and develop into a diverse range of specialized cell types. For the purposes of this policy, human stem cells

include all derivations of human stem cell lines and all research using human stem cells.

(2) Human Stem Cell Research Oversight (HSCRO) Committee: An ad-hoc group of the IBC created pursuant to the recommendations in the Guidelines for Human Embryonic Stem Cell Research and the National Institutes of Health Guidelines on Human Stem Cell Research to initially and periodically review, recommend modifications, secure approval, or recommend disapproval of research involving the use of human stem cells.

(3) Institutional Biosafety Committee (IBC): A university committee responsible for review and approval of research involving recombinant and synthetic nucleic molecules and other forms of research that entail ethical concerns and/or biohazardous materials as determined by the university. Committee consists of no fewer than five members. It is required that two members not be affiliated with the university. Members and the chair of the IBC are appointed by the Vice President for Research.

(4) Institutional Official (IO): The individual who, as a representative of senior administration, bears ultimate responsibility for the Program, communication to the relevant federal funding and regulatory agencies (e.g., National Institutes of Health, Center for Disease Control, etc.) as necessary, and is responsible for resource planning and ensuring alignment of Program goals with the institution's mission. At UToledo the IO is the Vice President for Research (VPR) or his/her designee.

(5) Potential biohazard: Any agent that presents a risk or particular risk to the health of humans, animals, or the environment. Biological agents or other substances which could be biohazards include, but are not limited to, infectious or parasitic agents; non-infectious microorganisms such as some fungi and algae; human and animal cell lines; human tissues, fluids, and other products[1]; human cadavers; human stem cells; plant products, and animal tissues, fluids, and other products. Biological hazards are classified as:

Biosafety Level 1	Agents of no or minimal hazard to laboratory personnel and the environment.
Biosafety Level 2	Agents of moderate potential hazard to personnel and the environment.
Biosafety Level 3	Agents involving indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.
Biosafety Level 4	Agents involving dangerous and exotic agents which pose a high individual risk of life-threatening disease.

(6) Recombinant or Synthetic Nucleic Molecules (rsNA): Under the NIH Guidelines, these are molecules constructed outside of living cells by joining natural or synthetic nucleic acid segments to nucleic acid molecules that can replicate in a living cell, or molecules that result from their replication.

(7) Select agents or toxins: Agents that HHS and United States Department of Agriculture (USDA) consider to have the potential to pose a severe threat to human, animal or plant health. A list of these

[1] Human tissues, fluids, and other products (including blood, urine, saliva, fecal materials, etc.) are only included if they are taken to or analyzed in the research laboratory. Human tissues, fluids, and other products that are taken to and analyzed in the hospital clinic or pathology laboratory exclusively are not included.

agents may be found in the select agents' regulation (42 CFR 73). High consequence livestock pathogens and toxins are agents that the USDA considers to have the potential to pose a severe threat to animal or plant health or to animal or plant products. The plant pathogens listed by USDA have been deemed a threat to planthealth or products. Agents that pose a severe threat to animal health, animal products and also public health are referred to as "Overlap agents." These agents appear on both the HHS and USDA list of agents and toxins.

(E) IBC Authority

(1) The authority of and the requirement for the Institutional Biosafety Committee (IBC) are derived from the NIH Guidelines, Guidelines for Human Embryonic Stem Cell Research, the National Institutes of Health Guidelines on Human Stem Cell Research, policy 3364-70-29 (Dual Use Research of Concern) and this policy. The UToledo IBC has responsibility to establish and maintain a system for the control of biohazards and also to provide ethical review for research involving the use of recombinant and synthetic nucleic acid molecules, biological and infectious agents, gene therapy, select agents, and stem cells at the university.

(2) At its discretion, UToledo may choose to utilize an externally-managed IBC to provide local review and oversight of research involving biological materials (e.g., recombinant or synthetic nucleic acid molecules, biohazardous or infectious materials), select agents and toxins (e.g., carcinogens), human gene transfer, and stem cells.

(3) Research utilizing recombinant and synthetic nucleic acid technology, biohazardous or infectious materials, select agents and toxins, or stem cells may not be initiated until after IBC approval, or written confirmation of exempt status is obtained. When such agents are to be introduced into live vertebrate animals**,** final approval of the associated animal use by the applicable university institutional animal care and use committee (IACUC) will be contingent upon IBC approval of the associated protocol. When such agents are to be introduced into live humans, final approval of the associated human use by the applicable university institutional review board (IRB) will be contingent upon IBC approval of the associated protocol. Approval by the committee will be transmitted to the investigator in the form of a memorandum from the committee chair or the designee.

(F) IBC Roles and Responsibilities:

(1) To recommend to the Vice President for Research guidelines and procedures which provide for the safe conduct of research work involving recombinant and synthetic nucleic acid molecules, biohazardous materials, select agents, and/or toxins;

(2) To review and approve protocols involving the use of potentially biohazardous materials, recombinant and synthetic nucleic acid molecules, select agents and/or toxins at UToledo;

(3) To keep current with associated UToledo policies, and federal, state, and sponsor regulations andguidelines;

(4) To review incident reports regarding: exposures of individuals to or accidents involving recombinant or synthetic nucleic acid molecules and any non-compliance with IBC

requirements and determinations or the *NIH Guidelines*. Reports of such verified incidents will be reported to the Institutional Official and the NIH Office of Science Policy within 30 days, according to NIH regulation.

(5) To develop procedures for evaluating high risk operations involving biohazardous materials, recombinant and synthetic nucleic acid molecules, select agents and toxins;

(6) To appoint a liaison to the safety and health committee to maintain communication, and assist in laboratory inspection and certification;

(7) To serve as a resource to provide guidance to investigators using biohazardous materials, recombinant and synthetic nucleic acid molecules, and select agents and toxins.

(G) Responsibilities of the PI/PD

(1) Only university faculty may be a principal investigator (PI) on a UToledo IBC protocol. University-designated emeritus faculty may serve as PIs on IBC protocols, provided they hold less than a 50 percent appointment and/or employment with another (non-UToledo) institution or company. Any exceptions to the above criteria regarding the eligibility of an individual toserve as the PI of an IBC protocol must be approved by the IBC and Vice President for Research.

The PI must be in a position to provide direct, personal, day-to-day oversight of activities and personnel associated with the IBC protocol, and guide personnel in compliance with university research policies and IBC procedures, including potential risks associated with the research project.

(2) The PI/PD or a co-investigator on any research grant, agreement or contract requiring IBC approval must be the PI/PD on the protocol(s) supporting the work described in the research grant, agreement or contract. In the case of a Fellowship application, the faculty sponsor/mentor for the trainee applicant must be the PI on the regulatory IBC protocol(s) supporting the work described in the application, and the trainee applicant must be among the authorized personnel on the same regulatory protocol(s).

(3) To acquire knowledge and information needed to recognize and control biohazardous materials in the laboratory, prior to receiving biohazardous materials;

(4) To select and employ laboratory practices and engineering controls that reduce the exposure to biohazardous materials to the lowest practicable level;

(5) To obtain prior approval, when required, from the IBC to conduct a high-risk protocol or procedure involving biohazardous materials, recombinant and synthetic nucleic acid molecules, select agents and toxins;

(6) To adhere to IBC-approved research protocols involving the use of potentially biohazardous materials, recombinant and synthetic nucleic acid molecules, select agents and/or toxins;

(7) To inform all personnel for whom the investigator is responsible, of the hazards associated

with research involving the use of biohazardous agents, recombinant and synthetic nucleic acid molecules, and select agents and/or toxins; instruct them in the use of laboratory practices, engineering control, and procedures for safe handling and for dealing with accidents involving such materials;

(8) To supervise the safety performance of laboratory staff to ensure that the required laboratory practices and engineering controls are employed;

(9) To arrange for immediate medical attention and occurrence reporting of any incident that results in (a) inoculation of biohazardous materials, (b) ingestion of biohazardous materials, or (c) any incident resulting in overt exposure of personnel or danger of environmental contamination by biohazardous materials and immediately notify UToledo Environmental Health and Radiation Safety;

(10) To investigate and report protocol deviations and problems pertaining to operation and implementation of timely laboratory practices and engineering controls to the biosafety officer and IBC; in accordance with applicable policy, procedure, law, or regulation;

(11) To report any accidents or exposures involving recombinant or synthetic nucleic acid molecules to the Biosafety Officer in Environmental Health and Radiation Safety.

(H) Responsibilities of laboratory personnel, including students:

(1) Comply with safety guidelines, regulations, and procedures required for the task assigned;

(2) Report unsafe conditions to the principal investigator, immediate supervisor, or the department of environmental health and radiation safety;

(3) Report to the principal investigator or immediate supervisor all facts pertaining to accidents resulting in exposure to biohazardous materials.

(4) Have thoroughly read IBC-approved research protocol(s) related to their research activities and reviewed the protocol(s) with the PI.

Appendix

The NIH "Guidelines for research involving recombinant and synthetic nucleic acid Molecules" can be obtained at <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>.

Additional information regarding the process for applying for approval for research involving recombinant DNA and/or biohazardous materials and/or select agents/toxins may be obtained from the IBC office. The application form is available via the university research and sponsored programs web site < http://www.utoledo.edu/research/rsp/rc/biosafety.html>.

See also the following university policy and federal publications:

HHS "United States Government Policy for Institutional Oversight of Life Sciences DURC"\
http://phe.gov/s3/dualuse/Pages/InstitutionalOversight.aspx

HM-08-009	"Biohazardous Agents Standard (Universal) Precautions for Laboratories"
CDC/NIH	"Biosafety in Microbiological and Biomedical Laboratories," 5th edition, https://www.cdc.gov/labs/BMBL.html
CDC/USDA	https://www.selectagents.gov/SelectAgentsandToxinsList.html
NIH	"National Institutes of Health Guidelines for Human Stem Cell Research" https://stemcells.nih.gov/policy/2009-guidelines.htm
NRC	Guidelines for Human Embryonic Stem Cell Research (2005) https://www.nap.edu/read/11278/chapter/1

Approved by:

/s/_____
Gregory C. Postel, M.D.
President

March 17, 2022_____
Date

Review/Revision Completed by:
Institutional Biosafety Committee, SLT

Policies Superseded by This Policy:

- *03-006 Use of biohazardous materials and recombinant DNA in research (previous Health Science Campus policy, review date 07/01/03)*

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