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| **Name of Policy**: Use of biohazardous materials, recombinant DNA and select agents and toxin in research.<br><br>**Policy Number**: 3364-70-06<br><br>**Approving Officer**: President<br><br>**Responsible Agent**: Vice President for Research<br><br>**Scope**: All University of Toledo Campuses | **Review date:** August 19, 2011<br>**Effective date**: March 25, 2008 |

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

Special note: This policy governs laboratory-based research. Gene transfer research involving human subjects is the subject of very specific and very stringent federal regulations and review by a special NIH commission. University investigators contemplating gene transfer studies should consult with the university biomedical IRB office and the center for clinical research.

(A) Policy statement

The University of Toledo assumes responsibility for reviewing all proposed research involving recombinant DNA, biohazardous materials, and select agents and toxins conducted under the auspices of this institution. The University of Toledo is guided in that respect by the "Guidelines for Research Involving Recombinant DNA Molecules" (NIH Guidelines) effective June 4, 1994 (59 FR 34496), and the most recent amendments to these Guidelines (59 FR 40170, 60 FR 20726, 61 FR 1482 and 61 FR 10004). The institution is also guided by "Biosafety in Microbiological and Biomedical Laboratories," current edition, published by the Centers for Disease Control (CDC), the HHS select agent regulations (42 C.F.R. 73) and the NIH for recommended combinations of microbiological practices, laboratory facilities, and safety equipment for use in four categories or biosafety levels of laboratory operation with selected agents infectious to humans.

(1) The University of Toledo (UT) has established an institutional biosafety committee (IBC) appointed by the vice president for research to implement the policies and guidelines for research involving recombinant DNA molecules, biohazardous materials, and select agents and toxins.

(2) The University of Toledo filed an assurance with the NIH's office of biotechnology activities (OBA), stating that all research utilizing recombinant DNA molecules will be reviewed by the institutional biosafety committee and will be in compliance with the "Guidelines for Research Involving Recombinant DNA Molecules" (NIH Guidelines) effective June 4, 1994 (59 FR 34496), and the most recent amendments to these

guidelines, April 2002 (59 FR 40170, 60 FR 20726, 61 FR 1482 and 61 FR 10004). The purpose of these guidelines is to specify safe practices for constructing and handling recombinant DNA molecules, and organisms and viruses containing recombinant DNA molecules.

(3) The responsible party (i.e., principal investigator/program director (PI/PD)) for research submitted to the university IBC for approval must be a salaried university faculty member or other salaried university contract personnel. The PI/PD must be in a position to provide direct, personal, day-to-day oversight of activities and personnel associated with the biosafety protocol. Any exceptions to the above criteria regarding the eligibility of an individual to serve as the PI/PD of a biosafety protocol must be approved by the vice president for research.

(4) All research at the university which utilizes recombinant DNA technology must be reviewed by the IBC committee. If research is exempt according to the Guidelines, review by the full committee will not be required and a memorandum confirming the exempt status of the protocol will be provided to the investigator by the committee chair. The committee chair will determine if the experiments require IBC approval before initiation or if the experiments require IBC notification simultaneous with initiation. If review by the full institutional biosafety committee is required, the protocol will be reviewed at the next scheduled meeting of the committee, and all other approvals will be ratified by the full committee at the next scheduled. Research utilizing recombinant DNA technology may not be initiated until after institutional biosafety committee approval, or confirmation of exempt status is obtained. Approval by the committee will be transmitted to the investigator in the form of a memorandum from the committee chair or the designee.

(5) All research involving the use of potential biohazards must be submitted to the university IBC for review and approval. When such agents are to be introduced into live vertebrate animals**,** final approval of the associated animal use protocol by the applicable university institutional animal care and use committee (IACUC) will be contingent upon university IBC approval of the associated protocol for use of a biohazard.

A potential biohazard is defined as: “Any biological agent that has the capacity to produce deleterious effects upon other biological organisms, particularly humans. 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; plants and plant products, and animals and animal products which cause occupational disease." Biological hazards are classified as:

Class 1 Agents of no or minimal hazard to laboratory personnel and the environment.
Class 2 Agents of moderate potential hazard to personnel and the environment.

Class 3 Agents involving indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.

Class 4 Agents involving dangerous and exotic agents which pose a high individual risk of life-threatening disease.

Select agents or toxins are agents that HHS and USDA consider to have the potential to pose a severe threat to human, animal or plant health. A list of these agents may be found in the select agents regulation (42 CFR 73) or at <http://www.selectagents.gov/agentToxinList.htm>. 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 plant health or products. Agents that pose a severe threat to animal health, animal products and also public health are referred to as "Overlap agents." These agent appear on both the HHS and USDA list of agents and toxins. Effective October 20, 2005, all select agents are required to be registered with the UT biosafety officer and the IBC committee prior to receipt of the select agent in any quantity.

(B) Responsibilities of the IBC

The IBC is responsible for:

(1) Recommending to the vice president for research policies which provide for the safe conduct of research work involving recombinant DNA molecules, biohazardous materials, select agents, and/or toxins;

(2) Reviewing and approving research protocols involving recombinant DNA molecules, the use of potentially biohazardous materials, select agents and/or toxins on the premises of the University of Toledo;

(3) Identifying biohazardous materials used or proposed for use at the University of Toledo which may pose a risk;

(4) Identifying select agents used or proposed for use at the University of Toledo which may pose a risk;

(5) Developing and instituting procedures for approving high risk operations involving recombinant DNA molecules, biohazardous materials, select agents and toxins;

(6) Maintaining communication with the safety and health council by appointing a liaison to that council;

(7) Assisting the principal investigator in the selection of laboratory practices and engineering control, such as fume hoods, biological safety cabinets, or glove boxes;

(C) Responsibilities of the principal investigator/program director

The principal investigator/program director has the primary responsibility for:

(1) Acquiring the knowledge and information needed to recognize and control biohazardous materials in the laboratory;

(2) Selecting and employing laboratory practices and engineering controls that reduce the exposure to biohazardous materials to the lowest practicable level;

(3) Obtaining prior approval, when required, from the IBC to conduct a high-risk protocol or procedure involving recombinant DNA molecules, biohazardous materials, select agents and toxins;

(4) Informing those employees or students, for whom the investigator is responsible, of the hazards associated with research involving recombinant DNA molecules, and the use of biohazardous agents select agents and/or toxins instructing them in the use of laboratory practices, engineering control, and procedures for safe handling and for dealing with accidents involving biohazardous agents;

(5) Supervising the safety performance of his or her staff to ensure that the required laboratory practices and engineering controls are employed;

(6) Arranging 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;

(7) Assisting representatives of the university safety and health council accident investigation task force in investigating accidents;

(8) Investigating and reporting to the biosafety officer any problems pertaining to operation and implementation of laboratory practices and engineering controls.

(D) Responsibilities of employees/students

Each employee/student is responsible for:

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

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

(3) Reporting to the principal investigator or immediate supervisor all facts pertaining to every accident resulting in exposure or exposure to biohazardous materials.

The most up-to-date version of the NIH "Guidelines for research involving recombinant DNA 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 located in the health science campus research and sponsored programs office. The most current version of the application form is available via the university research and sponsored programs web site <http://www.utoledo.edu/research>. The most current version of the application must be used for all submissions.

See also the following university policy and federal publication***s***:

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| HM-08-021 | "Biohazardous Agents Standard (Universal) Precautions for Laboratories" |
| CDC/NIH | "Biosafety in Microbiological and Biomedical Laboratories," 5th edition, http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm |
| CDC/NIH | "Primary Containment for Biohazards" http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm |
| CDC/USDA | http://www.selectagents.gov/agentToxinList.htm |

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| Approved by:<br><br>/s/ laj<br>Lloyd A. Jacobs, MD<br>President<br><br>August 19, 2011<br>Date<br><br>Review/Revision Completed by:<br>Institutional Biosafety Committee | **Policies superseded by this policy:**<br>*03-006 Use of biohazardous materials and recombinant DNA in research (previous Health Science Campus policy, review date 07/01/03)*<br><br>Initial effective date: March 25, 2008<br>Review/Revision Date: August 19, 2011<br>Next review date: August 19, 2014 |