

Policy Institutional Biosafety Office of Research

Applies To

This Policy applies to all Ohio State University faculty and staff members and students who use potentially pathogenic agents/toxins and/or human tissue and body fluid in research, including recombinant DNA (rDNA), gene transfer, human stem cells and/or select agents.

Policy

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The Ohio State University is committed to the safe, legal, and ethical use of biologically-derived materials in research. This Policy describes the responsibilities of the university and individuals who engage in research activities involving recombinant DNA, gene transfer, human stem cells, biohazardous materials (e.g. potentially pathogenic substances/toxins, and/or human tissue and body fluid) and select agents, including the responsibility of the university and individuals to comply with the legal and ethical requirements for the responsible use of these agents.

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Definitions

Term	Definition
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 stem cell lines and all research using stem cells derived from 1) human blastocysts made for reproductive purposes and later obtained for research from in-vitro fertilization clinics; 2) human blastocysts made specifically for research using donated gametes; and/or 3) human blastocysts created for research using human somatic cell nuclear transfer (NT) into oocytes.
Human Stem Cell	An ad-hoc group of the IBC created pursuant to the recommendations in the National

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Research Oversight Committee (hSCRO)	Academy of Sciences Guidelines for Human Embryonic Stem Cell Research to initially and periodically review, recommend modifications, secure approval, or recommend disapproval of research involving the use of human stem cells.
Institutional Biosafety Committee (IBC)	A university committee created under the NIH Guidelines to review research involving recombinant DNA and other forms of research that entail ethical concerns and/or biohazardous materials as determined by the university.
Recombinant DNA molecules (rDNA)	Under the current NIH Guidelines, these are molecules constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from their replication.
Select Agents	A select agent is a biological agent or toxin that has the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. The National Select Agents Registry Program (NSAR) actively oversees the use of select agents and requires registration of facilities including universities, which possess, use or transfer biological agents and toxins.

Policy Details

I. IBC Authority

1. The authority of and the requirement for the Ohio State Institutional Biosafety Committee (IBC) are derived from the NIH Guidelines for Research Involving Recombinant DNA, the National Institutes of Health Guidelines on Human Stem Cell Research, and Chapter 4167 of the Ohio Revised Code, the Public Employees Risk Reduction Act. The Ohio State 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 rDNA, gene therapy, select agents, and human stem cells at the university.
2. Ohio State faculty, staff, students and the IBC shall comply with the authority and guidance from applicable State of Ohio and federal law, including the NIH Guidelines, the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, the Ohio Public Employee Risk Reduction Standards, the National Academy of Sciences (NAS) 2005 Guidelines for Human Embryonic Stem Cell Research, the 2007-2010 Amendments to the NAS Guidelines, and generally accepted good microbiological practices.
3. The Institutional Biosafety Officer (IBO) and the IBC are authorized to inspect research facilities, approve research practices and procedures, and to address any unresolved biosafety hazard.

II. IBC Responsibilities

The Institutional Biosafety Committee (IBC) is charged under federal guidelines and university policy with the oversight of all teaching and research activities involving rDNA, biohazards, human stem cells and gene transfer. On behalf of Ohio State, the IBC is responsible for the following:

1. Review rDNA, biohazard, gene transfer, select agent, and/or human stem cell research for compliance with all appropriate guidelines and regulations, and approve those research projects that are in conformity.
2. Keep abreast of mandated guidelines and other sources of good safety practices (GSPs).

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3. Establish laboratory compliance and inspection guidelines that facilitate documentation that the IBC has met Good Safety Procedure (GSP) requirements.
4. Publish the guidelines in the Ohio State Institutional Laboratory Biosafety Manual.
5. Make an independent assessment of the containment levels required for proposed research and of all the facilities, procedures and practices of the investigators proposing to carry out the research.
6. Set containment levels for research involving rDNA, gene transfer, and biohazards.
7. Initially and periodically inspect and certify that laboratory standards are being maintained.
8. Adopt emergency plans covering accidental spills and personnel contamination resulting from such research.
9. Report to the Vice President for Research and to the NIH Office of Biotechnology Activities (OBA) any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses.
10. Serve as a resource to and provide guidance for investigators who are conducting rDNA, biohazard, stem cell and gene transfer research and/or designing biosafety projects.
11. Make recommendations to the Office of Research and the appropriate colleges concerning biosafety issues.

III. IBC Membership and Governance

1. The IBC shall consist of a minimum of five (5) faculty, staff, and community representatives, which is consistent with NIH Guidelines, and additional members as may be required to meet university needs.
2. Committee members are appointed by the Ohio State Vice President for Research or the Vice President's designee. Composition of the IBC is consistent with recommendations found in the NIH Guidelines and National Academy of Sciences' Guidelines for Human Embryonic Stem Cell Research. The IBC membership provides subject matter expertise consistent with the nature and extent of the scientific research conducted at The Ohio State University.
3. The day-to-day work of the IBC shall be carried out by the full committee, the chair, the Institutional Biosafety Officer (IBO), and/or the Biosafety Coordinator.
4. To ensure that requisite expertise is available for protocol reviews, an alternating membership system will be employed (i.e., each IBC member shall have an alternate member with similar subject matter expertise). Alternate IBC members have equal status and responsibilities, will receive relevant materials on matters before the IBC, and may attend all IBC meetings. However, if both a primary member and their alternate are present, only one will count toward determining a quorum and only a single vote among the two may be contributed on any protocol or issue being acted upon by the IBC. In addition, Ad-Hoc IBC members may also be employed for some IBC protocol reviews, including human stem cell protocols, to provide the special expertise, e.g. medical and research ethics, for human stem cell protocol reviews.

5. An ad hoc advisory group of the IBC, the Human Stem Cell Research Oversight Committee (hSCRO), will consist of members with expertise in the following areas: medical ethicist, members with pertinent scientific and clinical expertise such as basic stem cell biology, developmental biology, or obstetrics and gynecology. The hSCRO will also have an unaffiliated community member selected by the Vice President for Research and a legal representative selected by the Ohio State University General Counsel. The hSCRO will review protocols involving human stem cells (hSC) that require full committee review as described in the [National Institutes of Health Guidelines on Human Stem Cell Research](#). Following review, the hSCRO shall provide a recommendation to the full IBC.

IV. Financial Conflict of Interest

1. An IBC member or consultant to the IBC is considered to have a conflicting interest when the member (or members of their immediate family (i.e., their spouse/partner or dependent children)) receives compensation for services or has a financial interest in the research sponsor, has intellectual property rights in commercial products used in the research, has an interest in competing research, or is competing directly for resources (e.g., funding or sponsorship), which would reasonably appear to be affected by the outcome of the proposed research.
2. IBC members are required to complete an Ohio State Financial Conflict of Interest Screening/Disclosure when they are appointed to the Committee if a current disclosure is not already on file with the Office of Research Compliance. Members are required to update their COI disclosure annually and whenever there are changes in their (or their immediate family members') financial interests.
3. IBC members will examine the IBC protocol materials assigned to them upon receipt to identify any financial and/or non-financial conflicts of interests. Examples of non-financial conflicts of interest include reviewing or voting on a protocol when the IBC member, the member's immediate family, or a close personal friend is the protocol principal investigator (PI), co-investigator or study coordinator; or reviewing or voting on a protocol when the protocol's PI is the IBC member's supervisor. If a conflict exists, the member should immediately contact the IBC chair so that the review can be reassigned to another IBC member.
4. IBC members may contact the Conflict of Interest Administrator at the Office of Research Compliance, or appropriate IBC chair or vice chair for information or assistance with conflict of interest questions. The IBC chair or vice-chair will make the final determination about whether a conflict of interest exists as defined by this Policy.
5. In addition, faculty and staff should be aware that they are also subject to various provisions of Ohio law governing ethics and conflicts of interest in public employment.

V. Corrective Measures

Failure of researchers to follow the requirements of this Policy may result in personal civil and criminal liability under state and federal law and university disciplinary action under applicable faculty, staff or student policies. Disciplinary actions may include a loss or limitation of an investigator's privilege to use biologically-derived hazardous materials in research at the university.

Procedures

1. The full IBC shall physically meet at least once every three months. Members may participate by tele- or videoconferencing.
2. IBC protocols that require full committee review, such as rDNA protocols, will be reviewed at the next convened IBC meeting. Protocols will be made available approximately one week before the meeting. The IBC chair will assign a primary and secondary reviewer, but any committee member can provide comments. Administrative review for exempt rDNA, human source materials and exempt human stem cell will be conducted by the IBC chair or designee. All administrative reviews conducted will be noted in the minutes of the IBC.
3. Protocols limited to biohazards (i.e., no rDNA or no stem cells) may be reviewed by e-mail when a face-to-face meeting is not required under procedure section 2 above.
4. All meetings involving the discussions of rDNA must be open to the public; however, meetings involving the use of select agents will be closed to the public for security reasons.
5. All members will have access to the eProtocol system for review of protocols.
6. Members will be notified when a protocol is assigned to full committee review at least one week before the convened meeting. Members will be asked to provide comments at least 24 hours before the meeting.
7. The IBC chair will individually review replies and comments received from researchers in response to IBC requests for clarification of protocols, unless the committee determines at the convened meeting that responses need to be reviewed by additional IBC members.
8. All clarifications requested and any discussion concerning the use of rDNA, biohazards, gene transfer, or human stem cells will be recorded in the minutes.
9. hSCRO review of protocols involving hSCs involving full committee review will include the following:
 - a. At least one hSCRO member will be selected as a primary or secondary reviewer by the IBC chair.
 - b. hSCRO members will have voting rights only when a protocol involves hSC.
 - c. At least one member of the hSCRO will need to be present at the convened IBC meeting to provide information if needed.
 - d. Electronic review will be provided by a minimum of three hSCRO members.

Responsibilities

Position, or Office	List of Responsibilities
Institutional Biosafety Committee (IBC)	The IBC is responsible for providing oversight on all teaching and research activities involving rDNA, gene transfer, human stem cells, select agent, and/or biohazards at the Ohio State University.
Researchers and research staff	Responsible for using rDNA, gene transfer, human stem cells, select agent and/or biohazardous materials have primary responsibilities for: <ul style="list-style-type: none"> • Complying with all IBC and university policies and procedures • Ensuring the appropriate and ethical use of biohazardous substances
Office of Responsible Research Practices (ORRP)	Responsible for providing administrative support and professional expertise to the IBC and serving as a resource for investigators.
Principal Investigator (PI)	Responsible for the biosafety of co-investigators and research staff within their oversight; ethical use of human tissue, animals and the environment within their jurisdiction; setting a proper example by their own actions and to ensure compliance with this policy and the university's biosafety, gene transfer, select agent and stem cell research programs; promptly reporting biohazard incidents to the university Biological Safety Officer; assisting in any resulting decontamination efforts, investigations or reporting, which may be required; and attending any required biosafety, select agent or human stem cell research training sessions.
Chairs, Deans, Vice President for Research and the Provost	Responsible for enforcing faculty, staff and student compliance with this policy.

Resources

- [NIH Guidelines for Research Involving Recombinant DNA Molecules](#)
- [Institutional Laboratory Biosafety Manual](#)
- [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories](#) (current edition)
- [HHS and USDA Select Agents and Toxins List](#)
- [State of Ohio Public Employee Risk Reduction Standards](#)
- [National Academy of Sciences 2005 Guidelines for Human Embryonic Stem Cell Research and 2007-2010 Amendments](#)
- [National Institutes of Health Guidelines on Human Stem Cell Research](#)

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Contacts

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