



Human Gene Transfer Office of Research

Applies to: Faculty, staff, student employees, students, and volunteers involved in the design, conduct or reporting of human gene manipulation research.

POLICY *(required)*

Issued: 07/27/2005
Revised: 02/27/2009
Edited:
Reviewed:

This policy ensures that all research involving human gene manipulation at The Ohio State University (OSU) is in compliance with all State and Federal regulations and compliance standards developed by applicable OSU committees. This policy does not address non-human animal gene manipulation research.

Definitions

Term	Definition
Institutional Biosafety Committee (IBC)	The OSU Institutional Biosafety Committee has responsibility to provide public and occupational health review and approval of all human gene manipulation research studies at OSU.
Institutional Review Board (IRB)	The OSU Institutional Review Board has responsibility for review and approval of all human subject and human gene manipulation research studies at OSU.
Gene Manipulation Research	For the purpose of this policy, the term "human gene manipulation research" includes all experiments involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human research participants

Policy Details *(optional)*

- A. OSU Activities involving human gene manipulation research shall be in accordance with all applicable federal and state regulations.
- B. All human gene manipulation research must undergo the formal institutional review and approval process described in [Human Gene Transfer Research Institutional Review Process](#).
- C. Final institutional approval for all human gene manipulation research shall be provided by the Vice President, Office of Research.
- D. All gene manipulation research involving the use of human subjects shall require an IRB-approved individual consent form as well as a Health Insurance Portability and Accountability Act (HIPAA) individual authorization form signed by each subject.
- E. A faculty or staff researcher may not assume the role of Principal Investigator on a human gene manipulation research protocol funded by a company in which the faculty or staff member has a significant personal financial interest.
- F. Human gene manipulation research funded by third parties, or that involves the use of proprietary commercial agents, compounds, methods or materials may only be done as sponsored programs administered by the Ohio State University Research Foundation and shall require the submission of an approved "Authorization to Seek Off-Campus Funds" form (PA-005); or in cases that involve no external funding, through the execution of formal, written confidential disclosure or material transfer agreement(s) reviewed and approved by the OSU Technology, Licensing and Commercialization office (as applicable).
- G. All OSU activities involving human gene manipulation research shall comply with all applicable university policies and procedures, including but not limited to:



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- a. [Authorization to Seek Office-Campus Funding](#)
- b. [Financial Conflict of Interest Policy for Faculty](#)
- c. [Rules Governing Faculty and Staff Participation in Companies Commercializing University Research Foundation](#)
- d. [University Policy and Procedures Concerning Misconduct in Research](#)
- e. [Human Gene Transfer Research Institutional Review Process](#)
- f. [Human Research Protection Program](#)

Resources

[National Institutes of Health Guidelines for Research Involving the Use of Recombinant DNA Molecules](#)

[45 CFR §46 – Protection of Human Subjects](#)

[21 CFR §600 – U.S. Food and Drug Administration, Use of Biological Products](#)

Contacts *(required)*

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History *(required)*

All changes must be listed sequentially, including edits and reviews.

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