THE OHIO STATE UNIVERSITY

Human Gene Transfer

University Policy

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

Responsible Office

Office of Research

POLICY

Issued: 07/27/2005
Revised: 02/27/2009
Reviewed: 09/01/2016

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

Purpose of the Policy

To ensure compliance with laws, regulations, and standards.

Definitions

Term	Definition
Institutional Biosafety Committee (IBC)	The university Institutional Biosafety Committee has responsibility to provide public and occupational health review and approval of all human gene manipulation research studies at the university.
Institutional Review Board (IRB)	The university Institutional Review Board has responsibility for review and approval of all human subject and human gene manipulation research studies at the university.
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

I. University activities involving **human gene manipulation research** shall be in accordance with all applicable federal and state regulations.

II. Final institutional approval for all human gene manipulation research shall be provided by the vice president for research, or the provost in cases where a potential conflict may exist.

III. 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.

IV. 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.

V. 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 Office of Sponsored Programs and shall require the submission of an approved "Authorization to Seek Off-Campus Funding" 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 Technology Commercialization Office, as applicable.

VI. All university activities involving human gene manipulation research must comply with all applicable university policies and procedures, including but not limited to:

A. Faculty Financial Conflict of Interest policy
B. Research Misconduct policy
C. Rules Governing Faculty and Staff Participation in Companies Commercializing University Research

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

D. Authorization to Seek Off-Campus Funding
E. Human Gene Transfer Research Institutional Review Process
F. Human Research Protection Program

PROCEDURE

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I. All human gene manipulation research must undergo the formal institutional review and approval process described in Human Gene Transfer Research Institutional Review Process.

Resources

University Policies and Rules policies.osu.edu/

Faculty Financial Conflict of Interest policy, orc.osu.edu/files/2013/02/Policy-on-Faculty-Financial-Conflict-of-Interest.pdf

Research Misconduct policy, orc.osu.edu/files/2011/01/Misconduct_Policy.pdf

Rules Governing Faculty and Staff Participation in Companies Commercializing University Research, trustees.osu.edu/rules/university-rules/chapter-3335-13-university-property.html

Forms, Processes

Authorization to Seek Off-Campus Funding, rf.osu.edu/secure/ePA-005/

Human Gene Transfer Research Institutional Review Process, orc.osu.edu/files/2011/01/HGT-Institutional-Review-Process-06.28.12.pdf

Human Research Protection Program, orrp.osu.edu/irb/osupolicies/documents/HumanResearchProtectionProgram.pdf

Additional Resources

National Institutes of Health Guidelines for Research Involving the Use of Recombinant DNA Molecules, osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

45 CFR §46 – Protection of Human Subjects, http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subparta

21 CFR §600 – U.S. Food and Drug Administration, Use of Biological Products, www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=600

Contacts

Subject	Office	Telephone	E-mail/URL
Policy questions	Office of Research, Office of Research Compliance	614-292-4284 614-292-5714	orc.osu.edu/regulations-policies/hgt/
Biosafety questions	Office of Research, Office of Responsible Research Practices, Institutional Biosafety Committee	614-688-8457	orrp.osu.edu/ibc/
Institutional Review Board questions	Office of Research, Office of Responsible Research Practices, Institutional Review Board	614-688-8457 800-678-6251	orrp.osu.edu/irb/

History

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