

Policy on Human Gene Transfer Research

Date: July 6, 2017

Policy ID: 2.100

Status: Final

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Applies to: Any faculty member who wishes to conduct research involving the deliberate transfer into human research participants of either recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or synthetic nucleic acid molecules at the University of Virginia.

Reason for Policy: This policy will ensure that any research involving the deliberate transfer into human research participants of either recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or synthetic nucleic acid molecules will be carried out in accordance with University and Federal policies.

Policy

Human Gene Transfer (HGT) research is overseen by the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) and must comply with [Appendix M](#) of the [NIH guidelines for Research Involving Recombinant DNA and Synthetic Nucleic Acid Molecules](#).

Final approval of all HGT research at the University of Virginia is the responsibility of the Institutional Biosafety Committee (IBC) and the Institutional Review Board (IRB) of Record. The Principal Investigator (PI) is responsible for registering the protocol with NIH, and obtaining all appropriate approvals and complying with all post-monitoring requirements of the University and the NIH. Additional approvals may be required from the Food & Drug Administration, the UVA School of Medicine Clinical Research Office and/ or a Scientific Review Committee. Procedures to obtain approval for HGT research at UVA may be found in the document "Procedures for submitting HGT experiments at UVA".

Responsibilities

Institutional Biosafety Committee (IBC)

The IBC reviews and approves HGT experiments in compliance with the NIH Guidelines and will:

- Review and approve HGT experiments in accordance with [Appendix M](#) of the [NIH guidelines for Research Involving Recombinant DNA and Synthetic Nucleic Acid Molecules](#).
- Notify the SoM Dean about the proposed work and request, if necessary, additional expertise to review the protocol.
- Determine if review by the Recombinant DNA Advisory Committee (RAC) is required.
- Assess the containment levels for the proposed work.
- Inspect the laboratory and/or clinical facilities where work is performed as necessary.
- Ensure compliance with all UVA and NIH training and reporting requirements.

Institutional Review Board (IRB) of Record

The IRB will review and approve all HGT experiments to ensure compliance with federal regulations related to human subject research and will:

- Ensure the safety and welfare of human subjects
- Verify that approval from all other required review committees or bodies have been obtained.
- Confirm that all modifications requested by other review committees are incorporated into all final documents.

Gene Transfer Oversight Committee

A group made up of at least one person each from IRB-HSR, IBC, SOM Clinical Research Office, SOM Research Office, and the Cancer Center Protocol Review Committee will meet, as required, to review this policy and related compliance issues.

Policy History: Implemented January 1, 2002. Revised 3/20/08; 12/10/11; 12/19/11, 07/6/17