**General OVERVIEW**

**Human Gene Transfer** or “HGT” is used to describe research involving the transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules into human subjects. It is also sometimes referred to as “Gene Therapy.” Nucleic acids (DNA or RNA) may be transferred as "naked" nucleic acid, encapsulated nucleic acid, or nucleic acid within another organism, such as a virus.

At present, human gene transfer is experimental and is being studied to determine whether or not it can treat certain health problems by compensating for defective genes, producing a potentially therapeutic substance, or triggering the immune system to fight disease.

**Review REQUIREMENTS**

Special provisions are necessary for conducting HGT research at University of Cincinnati (UC).

Principal Investigators (PIs) must complete a process of multiple reviews and approvals at both federal and local/institutional levels.

First, HGT proposals must be registered with the NIH Office of Science Policy (OSP).

The project must be submitted to both UC Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) for review*.

IBC approval must be obtained from each institution at which recombinant or synthetic nucleic acid material will be administered to human subjects.

Protocols may be submitted to IBC and IRB at the same time, but IRB approval will only be granted after IBC approval.

*No research participant may be enrolled in an HGT study IBC and IRB approvals and applicable regulatory authorizations are obtained.*
IBC REGISTRATION – HGT Protocols

Review MATERIALS

The following documentation must be submitted to the IBC:

- Complete and signed UC HGT form
  The Biosafety Office can assist preparing this form.
- Complete Appendix M of NIH Guidelines
- Clinical Protocol
- Investigator Brochure
- OSP document certifying study registration
  and any additional RAC-Sponsor or -investigator correspondence
- Proposed Informed Consent Form

Reporting SAEs

**Serious Adverse Event (SAE)**  
DEFINITION

"An unexpected and related to the intervention, occurring at any dose that results in any of the following outcomes: death, a life-threatening event, in-patient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening or require hospitalization also may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the human gene transfer research subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition."

Investigators should not await definitive proof of association for reporting (possible) SAEs.
PIs at all sites must report qualifying SAEs to the OSP/NIH according to the guidance provided in Appendix M-I-C-4 of the NIH Guidelines. When SAE is **fatal or life-threatening**, report should **not exceed 7 calendar days** and for those that are not fatal or life-threatening, report should be submitted not later than 15 calendar days.

Principal Investigators may delegate to another party, such as a corporate sponsor, the reporting functions set forth in Appendix M, with written notification to the OSP/NIH of the delegation and of the name(s), address, telephone and fax numbers of the contact(s). The Principal Investigator is responsible for ensuring that the reporting requirements are fulfilled and will be held accountable for any reporting lapses.

In either case, any OSP/NIH reports concerning UC enrolled participants should also be submitted to the IRB and IBC. To report an SAE, complete and follow instructions in the **UC SAE HGT Form**.

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**Approval TIMELINE**

The full Committee meets on the **first Thursday of every month**.

Protocols that are submitted **2 weeks in advance** of the day of the meeting will be on the agenda.

Most protocols are completed/approved with only one review; however, if major modifications and additional information are requested, a protocol may be deferred to the next meeting which would delay approval for approximately 4 more weeks.