



## GUIDELINE FOR INTERNAL REVIEW OF HUMAN GENE TRANSFER RESEARCH

This guideline describes the internal review activities that are required for all human gene transfer protocols. The Institutional Biosafety Committee (IBC) may complete review of a human gene transfer protocol in parallel to the Research Subjects Review Board (RSRB) conducting its review, when the RSRB is the Reviewing IRB; however, IBC approval is required before RSRB approval will be granted. The Institutional Biosafety Committee (IBC) will complete review of a human gene transfer protocol prior to submission to the Reviewing IRB when the RSRB is the Relying IRB.

1. Institutional Biosafety Committee: The IBC will review the protocol to ensure that the Principal Investigator's facilities, procedures, practices, and personnel training and expertise are in compliance with the NIH Guidelines. The IBC is required to have members who can assess the safety of recombinant or synthetic nucleic acid molecule research and any potential risk to public health or the environment. For human gene transfer research, the IBC is required to have adequate expertise in gene transfer research. The IBC complies with this requirement through inclusion of standing IBC members with expertise in recombinant DNA, viral and bacterial vector systems and other gene delivery methods. Additionally, ad hoc consultants will be included as needed. IBC will upload documentation of its final review determination during the RSRB application sign-off process.
2. RSRB Review – When the RSRB is the Reviewing IRB: The RSRB will review the protocol in accordance with applicable regulations, as well as NIH and FDA guidelines. The RSRB complies with the requirement to have appropriate expertise during the review process either through the inclusion of standing members with expertise in gene transfer research or through the use of outside consultants. In addition, the RSRB may involve an IBC member for consultation during the RSRB review process.

The RSRB will conduct continuing review of gene transfer protocols every 6 months in accordance with its standard review procedures, with particular emphasis on the following assessments based on information provided in the continuing review report:

- a) Whether the protocol needs to be modified (e.g., changes in eligibility criteria, changes in dose, etc.); the Investigator Brochure needs to be updated; more frequent continuing review is required, or other appropriate action needs to be taken in connection with the study.
  - b) Whether any changes are needed to the consent form to reflect new risks, benefits, or other information that affects subject safety.
  - c) Whether any other issue need to be addressed that may affect the subject's decision regarding continued participation.
3. RSRB Review – When the RSRB is the Relying IRB: The RSRB will complete institutional review of the protocol according to [OHSP Policy 504 RSRB Reliance for Review](#).
  4. Quality Improvement Review: An OHSP Quality Improvement review of gene transfer protocols will be conducted once before the first subject is enrolled and at least once during the course of the study.