Revised Process for Submitting New Human Gene Transfer (HGT) Protocols

On March 22, 2016, the National Institutes of Health (NIH) announced a **new review process** for human gene transfer protocols (HGT) subject to the ***NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*** (NIH Guidelines). These changes are effective on **April 27, 2016**.

This **new process** eliminates the initial submission for NIH Recombinant DNA Advisory Committee (RAC) review with the rationale that RAC "review of individual human gene transfer trials should be limited to cases in which an oversight body such as an Institutional Biosafety Committee (IBC) or an Institutional Review Board (IRB) determines that a protocol would significantly benefit from RAC review" based upon one or more criteria detailed in the revised Guidelines.

As before, "HGT protocols may also be reviewed by the RAC if the NIH Director determines a protocol presents significant scientific, societal, or ethical concerns." As before, all human gene transfer protocols subject to the NIH Guidelines must be reviewed and approved by institutional oversight bodies such as the IBC and IRB, and registered with the NIH.

The **principal investigator remains responsible** for submitting documentation regarding a proposed human gene transfer protocol to Penn's IRB and IBC, and to the NIH as outlined in the amended NIH Guidelines, but documentation submitted to the NIH shall also include **written assessments** originating from Penn's IBC review as to whether RAC review is warranted.

The **new registration process** at Penn will be implemented as follows:

- The PI submits a new HGT protocol to Penn's IRB. Submission to the NIH Office of Biotechnology Activities (OBA) will no longer be required.
- Once IRB requirements/revisions are satisfied, the protocol is submitted to Penn's IBC for review.
- The IBC will review the protocol and will provide a **written assessment** as to whether RAC review is warranted.
- Upon receipt of the IBC **written assessment**, the PI must complete registration of the protocol with the NIH. The NIH Office of Science Policy will notify the PI "that protocol registration is complete" within 10 days of receipt of all required documentation.
- Upon receipt of confirmation "that protocol registration is complete" the IBC will complete review and will issue an IBC registration **approval letter**.
- Enrollment in the study can commence after both IBC registration **approval letter** and IRB protocol approval are received.