Revised Review Process for Human Gene Transfer Protocols Subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

(NIH Guidelines)

With the benefit of decades of experience with recombinant DNA technology, and its ubiquitous use in both basic and clinical research, the NIH is announcing a streamlined review process for human gene transfer protocols subject to the *NIH Guidelines*. The changes to the human gene transfer protocol review process are being made after NIH, in consultation with the Institute of Medicine, determined that the NIH Recombinant DNA Advisory Committee's (RAC) review of individual human gene transfer protocols 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, and has been determined to meet one or more of the following criteria:

- The protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk; or
- The protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value; or
- The proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies involved to evaluate the protocol rigorously.

Human gene transfer protocols may also be reviewed by the RAC if the NIH Director determines the research presents significant scientific, societal, or ethical concerns.

As before, all human gene transfer protocols subject to the *NIH Guidelines* will continue to be registered with the NIH and be reviewed and approved by institutional oversight bodies such as the IBCs and IRBs. However, to accommodate the new registration and review process described in the amended *NIH Guidelines*, several changes are being implemented. The principal investigator will remain responsible for submitting documentation regarding a proposed human gene transfer protocol to local oversight bodies and to the NIH as outlined in the *NIH Guidelines*, but documentation submitted to the NIH shall also include written assessments originating from all oversight bodies involved in the review at an initial site(s) as to whether RAC review is warranted. Also, in an effort to reduce administrative burden associated with the protocol registration process, the NIH is reducing the document submission requirements as outlined in Appendix M-I-A.

For a complete description of the revised review process for human gene transfer protocols, please see the notice published in the Federal Register on March 22, 2016. The revisions outlined in this notice will become effective on April 27, 2016. A set of FAQs containing more detailed information will be posted to the OSP Website in the upcoming weeks.

Questions about these revisions can be sent to SciencePolicy@od.nih.gov.

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