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Oversight and Review of Clinical Gene Transfer Protocols: Assessing the Role of the Recombinant DNA Advisory Committee

Author(s)

Anonymous

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Gene transfer research is a rapidly advancing field that involves the introduction of a genetic sequence into a human subject for research or diagnostic purposes. Clinical gene transfer trials are subject to regulation by the U.S. Food and Drug Administration (FDA) at the federal level and to oversight by institutional review boards (IRBs) and institutional biosafety committees (IBCs) at the local level before human subjects can be enrolled. In addition, at present all researchers and institutions funded by the National Institutes of Health (NIH) are required by NIH guidelines to submit human gene transfer protocols for advisory review by the NIH Recombinant DNA Advisory Committee (RAC). Some protocols are then selected for individual review and public discussion. Oversight and Review of Clinical Gene Transfer Protocols provides an assessment of the state of existing gene transfer science and the current regulatory and policy context under which research is investigated. This report assesses whether the current oversight of individual gene transfer protocols by the RAC continues to be necessary and offers

recommendations concerning the criteria the NIH should employ to determine whether individual protocols should receive public review. The focus of this report is on the standards the RAC and NIH should use in exercising its oversight function. Oversight and Review of Clinical Gene Transfer Protocols will assist not only the RAC, but also research institutions and the general public with respect to utilizing and improving existing oversight processes.

Read *Oversight and Review of Clinical Gene Transfer Protocols: Assessing the Role of the Recombinant DNA Advisory Committee*

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