OFFICE OF RESEARCH ADMINISTRATION

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NIH Amends NIH Guidelines to Modernize Gene Therapy Oversight and Establishes a Forum for Emerging Biotechnology

Today, the National Institutes of Health (NIH) finalized a proposal to amend the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) to streamline the oversight of gene therapy research. This proposal, which was developed in conjunction with the Food and Drug Administration, included amending the *NIH Guidelines* to eliminate duplicative review and reporting requirements for human gene transfer protocols and refocuses the role of the NIH Recombinant DNA Advisory Committee (RAC) as a transparent forum for science, safety, and ethics of emerging biotechnologies. After a 60-day public comment period, the *NIH Guidelines* have been updated to reflect these changes and the RAC has been renamed the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC).

For more information about the importance of these revisions, please read a Director's statement by Dr. Francis Collins as well as an "*Under the Poliscope*" blog by Dr. Carrie D. Wolinetz:

NIH Director's Statement

Under the Poliscope blog "Introducing the NExTRAC"

Questions may be sent to the NIH Office of Science Policy at SciencePolicy@od.nih.gov