



## NIH Streamlines the Review of Gene Therapy Trials

On **April 25, 2019**, the **NIH Office of Science Policy** published an amended version of the **NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules**.

The **guidelines** detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules.

The revised guidelines amended two key elements:

- eliminating the human gene transfer (HGT) protocol submission and reporting requirements to the NIH, and individual HGT protocol review by the Recombinant DNA Advisory Committee (RAC)
- modifying the roles and responsibilities of investigators, institutions, Institutional Biosafety Committees (IBCs), the RAC, and the NIH, to be consistent with these goals:
  - modifying the roles of IBCs in reviewing HGT to be consistent with review of other covered research
  - eliminating the roles of the RAC in HGT and biosafety

Although NIH has streamlined individual protocol reporting requirements, it is **important to note** that ***oversight of gene therapy trials is still required as per federal and local oversight (i.e., FDA, IRBs, IBCs) before any research with human participants can be initiated.***

**Important links:**

- [NOT-OD-19-106](#)
- [NIH Director Statement](#)
- [Final Guideline in the Federal Register](#)
- [Summary of the Guideline](#)
- [April 2019 PDF of the Amended Guideline](#)
- NIH Office of Science Policy email: [SciencePolicy@od.nih.gov](mailto:SciencePolicy@od.nih.gov)