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Report on Research Compliance Volume 16, Number 6. May 22, 2019 New Gene Policy, Loss of RAC May Necessitate Greater Local Expertise

By Theresa Defino

Now that NIH has officially disbanded (reconstituted, it says) a long-standing gene research review board that had recently become virtually inactive, institutional oversight panels will take on greater significance and their roles likely will need to be revised.

On April 26, NIH published a *Federal Register* notice announcing "final action" regarding research involving recombinant or synthetic nucleic acid molecules to "streamline oversight for human gene transfer clinical research protocols and reduce duplicative reporting requirements already captured within the existing regulatory framework." The notice finalized draft changes announced in August.

Although there were other important ones, the primary change was to eliminate review by the Recombinant DNA Advisory Committee (RAC), which had been operational since 1974. NIH ceased reviews in August when the revisions were proposed.

Other changes, which went into effect with publication of the notice, redefine the role of the institutional biosafety committees (IBCs) and may place greater responsibility on institutional review boards (IRBs), according to Daniel Kavanagh, scientific lead in the Institutional Biosafety Committee of WIRB-Copernicus Group.

Along with the Food and Drug Administration, NIH introduced new guidelines that "remove the requirement to register and report on human gene therapy protocols," referring to RAC reviews. The agency added that "[r]obust oversight continues under the FDA, which has regulatory oversight of all human gene therapy clinical trials. In addition, NIH-funded human gene therapy research remains subject to the usual NIH oversight that applies to all NIH-funded research, and oversight by local authorities," for example, IBCs and IRBs.

New Panel to Advise on Emerging Technologies

In announcing that the RAC would be disbanded and renamed, NIH Director Francis Collins said a panel would perform "a role closer to its original mandate, which was to follow and provide advice on safety and ethical issues associated with emerging biotechnologies. Today, these emerging areas of research include, but are not restricted to, technologies surrounding advances in recombinant or synthetic nucleic acid research."

NIH explained that it "refocused" the RAC "into a role closer to its original mandate, which was to follow and provide advice on safety and ethical issues associated with emerging biotechnologies," and renamed it the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC).

According to its charter (an amended version of the RAC charter), the panel falls under the Federal Advisory Committee Act, meaning its meetings will be public and members must undergo certain conflict of interest vetting. It is expected to meet twice per fiscal year.

The NIH Office of Science Policy will appoint a designated federal official (DFO) to run the committee, who can

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call additional meetings and establish NExTRAC meeting agendas. The committee is expected to have "up to" 25 members, to be appointed by Collins, and may form subcommittees. Its first meeting is expected to occur later this year.

Members will make "recommendations on research involving the use of, and developments in, emerging biotechnologies" and "address scientific, safety, ethical, and social issues associated with areas of emerging biotechnology research for which the NIH requests advice or guidance." With DFO approval, the committee also could "call upon special consultants, assemble ad hoc working groups, and convene conferences, workshops and other activities.

Collins said he was "look[ing] forward to working with the NExTRAC to evaluate new biotechnologies and emerging applications that represent both great scientific opportunities and significant ethical and safety challenges. The advice NIH receives from the NExTRAC will be essential to the agency in appropriate stewardship of its investment in cutting-edge science."

He added a note of thanks to the RAC.

"I would also like to take a moment to express my deep appreciation for the role the RAC played in the advancement of recombinant DNA technology and gene therapy, and the multitude of members who have served on this committee throughout the decades," Collins said. "The steady and guiding hand of the RAC helped the field through some of its most challenging years. Without their expertise provided over the years, the field of gene therapy would not have advanced to where it is now."

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