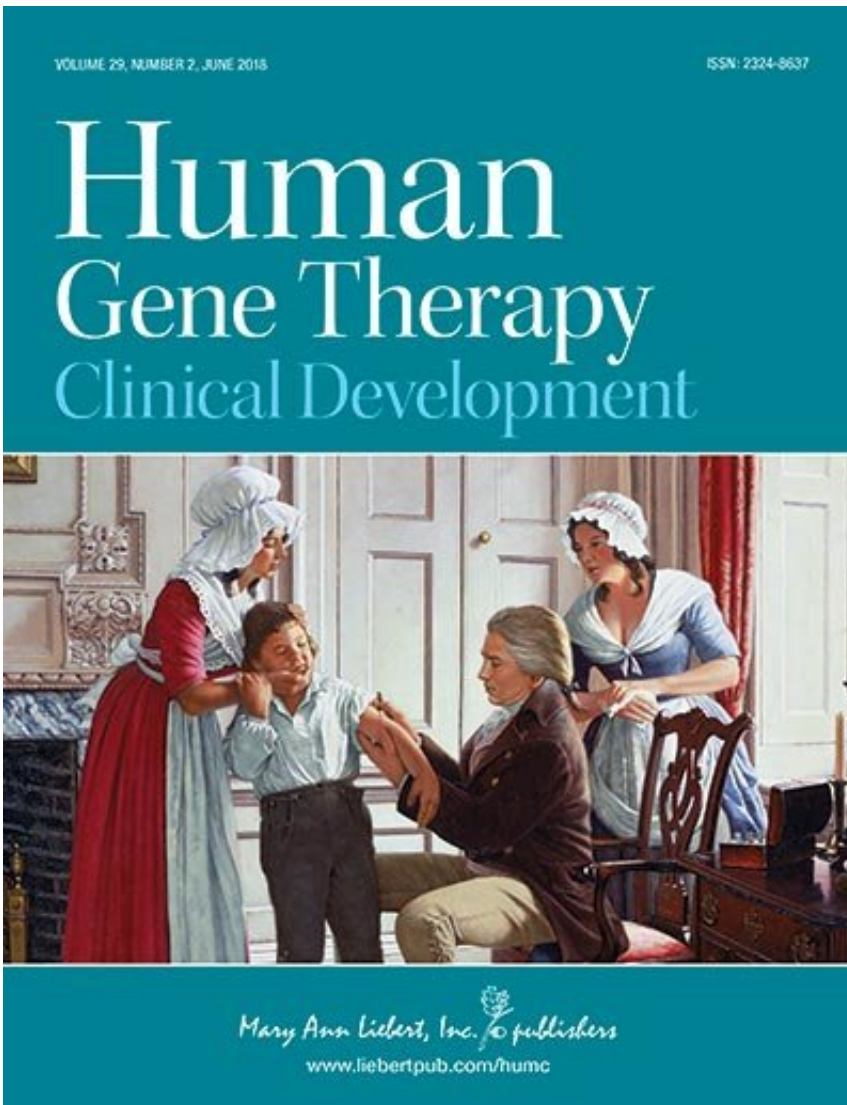


Is the end of the recombinant DNA Advisory Committee (RAC) a good thing?

September 19 2018



Human Gene Therapy presents reports on the transfer and expression of genes in mammals, including humans. Credit: Mary Ann Liebert, Inc., publishers

Recently, the U.S. National Institutes of Health (NIH) and Food and Drug Administration (FDA) called for the eliminating involvement of the Recombinant DNA Advisory Committee (RAC) in human gene therapy experiments, marking the end of an era of federal government oversight. While the RAC played an essential role in helping human gene therapy research evolve to where it is today, James M. Wilson, MD, Ph.D., Editor, *Human Gene Therapy Clinical Development*, believes this is the right moment for it to exit the stage, as he explains in his Editorial "The RAC Retires After a Job Well Done," *Human Gene Therapy Clinical Development*.

The RAC initially set guidelines for DNA research, and its role was later expanded to encompass the review and approval of human gene [therapy](#) research. The Committee was composed of stakeholders, including basic scientists, physicians, ethicists, theologians, and patients advocates. "The deliberations often became theatrical and, at times, quite contentious," says Dr. Wilson. Over the years, as the field of human gene therapy matured and became more integrated into the biopharmaceutical industry the potential re-dundancies between the roles of the FDA and the RAC became an increasingly important issue.

"The 2018 proposal...is to completely eliminate the RAC's role in reviewing or monitor-ing [human gene therapy](#) studies," says Dr. Wilson. "The new recommendations retain the role of local Institutional Biosafety Committees in the review process, while limiting their evaluation to an assessment of biosafety risks."

More information: James M. Wilson, The RAC Retires After a Job Well Done, *Human Gene Therapy Clinical Development* (2018). [DOI: 10.1089/humc.2018.29034.wil](https://doi.org/10.1089/humc.2018.29034.wil)

Provided by Mary Ann Liebert, Inc

Citation: Is the end of the recombinant DNA Advisory Committee (RAC) a good thing? (2018, September 19) retrieved 28 January 2023 from

<https://medicalxpress.com/news/2018-09-recombinant-dna-advisory-committee-rac.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.