OBA News

News from the NIH Office of Biotechnology Activities
March 27, 2009
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NIH Proposes Revisions to the *NIH Guidelines for Research Involving Recombinant DNA Molecules*

For the purposes of clarification and in acknowledgement of the rapidly developing field of synthetic biology, the NIH is proposing several amendments to the current *NIH Guidelines.*

The proposed revisions to the *NIH Guidelines* include:

- Broadening the scope of the *NIH Guidelines*, which currently cover laboratory and clinical research involving DNA molecules created via recombinant techniques (i.e., joining of DNA molecules). NIH proposes to encompass nucleic acids that are synthesized chemically or by other means without the use of recombinant technology.

- Revising the criteria for determining when introduction of a drug resistance trait into a microorganism must be reviewed and approved by the NIH Director. NIH proposes to remove the current language regarding a microorganism's ability to acquire the trait naturally, since this criterion may not be determinative of the safety and public health implications of the research. As proposed, this portion of the *NIH Guidelines* would state, "the deliberate transfer of a drug resistance trait to microorganisms, if such acquisition could compromise the ability to treat or manage disease caused by that microorganism in human and veterinary medicine, or agriculture." The proposed amendment also contains additional language requiring consideration of the utility of the drug in certain subpopulations.

- Changing the level of review for recombinant or synthetic experiments involving more than half but less than two-thirds of the genome of certain viruses in tissue culture, as described in Section III-E-1 of the *NIH Guidelines.*

The full version of the proposed changes may be found in the March 4, 2009 Federal Register, Volume 74, Number 41.

The public is encouraged to submit comments on the proposed revisions. Comments may be submitted to OBA to the attention of the "RAC Executive Secretary" via email at oba@od.nih.gov or mailed to: 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892-7985. All comments on the proposed revisions must be submitted by **May 4, 2009**.

If you have questions or require additional information about these proposed revisions, please feel free to contact OBA at 301-496-9838 or oba@od.nih.gov