Preliminary Agenda for the March 7-8, 2012, RAC Meeting Now Available - The preliminary agenda for the March 7-8 meeting of the NIH Recombinant DNA Advisory Committee (RAC) is now available on the OBA Web site.

The RAC will review and discuss human gene transfer protocols selected for public review, including:

- A trial involving AAV8-mediated low density lipoprotein receptor gene replacement in subjects with homozygous familial hypercholesterolemia;

- A Phase II, randomized, active control, open-label, multi-center study to evaluate the safety and efficacy of EPODURE, a biopump that will use autologous tissue transduced with an adenoviral vector containing the transgene for erythropoietin, for sustained treatment of anemia in hemodialysis patients; and

- In addition, the RAC will hear the results from a Phase I study evaluating the use of allogeneic T cells transduced with an inducible Caspase 9 suicide gene after haploidentical stem cell transplantation.

The RAC will also discuss ways to facilitate IBC review of certain multisite trials that use low biosafety risk vectors.

The meeting will be held at the NIH Campus, Building 31, 6th Floor, Conference Room 6, 9000 Rockville Pike, Rockville, MD 20852. All portions of the meeting are open to the public and will be webcast. Please visit the meetings page of the OBA Web site to access the link to the webcast and to obtain a copy of the complete agenda.

OBA will be piloting a new system to offer those members of the public viewing the meeting via webcast the opportunity to submit comments to be read during the scheduled public comment periods. Individuals wishing to submit comments should use the comment form, which will accommodate comments up to 1500 characters in length, and will be available on the OBA Meetings Page during the meeting. In the subject line, please indicate the agenda item on which you are commenting in the following format:

RAC Meeting Question: Agenda item [insert protocol name or number or name of agenda item]
Please submit your comment prior to the start of the public comment period. Please limit your comment to a statement that can be read in one to two minutes. Please include your name and affiliation with your comment.

OBA will read comments into the record during the public comment periods that are specified on the agenda. Please note, while every effort is made to keep the meeting discussions to the times stated on the agenda, it is not unusual for the meeting to run ahead or behind schedule due to changes in the time needed to review a protocol. It is advisable to monitor the webcast to determine when public comments will be read. Comments submitted electronically will follow any comments by individuals attending the meeting in person. Comments will be read in the order received and your name and affiliation will be read with the comment. Please note that OBA may not be able to read every comment received in the time allotted for public comment. Even if your comment is not read, it will be included as part of the public record.

For more information, please contact Chezelle George, NIH Office of Biotechnology Activities, by email at georgec@od.nih.gov or by telephone at 301-496-9838.