The following is a joint announcement from the administrative offices supporting the Institutional Review Board (IRB) and Institutional Biosafety Committee (IBC).

Change in RAC Review for Human Gene Transfer (HGT) Studies

The latest version of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* changes the NIH Recombinant DNA Advisory Committee (RAC) review process for human gene transfer (HGT) studies. RAC review was previously required for all HGT studies. The UCLA Institutional Review Board (IRB) and Institutional Biosafety Committee (IBC) also required submission of RAC documentation prior to approval.

As of April 27, 2016, RAC will review HGT studies only in two exceptional circumstances:

1. the NIH Director determines it is necessary, or
2. the IRB or IBC at any initial site(s)[1] determine that a protocol would significantly benefit from RAC review AND meets any of the following criteria:
   - The protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk; or
   - The protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value; or
   - The proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies involved to evaluate the protocol rigorously.

Therefore, if UCLA is an initial site[2] for new HGT studies, please follow this modified process for applying to the IRB, IBC, and the Cancer Center's Internal Scientific Protocol Review Committee (ISPRC):

1. Submit a Biological Use Authorization (BUA) application in the IBC online system at https://safetynet.research.ucla.edu. Please DO NOT submit IRB or ISPRC applications at this time.
   - IBC review will take place as normal, with the BUA being reviewed at a convened meeting following completion of the pre-review process. At this review, the IBC will make their recommendation regarding the need for RAC review.
   - At the same time, the IRB will receive and evaluate the documents from the IBC and make its recommendation regarding RAC.
   - The IRB and IBC will provide a letter to the PI with their determinations regarding RAC.

2. If either the IRB or IBC recommend RAC review, skip to the next step. Otherwise, submit applications to the IRB and ISPRC at this time and the IRB, IBC, and ISPRC processes will continue as normal. While the reviews continue, proceed to the next step.

3. Register the study with NIH and include the determination letter from the IRB and IBC. Once registration is complete (including RAC review if necessary), NIH will provide confirmation.

4. Upon NIH confirmation, submit IRB and ISPRC applications if you have not yet done so and provide the confirmation of NIH registration to the IBC to finalize IBC approval. Provide the final IBC and ISPRC approvals to the IRB.

Please see the RAC Revision Factsheet and contact the staff of the IRB (mirb@research.ucla.edu or 310-82**5-5344**) and/or IBC (oibc@research.ucla.edu or 310-79**4-0262**) if you have any questions.

---

[1] An initial site is any site added before completion of the NIH protocol registration process.

[2] If UCLA is being added to a multi-site protocol already registered with NIH, do not follow this process. Submit to the IRB, IBC and/or ISPRC as you would normally.