



## Compliance Note

## Instructions for Application for Human Gene Transfer Clinical Trials

Revision date: April 2007

HSD-BSC-006

*This information is for your use and as a way of providing consistent information. This information is based on current UCHSC Policy, and/or Federal, State or Local regulatory requirements.*

### Instructions for Application for Human Gene Transfer Clinical Trials

1. All work with recombinant DNA, to include [Human Gene Transfer \(HGT\)](#), is governed by the [NIH Guidelines for Research Involving recombinant DNA](#).
2. All clinical trials at UCDHSC, involving the use of recombinant DNA molecules, using viral vectors or other modes of drug administration, is subject to the review and oversight of the [Institutional Biosafety Committee](#) and the Biosafety Office, in addition to the COMIRB review.
3. The UCHSC [Institutional Biosafety Committee](#) is constituted under the auspices of the [NIH Guidelines](#) and is administratively managed by the Biosafety Office, Dept. of Environmental Health and Safety, Office of the AVC for Regulatory Compliance.
4. IBC meetings are scheduled monthly. All submissions are due on the first business day of each month to be included on that month's agenda. A schedule is posted on [the IBC website](#).
5. The University policy on Human Gene Transfer clinical trials is on the web at: <http://www.uchsc.edu/safety/Policies/index.htm>.
6. In addition to all FDA requirements, HGT clinical trials must meet the requirements of Appendix M of the NIH Guidelines.
7. Requirements for Protocol Submission  
The following documentation must be submitted (in printed or electronic form) by the UCDHSC Principal Investigator, to the IBC, Mailstop F484.
  - a. [UCDHSC Biosafety Authorization Form](#) (BSF-001)
  - b. UCDHSC Application for Human Gene Transfer Clinical Trial (BSF-003)  
Written responses must be provided to each of the specific questions of the UCDHSC forms, as the clinical trial is to be conducted at UCDHSC. Investigators should indicate points that are not applicable with a brief explanation.
  - c. A cover letter on institutional letterhead, signed by the Principal Investigator(s), that:
    - i. acknowledges that the documentation submitted complies with the requirements set forth in the [NIH Guidelines](#), Appendix M-I-A, *Requirements for Protocol Submission*;
    - ii. identifies proposed clinical trial site(s) for the protocol with building addresses or designation, and room numbers, including; and
    - iii. acknowledges that no research participant will be enrolled (see definition of enrollment in [Section I-E-7](#)) until the Institutional review process has been completed, i.e. IBC approval (from the clinical

trial site) has been obtained; IRB approval has been obtained; and all applicable regulatory authorizations have been obtained.

And the following, (in triplicate if you are submitting hardcopy)

- d. The scientific abstract.
- e. the non-technical abstract.
- f. The proposed clinical protocol, including tables, figures, and relevant manuscripts, to include documentation of how all safety reporting and adverse events reporting will be conducted.
- g. documentation of the sponsor's submission to the NIH RAC and any responses from the RAC including:
  - i. receipt by the Principal Investigator(s) of a letter from NIH OBA indicating that the submission does not present characteristics that warrant public RAC review and discussion; or
  - ii. receipt by the Principal Investigator(s) of a letter from NIH OBA after public RAC review that summarizes the committee's key comments and recommendations (if any) with the investigator(s) responded to each of the RAC's recommendations on the protocol (if applicable); and
  - iii. the [FDA Investigational New Drug Application \(IND\)](#) number and any modifications to the protocol as required by [FDA](#).
- h. the proposed informed consent document (see [Appendix M-III, Informed Consent](#)).
- i. curriculum vitae of the principal investigator(s) (no more than two pages in biographical sketch format) and NIH grant numbers(s) if applicable.

Additional review for clinical trial sites at UCH facilities are conducted through the auspices of the UCH Infection Control Committee and the UCH-HRRC.

Other affiliate sites must consult with their internal administration for compliance with [NIH Guidelines](#) before an HGT clinical trial site may be added.

If you have any questions regarding clinical research involving Human Gene Transfer, contact the Biosafety Office of the Department of Environmental Health and Safety, 303-724-0235.