

Executive Board

New UCLA Policy: Human Gene and Cell Therapy Program

Table of Contents

Exec Divisional Response - EB re Human Gene and Cell Therapy Policy_2023-10-20	1
COR Final Response	3
Exec UCLA Policy Gene Therapy draft_ 5-16-2023	4
---I. PURPOSE & SCOPE	4
---II. DEFINITIONS	4
---III. POLICY STATEMENT	5
---IV. CONTACT INFORMATION	6
---V. REFERENCES	6
---VI. ATTACHMENTS	6

October 20, 2023

Roger Wakimoto
Vice Chancellor for Research and Creative Activities

Re: **Proposed UCLA Policy on Human Gene and Cell Therapy Program**

Dear Vice Chancellor Wakimoto,

At the October 12th, 2023 meeting of the Executive Board, members reviewed the proposed UCLA Policy on Human Gene and Cell Therapy Program.

Members voted to decline to endorse the proposal, and reiterate long-standing and historical objections to the Scientific Review Committee (SRC). They noted that faculty were steered to send their research proposals through SRC with no apparent benefit and yet a requirement to pay for these services. Members expressed concern that the proposed policy would further empower the health system rather than faculty and academic departments to have control over this intellectual activity and the associated funding.


Members noted that the divisional Academic Senate had raised repeated concerns about the Scientific Review Committee (SRC) in the past:

<https://dms.senate.ucla.edu/issues/issue/?2015.Scientific.Review.and.IRB>.

The Executive Board requests a response to this proposal that addresses its intended benefits: What problem is the proposed policy trying to solve? How does the proposed policy further the academic mission of research, teaching and service of the University?

We appreciate the opportunity to advise on this matter and look forward to reviewing a revised proposal.

Sincerely,



Andrea Kasko
Chair, UCLA Academic Senate

Encl.

Cc: Kathleen Bawn, Vice Chair/Chair Elect, UCLA Academic Senate
Jessica Cattelino, Immediate Past Chair, UCLA Academic Senate
April de Stefano, Executive Director, UCLA Academic Senate

Anna Joyce, Director, Administrative Policies and Strategic Initiatives

October 12, 2023

Andrea Kasko, Chair
Academic Senate

Re: New UCLA Policy: Human Gene and Cell Therapy Program

Dear Chair Kasko,

At its meeting on October 4, 2023, the Council on Research (COR) reviewed and discussed the draft new UCLA Policy on Human Gene and Cell Therapy Program.

Members agreed that the policy formalizes what had been common practice. Members commented that the proposed policy is appropriate and straightforward.

Thank you for the opportunity to review and comment. If you have any questions for us, please do not hesitate to contact me at asampath@jsei.ucla.edu or via the Council's analyst, Elizabeth Feller, at efeller@senate.ucla.edu.

Sincerely,

Alapakkam Sampath, Chair
Council on Research

cc: Kathy Bawn, Vice Chair/Chair-Elect, Academic Senate
Jessica Cattelino, Immediate Past Chair, Academic Senate
April de Stefano, Executive Director, Academic Senate
Elizabeth Feller, Associate Director, Academic Senate
Members of the Council on Research

UCLA Policy #: Human Gene and Cell Therapy Program Draft for Review 5/16/2023

Issuing Officer: Vice Chancellor for Research and Creative Activities
Responsible Department: Vice Chancellor for Research and Creative Activities
Effective Date: TBD
Supersedes: New

I. PURPOSE & SCOPE II. DEFINITIONS III. POLICY STATEMENT IV. CONTACT INFORMATION V. REFERENCES VI. ATTACHMENTS

I. PURPOSE & SCOPE

The UCLA Human Gene and Cell Therapy Program (HGCTP) is a joint effort of the David Geffen School of Medicine, the Jonsson Comprehensive Cancer Center, and the Eli and Edythe Broad Center for Regenerative Medicine and Stem Cell Research.

The HGCTP includes scientific and quality assurance oversight of all Human Gene Transfer Clinical Trials conducted at UCLA and a manufacturing facility for cell and gene transfer products. Attachment A is a schematic representing the essential components of the program.

This Policy sets forth the requirements for oversight of the conduct of Human Gene Transfer Clinical Trials at UCLA and applies to all Human Gene Transfer Clinical Trials regardless of funding source (i.e. extramural industry funding, extramural non-profit or government funding, and/or intramural funding).

II. DEFINITIONS

For the purposes of this Policy:

Clinical Trial as defined by the NIH is a research study in which one or more human subjects are [Prospectively Assigned](#) to one or more [Interventions](#) (which may include placebo or other control) to evaluate the effects of those interventions on [Health-Related Biomedical or Behavioral Outcomes](#). Refer to the NIH Clinical Trial Decision tool (<https://grants.nih.gov/ct-decision/index.htm>).

Human Gene Transfer is defined as the deliberate transfer into human research participants of either:

1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:
 - a. Contain more than 100 nucleotides; or
 - b. Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration); or
 - c. Have the potential to replicate in a cell; or
 - d. Can be translated or transcribed.

Key Personnel is defined as the Principal Investigator, other investigators and research personnel who are directly involved in conducting research with study participants or who are directly involved with handling private information related to study participants during the course of a research project. Key Personnel also include Faculty Sponsors who oversee student Principal Investigators in their conduct of human subjects research.

Principal Investigator is defined in [UCLA Policy 900](#).

III. POLICY STATEMENT

All Human Gene Transfer Clinical Trials at UCLA must complete the requirements as outlined in this Policy.

A. Approval by Institutional Bodies

All Human Gene Transfer research studies at UCLA are required to receive favorable review/regulatory approvals by the following institutional bodies.

1. Institutional Review Board (IRB)
2. [Jonsson Comprehensive Cancer Center \(JCCC\) Internal Scientific Peer Review Committee](#) (ISPRC) for oncology studies OR [UCLA Scientific Review Committee](#) (SRC) for non-oncology studies
3. Institutional Biosafety Committee (IBC)
4. Medical Radiation Safety Committee (MRSC) (if applicable)

B. Scientific and Quality Assurance Oversight

Scientific review, data, and safety monitoring and quality assurance must be completed.

1. The JCCC ISPRC for oncology clinical trials and UCLA SRC for non-oncology clinical trials, will review the clinical protocol, statistical plan, and other factors such as adequate staffing, competing trials etc.
2. In addition to scientific integrity, the committees also review data and safety monitoring plans for the studies and if necessary, recommend trial oversight by their respective data and safety monitoring board (DSMB).
3. All studies overseen by an institutional DSMB are subject to monitoring and auditing by the quality assurance officers within either the JCCC or the Clinical and Translational Science Institute (CTSI).

For more information, please see the JCCC ISPRC website: <https://cancer.ucla.edu/research/clinical-research-unit/internal-scientific-peer-review-committee> and CTSI ORA website: <https://www.researchgo.ucla.edu/office-regulatory-affairs>

C. Training

1. Required Training

All UCLA Key Personnel involved with Human Gene Transfer Clinical Trials must complete and be up to date with the following:

- Good Clinical Practice course via CITI (Collaborative Institutional Training Initiative Program)([See UCLA Policy 917](#));
- NIH Recombinant DNA Guidelines course via CITI; and
- Human Gene Transfer course via CITI.

2. Training Responsibility

Principal Investigators are responsible for assuring that all Key Personnel associated with Human Gene Transfer research have completed these training requirements.

3. Training Enforcement

During initial and continuing scientific review of Human Gene Transfer Clinical Trials, the designated Scientific Review Committee will ensure that the Key Personnel have completed the three required courses. All Key Personnel must complete the required trainings before Scientific Review Committee approval can be issued.

D. Manufacturing of Gene Transfer Products

The UCLA Human Gene and Cell Therapy Facility (HGCTF) supports manufacturing of gene and cell therapy products for UCLA Principal Investigators as well as other academic and industry partners conducting Clinical Studies in which a cell or gene therapy product is manufactured under an FDA IND. For more information, please see the HGCTF website: <https://medschool.ucla.edu/research/human-gene-and-cell-therapy-facility>

IV. CONTACT INFORMATION

For oncology-related studies, please contact the [Jonsson Comprehensive Cancer Center \(JCCC\) Internal Scientific Peer Review Committee](#) (ISPRC): CORA@mednet.ucla.edu

For non-oncology studies, please contact the Clinical and Translational Science Institute (CTSI) Office of Regulatory Affairs (ORA): ctsiora@mednet.ucla.edu

For questions related to manufacturing a cell or gene transfer product, please contact the Human Gene and Cell Therapy Facility: GMP@mednet.ucla.edu

V. REFERENCES

1. OHRPP - Human Subjects Protection Certification via CITI
(<http://ora.research.ucla.edu/OHRPP/Pages/CITITraining.aspx>)
2. CITI Program Homepage (<https://about.citiprogram.org/en/homepage/>)
3. Human Gene and Cell Therapy Facility (HGCTF)
(<https://medschool.ucla.edu/research/research-resources/research-cores>)

VI. ATTACHMENTS

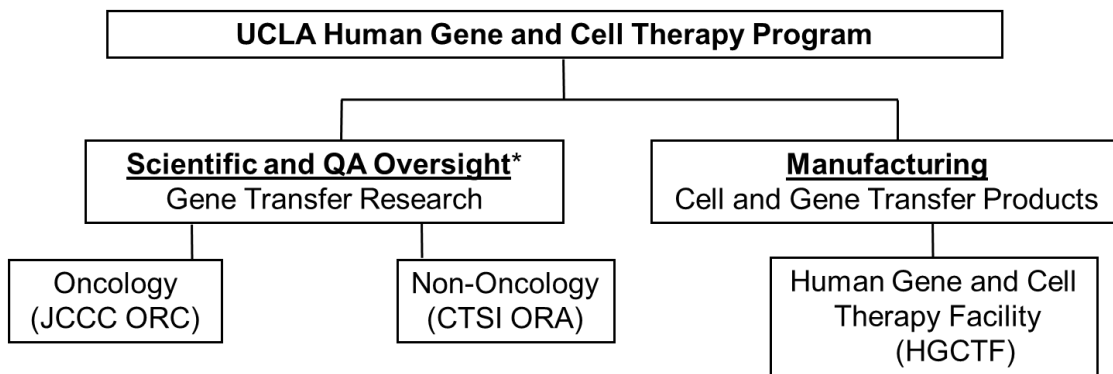
- A. UCLA Human Gene and Cell Therapy Program

Issuing Officer

/s/ Roger Wakimoto

**Questions concerning this policy or procedure should be referred to
the Responsible Department listed at the top of this document.**

ATTACHMENT A



*Oversight includes

1. Scientific review of protocols
2. Data and safety monitoring
3. Quality assurance (monitoring and auditing of trial conduct)
4. Training