APPENDIX 10-A

REGISTRATION OF CLINICAL TRIALS INVOLVING TRANSFER OF RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES INTO HUMAN STUDY PARTICIPANTS

Project Title:

IRB #: **Sponsor:**

IND # (if available)**:**

Phase of Study:

UNC Study Site:

☐ Primary ☐ Secondary

Protocol Submission Type:

☐ New Submission ☐ Amendment

SECTION I. OVERVIEW

UNC Principal Investigator: **UNC ONE Card (PID#):**

Position Title: Department:
Email address:

UNC Project Supervisor (person responsible in absence of PI):
Email Address:

UNC Study Coordinator / Regulatory Compliance:
Email Address: Phone Number:

	CB#	**Building and Room #**	**Campus Phone**	**After hour phone number or Pager**
PI				
Supervisor				

SECTION II. STUDY OVERVIEW

i. Please provide a brief summary of the clinical trial, highlighting the background and rationale behind the study, including the primary objective of the trial.

ii. What are the target cells for this gene therapy approach: Somatic cells ☐ Germline cells* ■
*Gene editing of human germline cells or embryos is prohibited.

SECTION III. THERAPEUTIC PRODUCT

i. Describe the structure and composition of any recombinant or synthetic nucleic acid materials (e.g. viral vectors, plasmids) used in the therapeutic product or for manufacture of the therapeutic product. If the therapeutic involves cells modified with recombinant DNA, describe the type and origin of the cells and the method by which they are modified with recombinant DNA.

ii. Will any recombinant microbes or vectors be administered directly to patients?
YES ☐ NO ☐ *If answered YES, answer questions below. If answered NO, skip to Section IV.*

iii. Is the recombinant microbe or vector replication-competent? YES ☐ NO ☐
Description of replication-competency:

iv. Is the recombinant microbe or vector attenuated? YES ☐ NO ☐
Description of attenuation:

v. Is the recombinant microbe or vector inactivated (e.g. irradiated, heat-killed)? YES ☐ NO ☐
Description of the method of inactivation and verification:

vi. Is there any possibility that live/replication-competent microbes or vectors could be spread from the recipient to close contacts? If so, what precautions are in place to prevent transmission?

SECTION IV. STUDY PERSONNEL

i. Please list all employees and personnel involved in the human gene transfer trial, including all personnel involved in the preparation or administration of the therapeutic product.

Name	PID	Status	Study Role

PID – All UNC-CH employees and students have a PID #, listed at the bottom of their UNC ONE CARD.
Status – **E** (EPA), **S** (SPA), **H** (UNC Hospitals), **U** (student), **N** (not E,S,H, or U)

ii. If any therapeutic product or clinical specimens will be shipped from UNC-CH during the trial at the conclusion of the trial, who is responsible for shipping the items?

Name	Title	EH&S Shipping Training Date

iii. Has the Principal Investigator completed UNC training on Recombinant DNA AND familiarized themselves with the ***NIH Guidelines*** detailing their roles and responsibilities in conducting Human Gene Transfer (HGT) experiments? YES ☐ NO ☐ *If answered NO, describe below.*

iv. Who is responsible for submitting reports (annual and safety) to the FDA?

Name	Affiliation

SECTION V. STUDY FACILITIES

A. Therapeutic Product Preparation

i. Where will the therapeutic product be stored and prepared at UNC-CH?

Building	Room	Storage	Preparation
		☐	☐
		☐	☐

ii. Describe how the therapeutic product will be prepared for administration to the patient.

iii. How will the therapeutic product preparation area be cleaned following preparation?

iv. How will the therapeutic product be transported from the preparation area to the administration area?

v. What personal protective equipment will be worn during preparation of the therapeutic product?

☐ Single gloves ☐ Double gloves ☐ Lab Coat ☐ Disposable lab coat/gown
☐ Eye protection ☐ Respirator (*e.g. N95 or PAPR*) List type: _____
☐ Other (list): _____

vi. What containment equipment (e.g. biosafety cabinet) will be used during preparation?

Equipment type	Certification Date

B. Therapeutic Product Administration

i. Where will the therapeutic product be administered?

Building	Room

ii. What personal protective equipment will be work by study personnel during administration?

☐ Single gloves ☐ Double gloves ☐ Lab Coat ☐ Disposable lab coat/gown
☐ Eye protection ☐ Respirator (*e.g. N95 or PAPR*) List type: _____
☐ Other (list): _____

iii. Describe how the therapeutic product will be administered to the patient.

iv. How will the administration area be cleaned following preparation?

SECTION VI. DISPOSAL

i. Describe how the following items will be discarded:

Item	Disposal Method
Sharps	
Contaminated consumables/disposables/reagents	
Personal Protective Equipment	
Excess therapeutic product	

ii. If an autoclave is to be used for disposal, please list where the autoclave is located:

Autoclave (Building)	Room

SECTION VII. EXPOSURES, SPILLS AND REPORTING

i. Describe any potential occupational exposure risks and hazards to study personnel handling or administering the therapeutic product and any procedure(s) in place to mitigate those risks.

ii. Have all study personnel handling or administering the therapeutic product been educated on the potential risks associated with an occupational exposure to the therapeutic product?

iii. Describe the response and reporting procedure(s) that will be followed in the event of an occupational exposure to the therapeutic product.

iv. Describe how spills of therapeutic product will be handled and reported.

SECTION VIII. ATTACHMENTS

Please submit the following materials directly to the IBC at ibc@unc.edu

A. **New Submissions**.

- ☐ Appendix 10-A
- ☐ Clinical Protocol
- ☐ Investigator's Brochure (IB)
- ☐ Informed Consent Forms
- ☐ Biosketch for each key individual participating in the trial

B. Amendments.

- ☐ A cover letter to the IBC detailing the request for an amendment to an approved trial and a summary of changes
- ☐ A copy of the original IBC approval letter for the trial
- ☐ Updated documents that have changed from the previous approved submission.

Note: ***The Principal Investigator, or a designee, may be expected to participate in the IBC's review by attending the IBC meeting, introducing the study as well as the risks associated with the recombinant DNA*.**

SECTION IX. Principal Investigator Acknowledgement of Responsibility

On behalf of the University, the PI is responsible for complying fully with the ***NIH Guidelines*** and with University policies in conducting any clinical trials involving recombinant or synthetic nucleic acids. The PI will report any serious adverse event to the IBC and the FDA and will consult with University Counsel for assistance with regard to trade secret or other confidential information before submitting their report to the FDA.

Signature:_____ Date:_____

Principal Investigator

***** FOR ADMINISTRATIVE USE ONLY *****

☐ APPROVED ☐ APPROVED WITH STIPULATIONS ☐ TABLED

IBC Committee Comments:

Signature:_____ Date:_____
IBC Chair