##### Research Integrity & Compliance

##### Institutional Biosafety Committee &

##### Institutional Review Board

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# Determination of Public RAC Review for Proposed Human Gene Transfer Studies Submission Form

Human Gene Transfer (HGT) studies in which USF is the initial site of the trial must receive a determination as to whether the study requires public RAC review prior to registration with the NIH. This assessment will be made by the USF Institutional Biosafety Committee (IBC) and/or Institutional Review Board (IRB). USF requires that all recombinant DNA work conducted at or supported by the University be reviewed and approved by the Institutional Biosafety Committee (IBC) and Institutional Review Board (IRB) prior to initiation of the project. For more information, contact Research Integrity & Compliance at 813-974-5638.

# Instructions:

Please complete the following information and submit this form via email to biosafety@research.usf.edu AND rsch-irb@usf.edu.

**Principal Investigator:** Name]

**Department:**

**E-mail:**

**PI’s Coordinator:** [Name]

**Coordinator’s E-mail:**

## Project Title

# Oversight bodies at the initial site for the study must review and make a determination as to whether the study would benefit from RAC review.

# Are you the initial site for this study?

**[ ] [ ] [ ]  Yes.**

**[ ] [ ] [ ]  No. If you are not the initial site for the study, this RAC determination is not required at this institution. (Please consult with the initial site to obtain the NIH registration confirmation to submit with the IBC application for this stusy)**

# Criteria for the Determination

# Please respond to the following three questions for the HGT protocol and provide justification for your response in the comments section below.

**Does the protocol use a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk?**

**[ ] [ ] [ ]  No.**

**[ ] [ ] [ ]  Yes.**

**If “Yes” is selected, specify what portion of the criteria (e.g. is a new vector? New genetic material? Method of delivery?) which is novel and represents an unknown risk. Additionally provide the rationale for why this requires RAC review**

**Does the protocol rely on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value?**

**[ ] [ ] [ ]  No.**

**[ ] [ ] [ ]  Yes.**

**If “Yes” is selected, specify what portion of this criteria and the rationale for why this requires RAC review**

**Is the proposed vector, gene construct, or method of delivery associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies involved to evaluate the protocol rigorously?**

**[ ] [ ] [ ]  No.**

**[ ] [ ] [ ]  Yes.**

**If “Yes” is selected, specify what portion of the criteria (e.g. is it the vector? The gene construct? Method of delivery?) which has the possible toxicity. Additionally provide the rationale for why this requires RAC review**

# Requirements for submission

**In order to make this determination, the IBC/IRB requires submission of the NIH** [**Appendix M-I-A**](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html#_Toc446948491) **documentation which includes the following items.**

1. A scientific abstract;

2. The proposed clinical protocol, including tables, figures, and any relevant publications;

3. The Investigator’s brochure or other document that includes:

* Summary of preclinical studies conducted in support of the proposed clinical trial or reference to the specific section of the protocol providing this information.
* A description of the product:

a. Describe the derivation of the delivery vector system including the source (e.g., viral, bacterial, or plasmid vector); and modifications (e.g., deletions to attenuate or self-inactivate, encapsulation in any synthetic complex, changes to tropisms, etc.). Please reference any previous clinical experience with this vector or similar vectors.

b. Describe the genetic content of the transgene or nucleic acid delivered including the species source of the sequence and whether any modifications have been made (e.g. mutations, deletions, and truncations). What are the regulatory elements contained in the construct?

c. Describe any other material to be used in preparation of the agent (vector and transgene) that will be administered to the human research subjects (e.g., helper virus, packaging cell line, carrier particles).

d. Describe the methods for replication-competent virus testing, if applicable.

e. Describe the intended ex vivo or in vivo target cells and transduction efficiency.

f. Describe the gene transfer agent delivery method; and

5. The proposed informed consent document(s).

**Required Signature:**

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##  Signature of Principal Investigator Date