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Non-Cancer Human Cell & Gene Transfer Scientific Review Committee

Instructions & Application Form

The Non-Cancer Human Cell & Gene Transfer Scientific Review Committee (HCGT-SRC) requires submission of the following materials prior to reviewing a study:

1. **The current protocol document (PDF)**
2. **Investigator Brochure (IB) and any other relevant materials provided by Sponsor**
3. **The Application Form consisting of:**
    a. A risk analysis completed by the PI
    b. A statement of the degree of novelty of the study
    c. Response to all applicable questions.

The non-cancer Human Cell & Gene Transfer Scientific Review Committee requires **a minimum of 15- business days prior to the next meeting** for application review. The Committee will provide feedback to the PI no more than seven (7) days from the date of committee meeting. If the Committee determines that the protocol requires revisions, the PI will have two (2) weeks to resubmit for secondary review. Please note that HCGT SRC approval is required before the MCW IRB can review or approve a protocol.

Application materials must be submitted via email to Dr. Jeffrey Medin (jmedin@mcw.edu), cc: to Jen Brown (jlbrown@mcw.edu).

Non-Cancer Human Cell & Gene Transfer Studies Scientific Review Committee (SRC) Application

Submit the below application form and full IRB protocol (PDF) as email attachments Dr. Jeffrey Medin (jmedin@mcw.edu), cc: to Jen Brown (jlbrown@mcw.edu), a minimum of 6 weeks prior to needed approval date.

Principal Investigator Name:

Study Name:

Protocol Type:
- ○ Gene manipulation
- ○ Cell therapy/transplantation
- ○ Other

Sponsor Type:
- ○ Industry-Sponsored
- ○ Investigator-Initiated
- ○ Other

1. What is the delivery system and its source (e.g., cellular viral, bacterial, or plasmid vector); and gene modifications if any (e.g., deletions to attenuate or self-inactivate etc.)?

2. Please describe the intended target cells and transduction efficiency achieved in prior experiments.

3. Is there any previous clinical experience with this vector or similar vectors? (Articles or a link to the pages of the protocol that describe this will suffice)

4. Are there any regulatory elements contained in the construct?

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

6. How will replication-competent virus testing be done? (if applicable)

7. How many potential study subjects will be accrued annually? How many local subjects will be approached for recruitment?

8. Have you completed feasibility analysis to ensure this study can be completed successfully (i.e. resources, staffing, patient population)? ☐ Yes ☐ No

IF APPLICABLE: For studies involving cell therapies (i.e. non-genetic manipulations)

1. What is the rationale for the current recommended starting dose?

2. Are the concerns from previous animal toxicity data?

3. Are there studies in the literature using similar dosing for analogous cell products?

Risk Analysis (completed by the PI):

Statement of the Degree of the Novelty of the Study: