UNIVERSITY OF MIAMI

SOP: Gene therapy Research and Human Studies Review Processes

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1 PURPOSE

1.1 The Institutional Review Board (IRB) is tasked with assuring that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. The Institutional Biosafety Committee (IBC) seeks to protect study personnel, the community and the environment from exposure to engineered genetic material and other biohazardous agents. Additionally, the IBC also assesses potential risks to the study subjects participating in Human Gene Transfer trials (HGT).

1.2 This SOP describes the associated processes between these two University-wide Institutional Regulatory Committees

2 REVISIONS

2.1 None

3 RESPONSIBILITIES OF IRB

3.1 The IRB reviews the proposed research, informed consent documents, and additional information, when applicable, to determine whether the criteria for approval found at 21 CFR 56.111 and 45 CFR 46.111 are met.

3.2 Clinical Trials involving Recombinant or Synthetic Nucleic Acid Molecules must be approved by the IBC prior to receipt of IRB approval. Studies involving DNA recombinant techniques including HGT will be routed to IBC by eProst upon receiving submission by the PI. The IRB will review the study concurrently with the IBC but will not issue an approval letter until both committees have approved the study.

3.3 The assigned IRB reviewer(s) may contact a qualified member of the University of Miami Institutional Biosafety Committee and external consultants, as necessary, to obtain independent guidance for the IRB.

4 RESPONSIBILITIES OF IBC

4.1 The IBC's review the Biosafety SOP, IBC Gene Transfer Form and IND/Sponsor protocol to determine whether

- 4.1.1 A thorough risk assessment has been done in regards to the risks associated with the genetically modified materials.
- 4.1.2 A comprehensive risk mitigation plan is in place prior to starting the research.
- 4.1.3 Appropriate microbiological training has been given for all individuals involved in handling the agent.
- 4.1.4 A site inspection has been conducted in the last year.

5 PROCEDURE FOR SUBMISSION FOR IRB

5.1 Investigators submit all information and documents required by the IRB in the eProst new study application.

- 5.1.1 The Informed Consent Documents must include appropriate descriptions of for the purpose and aims of the research, the related procedures and any reasonably foreseeable risks.

5.2 An eProst Notice is sent to the IBC office requiring signoff of original submissions, continuing reviews and modifications for all HGT studies.

6 PROCEDURE FOR SUBMISSION FOR IBC

6.1 Investigators submit all information and documents required by the IBC to the IBC support@miami.edu mail box.

- 6.1.1 Scientific Overview with references (2-3 Pages)

6.1.2 IBC Gene Transfer submission form (un-scanned version)

6.1.3 The UM Biosafety SOP template

6.1.4 IND Investigational Brochure or Sponsor's Protocol.

6.1.5 All correspondence submitted to and received from the FDA related to genetically manipulated agent.

6.1.6 PI Bio-Sketch

6.2 These materials are reviewed at the following IBC convened meeting for completeness, to ensure study personnel ae adequately protected, the community and the environment fare protected from exposure to engineered genetic material and other biohazardous agents, and to assess the risks to study subjects. The IBC Committee also ensures the site inspection was conducted within the last year and all research personnel have completed NIH/Biosafety training.

6.3 Once IBC approval is given for HGT studies, the IBC offices gives approval in eProst as an ancillary committee,

7 MATERIALS

7.1 None

8 REFERENCES

8.1 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)