1 PURPOSE

1.1 Studies conducted in UM need to safeguard the health of the individual as well as the providers. The IBC guidelines are designed mostly to ensure that such techniques are safe for the public and providers.

1.2 Genetics research may have significant implications with regard to a number of issues. Genetic characterization can affect employability and insurability and have a major psychological impact. For these reasons, genetic research must be undertaken with great sensitivity and awareness of its potential ramifications.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 GUIDING PRINCIPLES

3.1 The University of Miami IRBs require that special consideration be given during the review of studies involving genetic research and information, due to the potential predictive power of some genetic information, the familial nature of some genetic research and information, and the potential risks associated with genetic information.

3.2 The IRB requires investigators to provide a plan to ensure the privacy and confidentiality of participants, minimize the risks associated with genetic research, and provide adequate disclosure of genetic results that may be clinically relevant to the participant.

4 RESPONSIBILITIES

4.1 The **Institutional Review Board (IRB)** reviews the proposed research, informed consent documents, and additional information, when applicable, to determine whether:

- 4.1.1 The plan to ensure the privacy and confidentiality of participants is adequate;
- 4.1.2 The risks associated with genetic research are minimized;
- 4.1.3 The plan to disclose genetic results or incidental findings to the participant is adequate.

4.2 The **Institutional BioSafety Committee (IBC** must approve research involving Recombinant or Synthetic Nucleic Acid Molecules before IRB approval is effective. The HSRO's electronic system will route studies involving DNA recombinant techniques including HGT upon receipt of the submission.

4.3 The IRB will review the study concurrently with the IBC but will not issue an approval letter until both committees have approved the study.

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

- 4.4.1 When reviewing individual HGT studies, the IRB reserves the right to perform a RAC assessment review or to defer to the IBC to make this assessment, or abstain.

5 PROCEDURE

5.1 Investigators submit all information and documents required by the IRB and IBC for genetic research and/or gene transfer research in the eProst new study application.

- 5.1.1 The Informed Consent Documents must include appropriate descriptions of what the research will be used for, the related procedures and any reasonably foreseeable risks.

5.2 The IRB may determine that NIH Recombinant DNA Advisory Committee (RAC) review of human gene transfer protocols would support their ability to weigh the potential risks and benefits of the proposed protocol and attest that the criteria below apply:

5.2.1 The protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk.

5.2.2 The protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value.

5.2.3 The proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies to evaluate the protocol rigorously.

5.3 Any decisions of the IRB to request full RAC review, defer to the IBC for such a determination or abstain from making an assessment will be provided to the NIH in writing.

6 MATERIALS

6.1 None

7 REFERENCES

7.1 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines): Frequently Asked Questions about the Registration and Review Process for Human Gene Transfer Protocols (updated 2016)