UNIVERSITY OF MIAMI

SOP: Embryonic Stem Cell research and Human Studies Review Processes				
NUMBER	DATE	AUTHOR	APPROVER	PAGE
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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 Embryonic Stem Cell Oversight Committee (ESCRO) provides oversight over all issues related to derivation and use of human embryonic stem cells (hESCs) and human somatic cell nuclear transfer (hSCNT), including establishing and modifying policies and procedures; assures all research involving hESCs and hSCNTs conducted at the University or by University investigators is compliant with all relevant local, state and federal regulations and within the NAS/IOM report "Guidelines for Human Embryonic Stem Cell Research" or any subsequent revisions or replacements of those guidelines.

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

2 RESPONSIBILITIES OF IRB

2.1 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.

2.2 Clinical Trials involving hESCs and hSCNTs must be approved by the ESCRO committee prior to receipt of IRB approval. Studies involving hESCs and hSCNTs will be routed to ESCRO by eProst upon receiving submission by the PI. The IRB will review the study concurrently with the ESCRO committee but will not issue an approval letter until both committees have approved the study.

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

3 RESPONSIBILITIES OF ESCRO

3.1 The ESCRO committee maintains registries of hESC and hSCNT research conducted at the University and of hESCs derived or imported by University investigators; reviews the proposed research, informed consent documents, and additional information, when applicable, to determine whether the criteria for approval meets UM guidelines and relevant regulations and within the NAS/IOM report "Guidelines for Human Embryonic Stem Cell Research"

4 PROCEDURE FOR SUBMISSION FOR IRB

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

4.1.1 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.

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

5 PROCEDURE FOR SUBMISSION FOR IBC

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

5.1.1 ESCRO submission form

5.1.2 The Material Transfer document

5.1.3 Informed consent for the use of the obtained hESCs

5.2 Once ESCRO committee approval is given for ESCRO clinical studies, the ESCRO office gives approval in eProst as an ancillary committee,

6 MATERIALS

6.1 None

7 REFERENCES

7.1 National Academies of Sciences "Guidelines for Human Embryonic Stem Cell Research." (2005 and subsequent updates)