

AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD

REQUEST FOR DETERMINATION OF NON-HUMAN SUBJECT RESEARCH
For Stem Cell Research

For help, contact: THE OFFICE OF RESEARCH COMPLIANCE (ORC), 115 Ramsay Hall, Auburn University
Phone: 334-844-5966 e-mail: IRBAdmin@auburn.edu Web Address: http://www.auburn.edu/research/vpr/ohs

Revised 2/1/2014 Submit completed form to IRBsubmit@auburn.edu or 115 Ramsay Hall, Auburn University 36849.

Form must be populated using Adobe Acrobat / Pro 9 or greater standalone program (do not fill out in browser). Hand written forms will not be accepted.

All research involving human subjects at Auburn University must be reviewed by the IRB. If you are unsure whether your study is "research" or involves "human subjects", you may request a determination from the IRB. Determinations will be made after completion and submission of this form for IRB review.

Reference information:

- 1. List of identifiers that, if collected, would qualify the research as "human subject research"
2. Determination of "Research" or "Human Subject"

1. Project Personnel

Principal Investigator (PI):

Name Title Dept/School
Dept Head Address
Campus phone Alternate phone
AU E-mail Alternate e-mail

Co-Investigator (if applicable): (additional co-investigators may be added as an attachment)

Name Title Institution
Dept/School Address
Campus phone Alternate phone
AU Email Alternate Email

Faculty Advisor (if applicable):

Name Title Dept/School
Address
Campus phone Alternate phone
AU E-mail Alternate e-mail

2. Study Information

Title

Source of Funding: [] Investigator [] Internal [] External

List External Agency & Grant Number:

AU Facilities where research will be conducted:

BUA Authorization #:

3. Project Description

a. **Brief Summary:** Please include a brief non-technical description of your research aims and methods. Include a brief summary as to how the research is intended to benefit human health and /or advance science and knowledge. (If you are requesting determination for use of human induced pluripotent stem cells, indicate that your research does not involve any of the following which would require IRB approval: introduction of the cells into humans; introduction of the cells into the central nervous system of non-human primates; introduction of the cells into non-human animals and there is a reasonable possibility of the cells giving rise to gametes; or creation of gametes or embryos.

b. **Cell Line Information:** Please check the category that best describes this project and describe:

1) In vitro research involving human induced pluripotent stem cells (non-embryonic) – identify source, IRB approvals relating to how they were obtained and methods of de-identifying the cell line:

2) In vitro research involving human embryonic stem cells (HES) cell lines that are listed on the NIH Human Embryonic Stem Cell Registry. Include information describing source and identification of cell line:

Any other method of obtaining or use of human pluripotent stem cells would require submission of an IRB protocol with approval by the Auburn Stem Cell Oversight group and the IRB.

Signature of Investigator _____ Date _____

Signature of Faculty Advisor _____ Date _____

FOR ORC OFFICE USE ONLY

DATE RECEIVED IN ORC: _____ by _____ IRB Tracking #: _____

Auburn University's Institutional Review Board Determination

Based on the information provided by the Investigator, the Auburn IRB has determined that this project:

- DOES NOT** qualify as human subject research as outlined in 45 CFR 46.102(d) and (f) and **is not subject to oversight by the Auburn IRB.**
- DOES** qualify as human subject research. **PI must submit a request for protocol review.**

Comments:

IRB Reviewer:

Signature _____ Printed Name _____ Date _____