

**CERTIFICATIONS FOR THE PROTECTION OF HUMAN SUBJECTS AND
REGARDING THE USE OF HUMAN EMBRYONIC STEM CELL RESEARCH**

Principal Investigator Name and Title:

Research Project Title:

Principal Investigator's Institution:

CERTIFICATION FOR THE PROTECTION OF HUMAN SUBJECTS

It is the responsibility of the research institution to assure that the rights and welfare of all human subjects used in any Pennsylvania Department of Health sponsored research are protected. Any research involving human subjects must be reviewed and approved by an appropriate institutional review board ("IRB").

The applicant agrees to safeguard the rights and welfare of individuals who participate in research activities. The applicant agrees that all experimentation with human subjects shall be prohibited unless the applicant certifies that the prior written approval of its IRB is obtained or is not required, subject to all applicable laws, including but not limited to 42 U.S.C. Section 3515 (b) (relating to prohibitions on funding certain experiments involving human participants) and the regulations thereunder. In addition, such experimentation or research projects involving human subjects must be submitted to the Department's IRB on the form entitled, "Application to the Pennsylvania Department of Health Institutional Review Board for Approval of Research Project under the Federal Policy for the Protection of Human Subjects." Further, the applicant must obtain the written, voluntary, informed consent of each subject. If the subject is a minor, or incompetent, the applicant must obtain the written, voluntary, informed consent of their legal guardian. The applicant shall inform each potential subject prior to their consent that refusal shall not result in the loss of any benefits to which the subject is otherwise entitled from the federal government, the Commonwealth, the applicant, any subcontractor of the applicant, or any third-party insurer.

Please check the appropriate statement:

☐ No human subjects will be used in any of the proposed research.

☐ Human subjects will be used in the proposed research. This is to certify that the proposed activities on human subjects have been reviewed by an IRB on _____ (date) and found to be in accordance with current Department of Health and Human Services policy.

☐ Human subjects will be used in the proposed research. This is to certify that the proposed activities on human subjects have NOT been reviewed by an IRB and that prior to initiating research involving human subjects, the applicant will submit to the Department the form entitled, "Application to the Pennsylvania Department of Health

Institutional Review Board for Approval of Research Project under the Federal Policy for the Protection of Human Subjects.”

**CERTIFICATION REGARDING THE USE OF HUMAN EMBRYONIC STEM CELL
RESEARCH**

Please check the appropriate statement:

☐ No human embryonic stem cells will be used in any capacity in the proposed research.

☐ Human embryonic stem cells that are approved by the National Institutes of Health and derived from outside of Pennsylvania will be used in the proposed research project.

Applicant Organization

Name and Title of Applicant's Authorized Official

Signature of Applicant's Authorized Official

Date