Supporting Statement A for

Reinstatement of Approval for
NIH Form 2890
OMB Control Number 0925-0601

Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research (OD)

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Attachment 2 - Instructions for NIH Form 2890 - Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research
Attachment 3 – Decision tree to assist users with Selection of Method of Review

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

President Barack H. Obama issued Executive Order (EO)13505 *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells* on March 9, 2009. The EO states that the Secretary of Health and Human Services, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law. The EO also directs the Secretary, through the Director of NIH, to review existing NIH guidance and other widely recognized guidelines on human stem cell research, including provisions establishing appropriate safeguards, and issue new NIH Guidelines on such research.

The NIH Guidelines for Human Stem Cell Research (Guidelines) implementing the EO and establishing policy and procedures under which the NIH will fund such research became effective on July 7, 2009, and are available at http://stemcells.nih.gov/index.asp. The Guidelines provide scientists who apply for NIH funding with a specific set of standards reflecting currently recognized ethical principles and practices specific to embryo donation, and prescribe the assurances and supporting documentation necessary for NIH funding of research using hESCs, and describe research that is not eligible for NIH funding. The Guidelines establish a new NIH Registry of eligible hESC lines that comply with the set of standards described in the Guidelines. NIH will also post lines that are not approved for use in NIH funding.

OMB approved an emergency request on August 3, 2009, for data collection for the purpose of reviewing requests for inclusion of hESC lines in the NIH Human Embryonic Stem Cell Registry in order to establish eligibility for NIH funding. This is a reinstatement of the same data collection.

A.2 Purpose and Use of the Information Collection

The **Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research** (hereafter referred to as Form 2890) will be used by respondents who have hESC lines and wish for the lines to be approved for use in NIH funded research. NIH will review the requests in accord with the NIH Guidelines, by either Administrative Review, or review by the Working Group of the Advisory Committee to the [NIH] Director. Those hESC lines that NIH determines meet the criteria of the Guidelines will be posted on the NIH Registry and NIH funded researchers will be required to cite lines from the Registry when applying to the NIH for hESC funding. The information also will be used for program management, as well as for reporting to Congress and to the public on hESC lines that are eligible for NIH funding. Applicants will cite the lines on applicable grant applications, the PHS 398 and 398 components, and the PHS 416, approved by OMB under 0925-0001 and 0925-0002, respectively.

A.3 Use of Information Technology and Burden Reduction

Form 2890 will be provided exclusively in a web-based format on the NIH web site, and electronic submission of the data-collection instrument will be authenticated against personal profiles and sign-on credentials in the eRA Commons database. To the extent possible, data contained in the eRA Commons account of the respondent will be used to pre-populate the respondent's name, institution and contact information on Form 2890 to reduce the need for respondents to enter data already in an NIH system. The eRA Commons is already cleared under 0925-0001 as a secure, centralized electronic system used for NIH grant activity and other related resource access. This new web-based Form 2890 will be fully integrated with existing electronic systems to minimize the new data being collected. In addition, the NIH Registry is will be integrated with existing electronic systems used to support NIH grant application processes.

The IT System owner/manager is conducting a Privacy Impact Assessment for review and approval by the NIH Senior Official for Privacy.

A.4 Efforts to Identify Duplication and Use of Similar Information

The NIH Guidelines require that NIH conduct a de novo review of hESC lines to determine eligibility for NIH funding. Lines in the former NIH Registry were required to meet different criteria, and therefore do not necessarily comply with the new Guidelines. While NIH considered ethical standards and/or guidelines developed by various states, countries, and other entities such as the International Society for Stem Cell Research (ISSCR) in its development of the Guidelines, there is no existing registry or stem cell bank that includes hESC lines that conform to the exact specifications of the NIH Guidelines. Integration of Form 2890 with the existing eRA Commons will also eliminate any duplicative data collection.

A.5 Impact on Small Businesses or Other Small Entities

The procedures for small businesses and other small entities are the same as for other respondents and do not require special accommodation.

A.6 Consequences of Collecting the Information Less Frequently

Form 2890 represents a one-time information collection. NIH decisions regarding the inclusion on the Registry of a hESC line as eligible for NIH funding are final.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

No special circumstances are anticipated.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

NIH published draft guidelines for research involving hESCs in the Federal Register for public comment, 74 FR 18578, on April 23, 2009. The comment period ended on May 26, 2009. Approximately 49,000 comments on the draft guidelines were submitted to NIH by patient advocacy groups, scientists and scientific societies, academic institutions, medical organizations, religious organizations, private citizens, and members of Congress. Public comments on the draft Guidelines are available at http://stemcells.nih.gov/index.asp. NIH considered the comments that addressed provisions of the draft guidelines and published a summary and NIH response to the comments in the preamble to the final Guidelines (74 FR 32170).

The 60-day FR Notice concerning Form 2890 was published September 25, 2009 (74 FR 48973); no comments were received.

A.9 Explanation of Any Payment of Gift to Respondents

There are no plans for payments or gifts to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

Personally identifiable information stored in the eRA Commons database in association with the respondent is maintained in a Privacy Act record system (09-25-0036). Information submitted to NIH via Form 2890 will be subject to the Freedom of Information Act (FOIA). The Instructions to Form 2890 (Attachment 2) clearly notify respondents that all materials submitted or saved on the NIH server will be subject to the FOIA and instruct them not to submit consent documents with the personally identifying information of donor(s) of embryos (the individuals who sought reproductive treatment). Submission of consent documents with such information will cause NIH to invalidate a request and delete all submitted information from the NIH database.

A.11 Justification for Sensitive Questions

No questions of a sensitive nature are requested on Form 2890.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

A.12.1 Estimates of Hour Burden

Types of Respondents	Number of Respondents	Frequency of Response	Average Response Time	Annual Hour Burden
NIH grantees and others with hESC lines	100 per year	One time	3 hours	300

The estimated average time to complete Form 2890 is 3 hours, including 2.5 hours to collect and prepare supporting information and 30 minutes to physically complete the form and upload all supporting information. The average number of submissions per year is estimated to be 100.

A.12.2 Estimated Annualized Cost to Respondents

Average Hourly Rate	Annual Hour Burden	Frequency of Response	Annualized Cost to Respondents
$35.	300	One time	$10,500

The average hourly rate used for all burden hours ($35) represents an average of combined clerical ($15), administrative ($25), and professional staff ($45) hourly rates.

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

Other annual costs to respondents or record keepers are associated with customary and usual business or practices of organizations applying for PHS funding.

A.14 Annualized Cost to the Federal Government

The estimated annual cost to NIH is approximately $300,000 per year. This figure represents the approximate cost for the administration and management of the NIH Registry, including review of hESCs submitted via Form 2890 by NIH and by the Working Group of the ACD, posting the hESC lines on the Registry, maintenance of the Registry, etc.

A.15 Explanation for Program Changes or Adjustments

There are no substantive changes to the data collection. This is a reinstatement of a previously approved submission. The minor adjustments to Form 2890 and related

instructions are: (1) requests may be submitted by either the Signing Official for the organization, or another appropriate individual within the organization who has an eRA Commons UserID and Password, provided that the Signing Official approved the submission and provides the necessary certification and assurance via a signed letter on institutional letterhead, and, (2) NIH now encourages users to select NIH Administrative Review if they believe that the cell line meets the Section II(A) requirements of the Guidelines, and if NIH determines that the line is not approvable under Section II(A) then NIH will refer the submission for review by the Advisory Committee to the Director under Section II(B) of the Guidelines.

A.16 Plans for Tabulation and Publication and Project Time Schedule

This request is for approval of use of forms related to administration of PHS research programs; there is no tabulation, publication, or project time schedule.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The expiration date will be displayed on the main page of the web-based form.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

This project conforms to all of the 5 CFR 1320.9 requirements; no exceptions are requested.