Clarifying revisions in yellow 7 October 2019

Supporting Statement A for

Request for Human Embryonic Stem Cell Line to be Approved

for Use in NIH Funded Research (OD)

OMB Control Number 0925-0601, exp., date 7/31/2019

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Check off which applies:

- New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- X Extension
- Emergency
- Existing w/o OMB approval

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Attachments:

Attachment 1 NIH Form 2890: Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research

Attachment 2 NIH Form 2890 Privacy Impact Assessment

Attachment 3 30-day Federal Register Notice

A. Justification

This is an extension of 0925-0601, Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research. Executive Order (EO) 13505 states that NIH may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research. The NIH Guidelines for Human Stem Cell Research (Guidelines), implementing the EO, established an NIH Registry of eligible hESC lines that comply with the set of standards described in the Guidelines. The Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research will continue to be used by respondents who have hESC lines and wish for the lines to be approved for use in NIH funded research.

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 stated 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 directed 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/policy/pages/2009guidelines.aspx. 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, 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 established a new NIH Registry of eligible hESC lines that comply with the set of standards described in the Guidelines. NIH also posts information on cell lines that are not approved for use in NIH funding.

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; see Attachment 1) will continue to be used by respondents who have hESC lines and wish for the lines to be approved for use in NIH funded research. NIH will continue to 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 continue to be posted on the NIH Registry and NIH funded researchers will continue to be required to reference the hESC lines from the Registry proposed to be used when applying to the NIH for research funding that involves the use of hESCs. 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 the PHS 398 and 398 components and the PHS 416, approved by OMB under 0925-0001, Expiration Date: March 31, 2020; and the PHS2590 and NIH Implementation of the Research Performance Progress Report (RPPR) approved by OMB under 0925-0002,

Expiration Date: March 31, 2020. During the last three years, NIH has approved 36 hESC lines for use in NIH-funded research; NIH also disapproved 5 hESC lines due to inadequacies in the embryo donation consent process.

A.3 Use of Information Technology and Burden Reduction

Form 2890 will continue to be provided exclusively in a web-based format on the NIH web site, and electronic submission of the data-collection instrument is 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 is 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 web-based Form 2890 is fully integrated with existing electronic systems to minimize the new data being collected. In addition, the NIH Registry is integrated with existing electronic systems used to support NIH grant application processes.

The IT System owner/manager conducted a Privacy Impact Assessment (see Attachment 2), which was reviewed and approved by the NIH Senior Official for Privacy and has been renewed yearly.

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

There is no duplication in data collection by NIH about hESC lines, and no changes regarding the collection of information are proposed in this extension request.

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 an hESC line as eligible for NIH funding are generally final.

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

No special circumstances are anticipated.

A.8.1 Comments in Response to the Federal Register Notice

The 60-day FR Notice concerning Form 2890 was published on May 16, 2019, volume 84, number 95, page 22153; no comments were received.

A.8.2 Efforts to Consult Outside Agency

Within the last three years, Office of the Director staff have advised several applicants on how to minimize their burden in the submission of information to NIH.

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 (09-25-0225; Electronic Research Administration (eRA) Records, HHS/NIH/OD/OER). Information submitted to NIH via Form 2890 is subject to the Freedom of Information Act (FOIA). The Instructions to Form 2890 (see Attachment 1: NIH Form 2890) clearly notify respondents that all materials submitted or saved on the NIH server will be treated by NIH as information which may be made available to the public, and instructs them not to submit financial, commercial, confidential or proprietary information, including 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 delete the submitted information from the NIH database and could invalidate the request.

A.11 Justification for Sensitive Questions

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

A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

The estimated number of respondents in this extension request is smaller as compared to prior requests, because the actual number of respondents to NIH over the past few years has decreased.

Table 12-1 Estimated Annualized Burden Hours

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
2890	NIH grantees and others in possession of hESC lines	5	3	17	255
Total			15		255

A.12-2 ANNUAL COST TO RESPONDENT

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
NIH grantees and others in possession of hESC lines	255	$42.86	$10,929.30
TOTAL			$10,929.30

*Source: U.S. Bureau of Labor Statistics, May 2018 National Occupational Employment and Wage Estimates; https://www.bls.gov/oes/current/oes_nat.htm; occupation code 19-0000 life scientist

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

There are no other costs, other than time, to participate.

A.14 Annualized Cost to the Federal Government

The annualized cost to the government is $26,117.

Cost Descriptions	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
NIH Senior Policy Analyst	GS-15/Step 10	$164,200	10%		$16,420
NIH Policy Analyst	GS-13/Step 1	$96,970	10%		$9,697
Contractor Cost					
Total					$26,117

*the Salary in table above is cited from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/18Tables/html/DCB.aspx

A.15 Explanation for Program Changes or Adjustments

This is an extension of a currently approved submission. There are no substantive changes to the data collection. The estimated number of respondents in this extension request is smaller as compared to prior requests, because the actual number of respondents to NIH over the past few years has decreased. Through Form 2890, NIH receives information from institutions about human embryonic stem cell lines that they have derived. NIH then determines whether the embryo donation consent process meets the strict requirements in NIH policy for use of the cell lines by NIH-funded investigators. NIH does not fund the derivation of the cell lines and is not involved in the decisions that institutions make regarding derivation of new cell lines. In recent years, there have been fewer submissions to NIH about newly derived cell lines. So in the extension request, we are simply reflecting the most recent data in the number of submissions to NIH.

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. Data collection activities are ongoing.

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

None. 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

None