

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)**

April 2013

Name: Ellen Gadbois
Address: Office of Science Policy
National Institutes of Health
Building 1, Room 281, MSC 0166
9000 Rockville Pike
Bethesda, MD 20892
Telephone: 301-594-2567
Fax: 301-402-0280
Email: gadboisel@od.nih.gov

Table of contents

A. JUSTIFICATION.....3

A.1 CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY.....3

A.2 PURPOSE AND USE OF THE INFORMATION COLLECTION.....3

A.3 USE OF INFORMATION TECHNOLOGY AND BURDEN REDUCTION.....4

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION.....4

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES.....4

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY.....4

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5.....4

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE AGENCIES.....4

A.9 EXPLANATION OF ANY PAYMENT OF GIFT TO RESPONDENTS.....5

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS.....5

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS.....5

A.12 ESTIMATES OF HOUR BURDEN INCLUDING ANNUALIZED HOURLY COSTS.....5

A.13 ESTIMATE OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS.....6

A.14 ANNUALIZED COST TO THE FEDERAL GOVERNMENT.....6

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS.....6

A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE.....6

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE.....6

A.18 EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS7

LIST OF SUPPORTING STATEMENT ATTACHMENTS

Attachment 1 – PDF version of NIH web-based Form 2890 - Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research

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, 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 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) 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: 08/31/2015; and the PHS2590 and NIH Implementation of the Research Performance Progress Report (RPPR) approved by OMB under 0925-0002, Expiration Date: 08/31/2015.

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, 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

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, under prior Presidential policy, were required to meet different criteria, and therefore do not necessarily comply with the new 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 eliminates 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 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 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies

The 60-day FR Notice concerning Form 2890 was published Thursday, February 28, 2013 (78 FR 13688); 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 is 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 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 Estimates of Hour Burden Including Annualized Hourly Costs

A.12.1 Estimates of Hour Burden

Types of Respondents	Number of Respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
NIH grantees and others in possession of hESC lines	50	3	17	2,550

The estimated average time to complete Form 2890 is 17 hours, including time to collect and prepare supporting information, physically complete the form, and upload all supporting information. The average number of submissions per year is estimated to be 150.

A.12.2 Estimated Annualized Cost to Respondents

Average Hourly Rate	Annual Hour Burden	Frequency of Response	Annualized Cost to Respondents
\$35.35	2,550	One time per submission	\$90,143

The average hourly rate used for all burden hours (\$35.35) represents an average of combined office & administrative support (\$16.54), life scientist (\$37.32), and management (\$52.20) mean hourly rates. (Source: U.S. Bureau of Labor Statistics, May 2012 National Occupational Employment and Wage Estimates, United States. Occupation codes: 43-0000 office & administrative support, 19-1000 life scientist, 11-0000 management.)

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 \$187,000 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. The minor adjustments to Form 2890 and related instructions are: (1) clarification of the date format for responding to question 10, (2) a description of the potential types of supporting information pertaining to question 11, and (3) a slightly different process for making changes to a submission, described in the instructions under “Final Submission and Email Confirmation.”

The estimated annualized cost to respondents is lower than in the February 28, 2013, Federal Register notice, as it is based on additional information from institutions that have used the submission system.

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.