Supporting Statement A for

**Extension**

**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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## 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 a new 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 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/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 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: October 31, 2018; and the PHS2590 and NIH Implementation of the Research Performance Progress Report (RPPR) approved by OMB under 0925-0002, Expiration Date: October 31, 2018. During the last three years, NIH has approved 153 human embryonic stem cell lines for use in NIH-funded research.

### 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.8.1 Comments in Response to the Federal Register Notice**

The 60-day FR Notice concerning Form 2890 was published on March 25, 2016, page 16190; no comments were received.

**A.8.2 Efforts to Consult Outside Agency**

Staff from relevant NIH Institutes and Centers were consulted in developed of Form 2890, including Dr. Sally Rockey, Director, Office of Extramural Research; Ms. Barbara McGarey, NIH Legal Advisor, Office of the General Counsel; Dr. Story Landis, Director, National Institute of Neurological Diseases and Disorders; Dr. James Battey, Director, National Institute of Deafness and Communication Disorders; and additional staff from those offices and institutes.

**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 (See Attachment: Form 2890 Webpages Portfolio) 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 Estimated Annualized Burden Hours

**A.12-1 Estimated Annualized Burden Hours**

| Form Name | Type of Respondent | Number of Respondents | Number of Responses per Respondent | Average Burden Per Response (in hours) | Total Annual Burden Hour |
|---|---|---|---|---|---|
| 2890 | NIH grantees and others in possession of hESC lines | 50 | 3 | 17 | 2,550 |
| Total: | | 50 | 150 | | 2,550 |

### A.12-2 Annualized Cost to respondents

A.12-2 Annualized Cost to the Respondents

| Type of Respondent | Number of Respondents | Average Burden Per Response (in hours) | Hourly Wage Rate* | Respondent Cost |
|---|---|---|---|---|
| NIH grantees and others in possession of hESC lines | 50 | 51 | $35.35 | $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

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

### A.14 Annualized Cost to the Federal Government

| Staff | Grade/Step | Salary | % of Effort | Fringe (if applicable) | Total Cost to Gov't |
|---|---|---|---|---|---|
| **NIH Senior Policy Analyst** | GS-15/Step 7 | 123,178 | 10% | | 12,317 |
| **NIH Policy Analyst** | GS-14/Step 2 | 90,172 | 10% | | 9,172 |
| **NIH Policy Analyst** | GS-13/Step 1 | 73,846 | 10% | | 7,384 |
| **Total** | | | | | 28,873 |

### 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.

### 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

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

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