



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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To: Office of Management and Budget (OMB)

Through: Marilyn Tuttleman, NIH Project Clearance Officer, OPERA, OER, OD

From: Pam Gilden, Grants Policy Analyst
Division of Grants Policy
Office of Policy for Extramural Research Administration
Office of Extramural Research, OD, NIH

Subject: **Amendment to the PHS 416-9, Form Page 2 (OMB No. 0925-0002
Exp. Date 06/2012)**

OMB approved this form set on 6/30/2009. These forms enable public and private organizations to compete for funds appropriated to the various components of the Public Health Service. The particular form for which we are seeking a change is the PHS 416-9, Individual Fellowship Progress Report for Continuation Support. This form is submitted at the end of each non-competing year of a project period and used by NIH extramural program officials and grants management specialists to ascertain progress under an award, plans for the ensuing year, compliance with applicable policies, procedures and terms, collect workforce tracking data, and determining funding for the ensuing year under the project period.

Since the last submission of 0925-0002, President Barack H. Obama issued Executive Order 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*. NIH implemented the Executive Order, as it pertains to extramural NIH funded stem cell research, by establishing policy and procedures under which the NIH will fund such research, and, in accord with the Executive Order, ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. The NIH Guidelines on Human Stem Cell Research also establish a new NIH Registry of human embryonic stem cell (hESC) lines eligible for use in NIH-supported research.

In order to help evaluate hESC research conducted in NIH-funded projects, and grantee compliance with July 6, 2009 NIH Guidelines, we propose to add a line to the Individual Fellowship Progress Report for Continuation Support, Form Page 2, asking the grantee to identify whether there has been a change in the hESC line(s) used, and if

so, to address the change in the Progress Report. This places hESC research in the same category as the following other highly critical research issues about which the grantee must identify any changes over the preceding year: involvement of human subjects, use of vertebrate animals, select agent research, and multiple Program Investigator leadership plan. A copy of Form Page 2, with the new hESC change (item 15.) highlighted.

We request prompt evaluation of this change so that we may implement it simultaneously with the NIH Guidelines on Human Stem Cell Research.

We do not estimate that the total burden hours currently associated with the PHS 416-9 (see below) will change as a result of adding this yes/no checkbox.

Estimates of Hour Burden				
Types of Respondents	Number of Respondents	Frequency of Response	Average Response Time	Annual Hour Burden
NIH Grantees	1,832	annually	15 hours	27,480

OMB approval of this revised form will give NIH the necessary tool to track use of particular hESCs that are on the NIH Registry, ensure that when grantees add new hESCs that they only add lines that are eligible for NIH funding, and determine the level of use of various lines and the scientific value of certain lines for particular areas of research.

Thank you for your consideration of this proposed amendment to the PHS 416-9.

Attachment: Amended Form Page 2 with change highlighted.