(v) Disclosure of the possibility that the results of research on the human pluripotent stem cells may have commercial potential, and a statement that the donor will not receive financial or any other benefits from any such future commercial development; and

(vi) A statement that the research is not intended to provide direct medical benefit to the donor.

c. Derivation protocols should have been approved by an IRB established in accord with 45 CFR 46.107 and 46.108 or FDA regulations at 21 CFR 56.107 and 56.108.

III. Areas of Research Involving Human Pluripotent Stem Cells That Are Ineligible for NIH Funding

Areas of research ineligible for NIH funding include:

A. The derivation of pluripotent stem cells from human embryos;

B. Research in which human pluripotent stem cells are utilized to create or contribute to a human embryo;

C. Research utilizing pluripotent stem cells that were derived from human embryos created for research purposes, rather than for fertility treatment;

D. Research in which human pluripotent stem cells are derived using somatic cell nuclear transfer, *i.e.,* the transfer of a human somatic cell nucleus into a human or animal egg;

E. Research utilizing human pluripotent stem cells that were derived using somatic cell nuclear transfer, *i.e.,* the transfer of a human somatic cell nucleus into a human or animal egg;

F. Research in which human pluripotent stem cells are combined with an animal embryo; and

G. Research in which human pluripotent stem cells are used in combination with somatic cell nuclear transfer for the purposes of reproductive cloning of a human.

IV. Oversight

A. The NIH Human Pluripotent Stem Cell Review Group (HPSCRG) will review documentation of compliance with the Guidelines for funding requests that propose the use of human pluripotent stem cells. This working group will hold public meetings when a funding request proposes the use of a line of human pluripotent stem cells that has not been previously reviewed and approved by the HPSCRG.

B. In the case of new or competing continuation (renewal) or competing supplement applications, all applications shall be reviewed by HPSCRG and for scientific merit by a Scientific Review Group. In the case of requests to use existing funds or applications for an administrative supplement or in the case of intramural proposals, Institute or Center staff should forward material to the HPSCRG for review and determination of compliance with the Guidelines prior to allowing the research to proceed.

C. The NIH will compile a yearly report that will include the number of applications and proposals reviewed and the titles of all awarded applications, supplements or administrative approvals for the use of existing funds, and intramural projects.

D. Members of the HPSCRG will also serve as a resource for recommendations to the NIH with regard to any revisions to the NIH Guidelines for Research Using Human Pluripotent Stem Cells and any need for human pluripotent stem cell policy conferences.

Dated: August 17, 2000.

Ruth L. Kirschstein,

Principal Deputy Director, NIH.

[FR Doc. 00–21760 Filed 8–23–00; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notification of Request for Emergency Clearance; Modification of OMB No. 0925–0001/Exp. 2/01, ''PHS 398 Research and Research Training Grant Applications and Related Forms''

SUMMARY: In accordance with section 3507(j) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) hereby publishes notification of a request for Emergency Clearance for modification of the information collection related to the National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, published elsewhere in today's **Federal Register**. The currently approved information collection OMB No. 0925–0001 permits the NIH to request from applicant institutions information related to application, award, and continued compliance with the terms of Federal assistance for research and research-related training. The approval also covers the information collection authorized in accordance with 42 CFR 52, specifically the obtaining of ''[o]ther pertinent information the Secretary may require to evaluate the proposed project.'' (42 CFR 52.4(f))

The final National Institutes of Health Guidelines for Research Using Pluripotent Stem Cells requires submission of additional documentation in the form of additional institutional records from a limited number of institutions to enable an independent panel of non-Government experts to ascertain institutional compliance with the Guidelines. Compliance with the requirements of existing law and regulations is authorized under OMB No. 0925–0418, Exp. 1/01, ''Protection of Human Subjects: Assurance Identification/Certification/ Declaration.''

The present modification relates to the added reporting requirement of submission of documentation to permit the agency to exercise the oversight responsibility established under the Guidelines.

This modification is essential to the mission of NIH (42 USC 241 and 282(b)) and is of the highest scientific priority as determined by both internal review and external review by a panel of scientific and other experts in the field of stem cell research. After extensive consultation with the public and a public meeting, the NIH published proposed National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells in the **Federal Register** on December 2 , 1999 (**Federal Register**, Vol. 64, No. 231, pages 67576–67579). The comment period was extended to February 22, 2000. (**Federal Register**, February 3, 2000, Vol. 65, No. 23, page 539). Following the period of comment, NIH has proceeded to finalize the Guidelines, which are published elsewhere in this issue of the **Federal Register**.

These Guidelines are essential to ensure that NIH-funded research in this area is conducted in an ethical and legal manner. The NIH has determined that the oversight process stipulated in the Guidelines will achieve this objective. The Guidelines will require that institutions requesting or using NIH funds for research using human pluripotent stem cells submit additional documentation to the NIH in the form of institutional records that will permit NIH oversight in accordance with the Guidelines.

NIH has taken all practicable steps to consult with the scientific community and the public, through the process described above and through the careful consideration of all comments received from the public.

In view of the extensive period of comment and the thorough consideration of all views, both prior to the publication of the proposed Guidelines in December 1999 and subsequently, NIH is herewith requesting that OMB approve the modification of the collection of information simultaneously with the publication of the **Federal Register**

notice and the publication of the Guidelines in the **Federal Register**.

Proposed Collection

Title: Research and Research Training Grant Applications and Related Forms PHS–398 and PHS–2590.

Type of Information Collection Request: Revision.

Need and Use of Information Collection: The additional NEW reporting requirement is needed to ascertain compliance with the National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells. PHS–398 and PHS–2590 are used to apply for research project grants, Research Career Awards (RCA), and Institutional National Research Service Awards (NRSA).

Frequency of Response: On occasion and annually.

Affected Public: Individuals or households; business or other for-profit; not-for-profit institutions; Federal Government; and State, local or tribal government.

Type of Respondents: Research institutions.

The annual reporting burden was:

Estimated Number of Respondents: 111,482.

Estimated Number of Responses per Respondent: 1.05.

Average Burden Hours Per Response: 16.34.

Estimated Total Annual Burden Hours Requested: 1,913,166.

The NEW annual reporting burden is as follows:

Estimated Number of Respondents: 111,582.

Estimated Number of Responses per Respondent: 1.05.

Average Burden Hours Per Response: 16.33.

Estimated Total Annual Burden Hours Requested: 1,913,466.

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

FOR FURTHER INFORMATION CONTACT: The Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10235, Washington, D.C. 20503, Attention: Desk Officer for NIH.

Dated: August 17, 2000.

Ruth L. Kirschstein,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 00–21761 Filed 8–23–00; 8:45 am]

BILLING CODE 4140–01–P