agencies of Department of Health and Human Services (HHS), including the NIH, to authorize researchers conducting sensitive research to protect the privacy of human research subjects by enabling them to refuse to release names and identifying characteristics of subjects to anyone not connected with the research. At the NIH, the issuance of CoCs has been delegated to the individual NIH Institutes and Centers (ICs). To make the application process consistent across the entire agency, OER launched an electronic application system in 2015 that is used by research organizations that wish to request a CoC from any NIH IC. Having one system for all CoC applications to the NIH is more efficient for both applicants and NIH staff who process these requests. The NIH uses the information in the application to determine eligibility for a CoC and to issue the CoC to the requesting organization. It is anticipated that the NIH ICs will issue approximately 1300 new CoCs each year for eligible research projects.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total annualized burden hours estimate is 1,951.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Frequency of response	Average time per response (in hours)	Total annual burden hours
CoC Applicants—Private	455	1	90/60	683
CoC Applicants—State/local	650	1	90/60	975
CoC Applicants—Small business	130	1	90/60	195
CoC Applicants—Federal	65	1	90/60	98

Dated: October 25, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–26445 Filed 11–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Post-Award Reporting Requirements Including Research Performance Progress Report Collection (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Mikia P. Currie, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892, or call a non-toll-free number 301–435–0941 or Email your request, including your address to *trialsinfo@od.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Public Health Service (PHS) Post-award Reporting Requirements, Revision, OMB 0925–0002, Expiration Date 10/31/2018. Form numbers: PHS 2590, PHS 416–7, PHS 2271, PHS 3734, PHS 6031–1, and HHS 568. This collection represents a consolidation of post-award reporting requirements under the PRA, including the Research Performance Progress Report (RPPR). This collection includes the proposed additional reporting requirements for clinical trials.

Need and Use of Information Collection: The RPPR is now required to be used by all NIH, Food and Drug Administration, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality (AHRQ) grantees. Interim progress reports are required to continue support of a PHS grant for each budget year within a competitive segment. The phased transition to the RPPR required the maintenance of dual reporting processes for a period of time. Continued use of the PHS Non-competing Continuation Progress Report (PHS 2590), exists for a small group of grantees. This collection also includes other PHS post-award reporting requirements: PHS 416–7 National Research Service Award (NRSA) Termination Notice, PHS 2271 Statement of Appointment, 6031–1 NRSA Annual Payback Activities Certification, HHS 568 Final Invention Statement and Certification, Final Progress Report instructions, iEdison, and PHS 3734 Statement Relinquishing Interests and Rights in a PHS Research Grant. The PHS 416–7, 2271, and 6031–1 are used by NRSA recipients to activate, terminate, and provide for payback of a NRSA. Closeout of an award requires a Final Invention Statement (HHS 568) and Final Progress Report. iEdison allows grantees and federal agencies to meet statutory requirements for reporting inventions and patents. The PHS 3734 serves as the official record of grantee relinquishment of a PHS award when an award is transferred from one grantee institution to another. Pre-award reporting

requirements are simultaneously consolidated under 0925–0001 and the changes to the collection here are related. Clinical trials are complex and challenging research activities. Oversight systems and tools are critical for the NIH to ensure participant safety, data integrity, and accountability of the use of public funds. The NIH has been engaged in a multi-year effort to examine how clinical trials are supported and the level of oversight needed. The collection of more structured information in the PHS applications and pre-award reporting requirements as well as continued monitoring and update during the post-award reporting requirements will facilitate the NIH's oversight of clinical trials. In addition, some of the data reported in the RPPR will ultimately be accessible to investigators to update certain sections of forms when registering or reporting their trials with *ClinicalTrials.gov.*

Frequency of response: Applicants may submit applications for published receipt dates. For NRSA awards, fellowships are activated and trainees appointed.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 307,116.

ESTIMATED ANNUALIZED BURDEN HOURS

Information collection forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Reporting:				
PHS 416–7	12,580	1	30/60	6,290
PHS 6031–1	1,778	1	20/60	593
PHS 568	11,180	1	5/60	932
iEdison	5,697	1	15/60	1,424
PHS 2271	22,035	1	15/60	5,509
PHS 2590	243	1	15	3,645
RPPR—Core Data	32,098	1	8	256,784
Biosketch (Part of RPPR)	2,544	1	2	5,088
Data Tables (Part of RPPR)	758	1	4	3,032
PHS Inclusion Enrollment Report (Part of RPPR)	2,544	1	1	2,544
PHS Clinical Trial Report/Form (Part of RPPR)	8,264	1	1	8,264
Trainee Diversity Report (Part of RPPR)	480	1	15/60	120
Publication Reporting	32,341	3	5/60	8,085
PHS 3734	479	1	30/60	240
Final Progress Report	11,125	1	1	11,125
SBIR/STTR Phase II Final Progress Report	1,330	1	1	1,330
Reporting Burden Total	.....	.....	.....	306,741
Recordkeeping:				
SBIR/STTR Life Cycle Certification	1,500	1	15/60	375
Grand Total	.....	203,394	.....	307,116

Dated: October 22, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–26447 Filed 11–1–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the National Heart, Lung and Blood Institute, Office of Technology Transfer and Development, National Institutes of Health, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Methods for Artificial Oocyte Activation

Description of Technology

Available for licensing and commercial development for both human and veterinary uses is a method of activating mammalian oocytes. These methods include contacting a mammalian oocyte of interest arrested at metaphase II with an effective amount of a Regulator of G-Protein Signaling (RGS)2 inhibitor; and contacting the mammalian oocyte of interest with an effective amount of a G protein coupled receptor activator. In general, RGS proteins stimulate the hydrolysis of GTP bound to activated Gα subunits, leading to signal termination. RGS2, which inhibits both G-αq and G-αs signaling suppresses Ca2+ release in mature mammalian eggs. Regulators of G-Protein Signaling (RGS)2 inhibitor and a G protein coupled receptor activator can be used to artificially activate a mammalian oocyte such that it re-enters the cell cycle. Examples of RGS2 inhibitors can be nucleic acids like siRNAs or dsRNAs. G-protein coupled receptor activators can be acetylcholine, a neurotransmitter such as serotonin, hormones, natural or synthetic G