

TABLE 7—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS—Continued

PHS guideline section	Description of collection of information activity	21 CFR section (unless otherwise stated)
3.2.2	Document collaboration with accredited microbiology labs	312.52.
3.2.3	Procedures to ensure the humane care of animals	9 CFR parts 1, 2, and 3 and PHS Policy. ¹
3.2.4	Procedures consistent for accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) and consistent with the National Research Council's (NRC) Guide.	AAALAC International Rules of Accreditation ² and NRC Guide. ³
3.2.5, 3.4, and 3.4.1	Herd health maintenance and surveillance to be documented, available, and in accordance with documented procedures; record standard veterinary care.	211.100 and 211.122.
3.2.6	Animal facility SOPs	PHS Policy. ¹
3.3.3	Validate assay methods	211.160(a).
3.6.1	Procurement and processing of xenografts using documented aseptic conditions.	211.100 and 211.122.
3.6.2	Develop, implement, and enforce SOP's for procurement and screening processes.	211.84(d) and 211.122(c).
3.6.4	Communicate to FDA animal necropsy findings pertinent to health of recipient.	312.32(c).
3.7.1	PHS specimens to be linked to health records; provide to FDA justification for types of tissues, cells, and plasma, and quantities of plasma and leukocytes collected.	312.23(a)(6).
4.1.1	Surveillance of xenotransplant recipient; sponsor ensures documentation of surveillance program life-long (Justify >2 yrs.); investigator case histories (2 yrs. after investigation is discontinued).	312.23(a)(6)(iii)(f) and (g), and 312.62(b) and (c).
4.1.2	Sponsor to justify amount and type of reserve samples	211.122.
4.1.2.2	System for prompt retrieval of PHS specimens and linkage to medical records (recipient and source animal).	312.57(a).
4.1.2.3	Notify FDA of a clinical episode potentially representing a xenogeneic infection.	312.32.
4.2.2.1	Document collaborations (transfer of obligation)	312.52.
4.2.3.1	Develop educational materials (sponsor provides investigators with information needed to conduct investigation properly).	312.50.
4.3	Sponsor to keep records of receipt, shipment, and disposition of investigative drug; investigator to keep records of case histories.	312.57 and 312.62(b).

¹ The "Public Health Service Policy on Humane Care and Use of Laboratory Animals" (<https://www.grants.nih.gov/grants/olaw/references/phspol.htm>).

² AAALAC International Rules of Accreditation (<https://www.aaalac.org/accreditation/rules.cfm>).

³ The NRC's "Guide for the Care and Use of Laboratory Animals."

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 26, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

[FR Doc. 2019-08845 Filed 4-30-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; NIH Information Collection Forms To Support Genomic Data Sharing for Research Purposes (OD)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, for opportunity

for public comment on proposed data collection projects, the National Institutes of Health Office of the Director (OD) 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: Dr. Lyric A. Jorgenson, Acting Director, Division of Scientific Data Sharing Policy, Office of Science Policy, NIH, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892, or call non-toll-free number (301) 496-9838 or email your request including your address to: SciencePolicy@mail.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 minimize the burden of the collection of information from 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: NIH Information Collection Forms to Support Genomic Data Sharing for Research Purposes—0925–0670—Expiration Date 07/31/2019—EXTENSION—Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Sharing research data supports the National Institutes of Health (NIH) mission and is essential to facilitate the translation of research results into knowledge, products, and procedures that improve human health. NIH has longstanding policies to make a broad range of research data, including genomic data, publicly available in a timely manner from the research activities that it funds. Genomic research data sharing is an integral element of the NIH mission as it facilitates advances in our understanding of factors that influence health and disease, while also providing opportunities to accelerate research through the power of combining large and information-rich datasets. To promote robust sharing of human and non-human data from a wide range of large-scale genomic research and provide appropriate protections for

research involving human data, the NIH issued the NIH Genomic Data Sharing Policy (NIH GDS Policy). Human genomic data submissions and controlled-access are managed through a central data repository, the database of Genotypes and Phenotypes (dbGaP) which is administered by the National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH.

Under the NIH GDS Policy, all investigators who receive NIH funding to conduct large-scale genomic research are expected to register studies with human genomic data in dbGaP, no matter which NIH-designated data repository will maintain the data. As part of the registration process, investigators must provide basic study information such as the type of data that will be submitted to dbGaP, a description of the study, and an institutional assurance (*i.e.* Institutional Certification) of the data submission which delineates any limitations on the secondary use of the data (*e.g.*, data cannot be shared with for-profit companies, data can be used only for research of particular diseases).

Investigators interested in using controlled-access data for secondary research must apply through dbGaP and be granted permission from the relevant

NIH Data Access Committee(s). As part of the application process, investigators and their institutions must provide information such as a description of the proposed research use of controlled-access datasets that conforms to any data use limitations, agree to the Genomic Data User Code of Conduct, and agree to the terms of access through a Data Use Certification agreement. Requests to renew data access and reports to close out data use are similar to the initial data access request, requiring sign-off by both the requestor and the institution, but also ask for information about how the data have been used, and about publications, presentations, or intellectual property based on the research conducted with the accessed data as well as any data security issues or other data management incidents.

NIH has developed online forms, available through dbGaP, in an effort to reduce the burden for researchers and their institutional officials to complete the study registration, data submission, data access, and renewal and closeout processes.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 5,850.

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
Study Registration and Data Submission					
dbGaP Registration and Submission.	Investigator Submitting Data	300	1	1	300
	Institutional Official to Certify Submission.	300	1	30/60	150
Requesting Access to Data					
Data Access Request	Requester Submitting Request.	1,500	2	45/60	2,250
Data Access Request	Institutional Signing Official to Certify Request.	1,500	2	30/60	1,500
Project Renewal or Project Close-out					
Project Renewal or Project Close-out form.	Requester Submitting Request.	1,500 (same individuals as listed above).	2	15/60	750
Project Renewal or Project Close-out form.	Institutional Signing Official to Certify Request.	1,500 (same individuals as listed above).	2	18/60	900
Grand Total	6,600	12,600	5,850

Dated: April 23, 2019.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Cell Biology Integrated Review Group; Cellular Signaling and Regulatory Systems Study Section.

Date: May 23–24, 2019.

Time: 8:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Chevy Chase, 4300 Military Road NW, Washington, DC 20015.

Contact Person: David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892 301-435-1022, balasundaramd@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Behavioral Neuroscience.

Date: May 29–30, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront, 71 E Wacker Drive, Chicago, IL 60601.

Contact Person: Mei Qin, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, 301-875-2215, qinmei@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Social Sciences and Population Studies A Study Section.

Date: May 30–31, 2019.

Time: 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW, Washington, DC 20036.

Contact Person: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435-1712, ryansj@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 25, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-08780 Filed 4-30-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The cooperative agreement applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the cooperative agreement applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA-DK-18-014: Human Islet Research Network—Consortium on Targeting and Regeneration (HIRN-CTAR) (U01 Clinical Trial Not Allowed).

Date: June 5, 2019.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy

Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Najma S. Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, begumn@niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA-DK-18-015: Human Pancreas Analysis Program (HPAP-T1D).

Date: June 18, 2019.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Najma S. Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, begumn@niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA-DK-18-016: Human Pancreas Analysis Program for Type-2 Diabetes (HPAP-T2D).

Date: June 19, 2019.

Time: 12:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Najma S. Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, begumn@niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 25, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

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