

pharmaceuticals on the male reproductive system. The guidance discusses findings in nonclinical studies that may increase the level of concern for drug-related testicular toxicity. The guidance provides a general approach on how to weigh the relevance of nonclinical findings, considering factors that can confound the interpretation of these findings. If a concerning nonclinical signal is identified, the guidance presents suggestions for clinical monitoring when the product is initially administered to humans.

If a reasonable basis for concern of human testicular toxicity exists, a trial with a primary objective of evaluating drug-related testicular toxicity may be warranted. The guidance provides recommendations for the design of such a trial, including study conduct, endpoints, and presentation of results. These are general recommendations for defining the role of drugs in testicular injury; however, the specific details of an individual trial may vary depending on the context of use of the drug product.

This guidance finalizes the draft guidance of the same name issued on July 17, 2015 (80 FR 42501). Changes made to the guidance took into consideration written and verbal comments received. In addition to editorial changes primarily for clarification, the major changes in the guidance include revision of information on nonclinical study design (including species selection, chronic study design, histopathology assessment, sperm quality, and findings that increase concern for impaired fertility) and revision of information that, to the extent possible, subjects enrolled in the dedicated clinical safety trial represent the intended population.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the evaluation of testicular toxicity during drug development. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 (“Protection of Human Subjects: Informed Consent and Institutional Review Boards”) have been approved under OMB control number 0910–0755.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: October 19, 2018.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–23304 Filed 10–24–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0279]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 26, 2018.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0279

New-30D and project title for reference, to Sherrette.funn@hhs.gov, or call the Reports Clearance Officer at 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: 0990–0279—Extension—Institutional Review Board Registration Form.

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting an extension on a currently approved information collection by the Office of Management and Budget, on the Protection of Human Subjects, on the Institutional Review Board (IRB) Form. The purpose of the IRB Registration Form is to provide a simplified procedure for institutions engaged in research conducted or supported by HHS to satisfy the (1) HHS regulations for the protection of human subjects at 45 CFR 46.103(b), 45 CFR 46.107, and 45 CFR 46, subpart E, Registration of Institutional Review Boards; and, the Food and Drug Administration (FDA) regulations for institutional review boards at 21 CFR 56.106.

Likely Respondents: Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA’s requirements, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
IRB Registration Update	5,650	2	30/60	5,650

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE—Continued

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
IRB Registration Initial and Update	350	2	45/60	525
Total				6,175

Terry Clark,

Asst Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2018–23282 Filed 10–24–18; 8:45 am]

BILLING CODE 4150–36–P

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 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 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: Center for Scientific Review Special Emphasis Panel; Fellowships: Cell Biology, Developmental Biology, and Bioengineering.

Date: November 13–14, 2018.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4196, MSC 7812, Bethesda, MD 20892, 301–435–2902, gubina@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–HD–19–001 Safe and Effective Devices for Use in Neonatal, Perinatal and Pediatric Care Settings.

Date: November 15, 2018.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: JW Marriott New Orleans, 614 Canal Street, New Orleans, LA 70130.

Contact Person: Clara M. Cheng, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, 301–435–1041, chengc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Endocrinology, Metabolism, Nutrition and Reproductive Sciences.

Date: November 15–16, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: JW Marriott New Orleans, 614 Canal Street, New Orleans, LA 70130.

Contact Person: Clara M. Cheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, 301–435–1041, chengc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Translational Research in Pediatric and Obstetric Pharmacology and Therapeutics.

Date: November 16, 2018.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, dianne.hardy@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Discovery of Molecular Targets and Therapeutics for Pregnancy-Related Diseases; Drug Repurposing for Conditions Affecting Neonates and Pregnant Women.

Date: November 16, 2018.

Time: 3:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, dianne.hardy@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Blood and Vascular Biology.

Date: November 19–20, 2018.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ai-Ping Zou, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9497, zouai@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Musculoskeletal, Oral, Skin, Rheumatology and Rehab Sciences AREA (R15) Review.

Date: November 20, 2018.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Aftab A Ansari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, 301–237–9931, ansaria@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: October 19, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–23267 Filed 10–24–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning