

drugs. These incentives are only available to sponsors whose drugs are “MUMS-designated” by FDA. Minor use drugs are drugs for use in major species (e.g., cattle, horses, swine, chickens, turkeys, dogs, and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas. Minor species are all animals other than the major species (e.g., zoo animals, ornamental fish, parrots, ferrets, and guinea pigs). Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish,

and honeybees. Participation in the MUMS program is completely optional for drug sponsors, so the associated reporting only applies to those sponsors who request and are subsequently granted “MUMS designation.”

Our regulations in 21 CFR part 516 specify the criteria and procedures for requesting MUMS designation as well as the annual reporting requirements for MUMS designees. Section 516.20 provides requirements on the content and format of a request for MUMS-drug designation; § 516.26 provides requirements for amending MUMS-drug designation; § 516.27 provides for

change in sponsorship of MUMS-drug designation; § 516.29 provides for termination of MUMS-drug designation; § 516.30 contains the requirements for annual reports from sponsor(s) of MUMS-designated drugs; and § 516.36 sets forth consequences for insufficient quantities of MUMS-designated drugs.

Description of Respondents: The respondents to this information collection are pharmaceutical companies that sponsor new animal drugs.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING ¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
516.20; content and format of MUMS request	15	5	75	16	1,200
516.26; requirements for amending MUMS designation	3	1	3	2	6
516.27; change in sponsorship	1	1	1	1	1
516.29; termination of MUMS designation	2	1	2	1	2
516.30; requirements of annual reports	15	5	75	2	150
516.36; insufficient quantities	1	1	1	3	3
Total					1,362

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the investigational new animal drug/new animal drug application reporting requirements for similar actions by this same segment of the regulated industry and from previous interactions with the minor use/minor species community, and has not changed since the last OMB approval.

Dated: June 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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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 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: AIDS and Related Research Integrated Review Group, HIV Comorbidities and Clinical Studies Study Section.

Date: July 9–10, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Washington Marriott Georgetown, 1221 22nd Street NW, Washington, DC 20037.

Contact Person: Dimitrios Nikolaos Vatakis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3190, Bethesda, MD 20892, 301-827-7480, *dimitrios.vatakis@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fellowships: Physiology and Pathobiology of the Vascular and Hematological Systems.

Date: July 10, 2019.

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

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Katherine M. Malinda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 4140, MSC 7814, Bethesda, MD 20892, 301-435-0912, *Katherine_Malinda@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, RFA-AI-18-054 U.S.-Brazil Collaborative Biomedical Research Program.

Date: July 10, 2019.

Time: 9:00 a.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: Jin Huang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4095G, MSC 7812, Bethesda, MD 20892, 301-435-1230, *jh377p@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR Panel: Clinical Pediatric and Fetal Applications.

Date: July 11, 2019.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Khalid Masood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301-435-2392, *masoodk@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, RFA-AI-

18–054 U.S.–Brazil Collaborative. Biomedical Research Program.

Date: July 11, 2019.

Time: 11:00 a.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: Scott Jakes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, 301–495–1506, jakesse@mail.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: June 7, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–12365 Filed 6–11–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request: The Impact of Clinical Research Training and Medical Education at the Clinical Center on Physician Careers in Academia and Clinical Research (Clinical Center)

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 Clinical Center, 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, contact: Robert M. Lembo, MD, Office of Clinical Research Training and Medical Education, NIH Clinical Center, National Institutes of Health, 10 Center Drive, Room 1N252C, Bethesda, MD 20892–1158, or call non-toll-free number (301) 496–2636, or Email your request, including your address to: robert.lembo@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 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: The Impact of Clinical Research Training and Medical Education at the Clinical Center on Physician Careers in Academia and Clinical Research, OMB #0925–0602 Expiration Date: 8/31/19, Revision, Clinical Center (CC), National Institutes of Health (NIH).

Need and Use of Information Collection: The information collected will allow continued assessment of the value of the training provided by the Office of Clinical Research Training and Medical Education (OCRTE) at the NIH Clinical Center and the extent to which this training promotes (a) patient safety; (b) research productivity and independence; and (c) future career development within clinical, translational, and academic research settings. The information received from respondents is presented to, evaluated by, and incorporated into the ongoing operational improvement efforts of the Director of the Office of Clinical Research Training and Education, and the Chief Executive Officer of the NIH Clinical Center. This information will enable the ongoing operational improvement efforts of the OCRTE and its commitment to providing clinical research training and medical education of the highest quality to each trainee.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours 478.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours requested
CRTP/MRSP Alumni Survey	704	1	20/60	235
Summer Internship Program Alumni Survey	280	1	20/60	93
Graduate Medical Education Graduate Survey	350	1	20/60	117
Clinical Electives Program 1 Year Alumni Surveys	100	1	20/60	33
Total	1,434	1,434	n/a	478

Dated: June 4, 2019.

Laura M. Lee,

Project Clearance Liaison, NIH Clinical Center, National Institutes of Health.

[FR Doc. 2019–12387 Filed 6–11–19; 8:45 am]

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