regulated clinical investigations. In particular, the draft guidance provides recommendations on the following: (1) Deciding whether and how to use EHRs as a source of data in clinical investigations; (2) using EHRs that are interoperable with electronic systems supporting clinical investigations; (3) ensuring the quality and the integrity of EHR data that are collected and used as electronic source data in clinical investigations; and (4) ensuring that the use of EHR data collected and used as electronic source data in clinical investigations meet FDA's inspection, recordkeeping, and record retention requirements. In an effort to modernize and streamline clinical investigations, the goals of the draft guidance are to facilitate use of EHR data in clinical investigations and to promote the interoperability of EHRs and electronic systems supporting the clinical investigation.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the use of EHR data in clinical investigations. 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.

II. Paperwork Reduction Act of 1995

This draft guidance refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44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 The draft guidance pertains to sponsors, clinical investigators, contract research organizations, IRBs, and other interested parties who use EHR systems as electronic source data in FDA-regulated clinical investigations and who send certain information to FDA or others or who keep certain records and make them available to FDA inspectors. The collections of information discussed in the draft guidance are contained in our investigational new drug regulations in part 312 (21 CFR part 312), approved under OMB control number 0910–0014, including §§ 312.58(a) and 312.62(b); investigational device exemption regulations in § 812.140 (21 CFR 812.140) approved under OMB control number 0910–0078; and electronic records; electronic signatures regulations in 21 CFR part 11, approved under OMB control number 0910–0303. The use of EHR systems as a source of data, as described in the draft guidance, would not result in any new costs, including capital costs or operating and maintenance costs, because sponsors and others already have and are experienced with using computer-based equipment and software necessary to be consistent with the draft guidance.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/MedicalDevices/DeviceRegulation andGuidance/GuidanceDocuments/default.htm*, or *http://www.regulations.gov*.

Dated: May 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–11564 Filed 5–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases, Special Emphasis Panel, NIAID Peer Review Meeting.

Date: June 9, 2016.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Room 3G61, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Travis J Taylor, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G62B 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5082, *Travis.Taylor@nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases, Special Emphasis Panel, Rapid Assessment of Zika Virus (ZIKV) Complications (R21).

Date: June 14, 2016.

Time: 12:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health 3F100, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Amir E. Zeituni, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9834 Rockville, MD 20852, 301–496–2550, *amir.zeituni@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 11, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–11554 Filed 5–16–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; National Institutes of Health (NIH) Loan Repayment Programs; Office of the Director (OD)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Division of Loan Repayment (DLR), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 19, 2016, and page numbers 8514–8516, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office

of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

For Further Information: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Steve Boehlert, Director of Operations, Division of Loan Repayment, National Institutes of Health, 6011 Executive Blvd., Room 206 (MSC 7650), Bethesda, Maryland 20892–7650. Mr. Boehlert may be contacted via email at *BoehlerS@od.nih.gov* or by calling 301–451–4465. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: National Institutes of Health (NIH) Loan Repayment Programs (LRP). *Type of Information Collection Request:* Extension of a currently approved collection (OMB No. 0925–0361, expiration date 06/30/17). Form Numbers: NIH 2674–1, NIH 2674–2, NIH 2674–3, NIH 2674–4, NIH 2674–5, NIH 2674–6, NIH 2674–7, NIH 2674–8, NIH 2674–9, NIH 2674–10, NIH 2674–11, NIH 2674–12, NIH 2674–13, NIH 2674–14, NIH 2674–15, NIH 2674–16, NIH 2674–17, NIH 2674–18, NIH 2674–19, and NIH 2674–20.

Need and Use of Information Collection: The NIH makes available financial assistance, in the form of educational loan repayment, to M.D., Ph.D., Pharm.D., Psy.D., D.O., D.D.S., D.M.D., D.P.M., DC, N.D., O.D., D.V.M., or equivalent degree holders who perform biomedical or behavioral research in NIH intramural laboratories or as extramural grantees or scientists funded by domestic non-profit organizations for a minimum of two years (three years for the General Research Loan Repayment Program (LRP)) in research areas supporting the mission and priorities of the NIH.

The AIDS Research Loan Repayment Program (AIDS–LRP) is authorized by Section 487A of the Public Health Service Act (42 U.S.C. 288–1); the Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (CR–LRP) is authorized by Section 487E (42 U.S.C. 288–5); the General Research Loan Repayment Program (GR–LRP) is authorized by Section 487C of the Public Health Service Act (42 U.S.C. 288–3); the Clinical Research Loan Repayment Program (LRP–CR) is authorized by Section 487F (42 U.S.C. 288–5a); the Pediatric Research Loan Repayment Program (PR–LRP) is authorized by Section 487F (42 U.S.C. 288–6); the Extramural Clinical Research LRP for Individuals from Disadvantaged Backgrounds (ECR–LRP) is authorized by an amendment to Section 487E (42 U.S.C. 288–5); the Contraception and Infertility Research LRP (CIR–LRP) is authorized by Section 487B (42 U.S.C. 288–2); and the Health Disparities Research Loan Repayment Program (HD–LRP) is authorized by Section 485G (42 U.S.C. 287c–33).

The Loan Repayment Programs can repay up to $35,000 per year toward a participant's extant eligible educational loans, directly to financial institutions. The information proposed for collection will be used by the Division of Loan Repayment to determine an applicant's eligibility for participation in the program.

Frequency of Response: Initial application and one or two-year renewal application.

Affected Public: Individuals or households; Nonprofits; and Businesses or other for-profit.

Type of Respondents: Physicians, other scientific or medical personnel, and institutional representatives.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 33,242.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Estimated number of responses per respondent	Average burden hours per response	Annual burden hours requested
Intramural LRPs:				
Initial Applicants	40	1	10	400
Advisors/Supervisors	40	1	1	40
Recommenders	120	1	30/60	60
Financial Institutions	8	1	15/60	2
Subtotal	208			502
Extramural LRPs:				
Initial Applicants	1,650	1	11	18,150
Advisors/Supervisors	1,480	1	1	1,480
Recommenders	4,950	1	30/60	2,475
Financial Institutions	100	1	15/60	25
Subtotal	8,180			22,130
Intramural LRPs:				
Renewal Applicants	40	1	7	280
Advisors/Supervisors	40	1	2	80
Subtotal	80			360
Extramural LRPS:				
Renewal Applicants	1,000	1	8	8,000
Advisors/Supervisors	750	1	1	750
Recommenders	3,000	1	30/60	1,500
Subtotal	4,750			10,250

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Number of respondents	Estimated number of responses per respondent	Average burden hours per response	Annual burden hours requested
Total	13,218			33,242

Dated: May 11, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2016–11618 Filed 5–16–16; 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 invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results 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 and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850–9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850–9702, Tel. 240–276–5515 or email *ncitechtransfer@mail.nih.gov.* A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention: Method for Purifying Antibodies.

Description of Technology: This technology is a method for purifying a biologic composition, comprising diafiltering the biologic composition into a composition comprising phosphate buffered saline (PBS) to obtain a purified composition. The method is particularly useful for removing one or more impurities from the biologic composition, such as bis(2-hydroxyethyl)amino-tris(hydroxymethyl)methane (Bis-tris).The technology is directed to large scale manufacturing of Chimeric 14.18 (Ch14.18) monoclonal antibodies. Ch14.18 is an anti-GD2 monoclonal antibody and has been described in Gillies *et al., Journal of Immunological Methods* 125:191–202 (1989).

Potential Commercial Applications:

- Large scale manufacturing of chimeric monoclonal antibodies

Value Proposition:

- Cost effective means of removing impurities to produce GMP grade chimeric antibodies for regulatory approval.

Development Stage: Clinical Phase II, FDA/EMA approved Chemistry, Manufacturing and Controls (CMC) large scale manufacturing to produce GMP grade chimeric antibodies.

Inventor(s): David A. Meh (United Therapeutics Corporation), Timothy Atolagbe (United Therapeutics Corporation), G. Mark Farquharson (United Therapeutics Corporation), Samir Shaban (National Cancer Institute), Mary Koleck (National Cancer Institute), George Mitra (National Cancer Institute).

Intellectual Property:

HHS Ref. No. E–291–2014/0–US–01, corresponding to US Provisional Patent App. No. 62/028,994, filed July 25, 2014, entitled ''Method for Purifying Antibodies using PBS''

HHS Ref. No. E–291–2014/0–US–02, corresponding to US Patent App. No. 14/809,211, filed July 25, 2015, entitled ''Method for Purifying Antibodies using PBS''

HHS Ref. No. E–291–2014/0–PCT–03, corresponding to International Patent App. No. PCT/US2015/042241, filed July 27, 2015, entitled ''Method for Purifying Antibodies''

Publications:

1. FDA published document: *http://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125516Orig1s000TOC.cfm*

2. US Food and Drug Administration. FDA approves first therapy for high-risk neuroblastoma.*http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm437460.htm*

3. WO2016015048 METHOD FOR PURIFYING ANTIBODIES *https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2016015048*

Contact Information: Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: *john.hewes@nih.gov.*

Dated: May 11, 2016.

John D. Hewes,

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016–11556 Filed 5–16–16; 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 invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results 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 and/or co-development.

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