2024–D–3163 for ''Considerations for Generating Clinical Evidence From Oncology Multiregional Clinical Development Programs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lola Fashoyin-Aje, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–0205; or Sandra Casak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2200, Silver Spring, MD 20993, 301–796–3812; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Considerations for Generating Clinical Evidence From Oncology Multiregional Clinical Development Programs.'' This draft guidance is intended for sponsors who are planning global oncology clinical development programs for drugs to support a marketing application. The paramount consideration for FDA when evaluating MRCTs is whether the results are applicable to the intended use population in the United States, and to U.S. standard oncological care. Therefore, when planning a multiregional clinical development program, which includes all clinical trials intended to support approval in the United States, including the pivotal trials, the evidence generated should be derived from study populations that enable the results to be interpretable in the context of U.S. patients with the disease or condition and U.S. medical practice.

FDA is providing more detailed recommendations for MRCTs conducted to provide the evidence to support the safe and effective use of cancer drugs in the U.S. population. This guidance expands on principles described in FDA's existing guidance documents related to this topic, by providing additional recommendations for the planning, design, conduct, and analysis of an oncology MRCT that may facilitate FDA's assessment of applicability of the data to the U.S. population with the cancer being investigated and to U.S. medical practice.

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 ''Considerations for Generating Clinical Evidence From Oncology Multiregional Clinical Development Programs.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). 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 part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–20995 Filed 9–16–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Arunoday K. Bhan, Ph.D. (Respondent), who was formerly a Research Fellow, Department of Pediatrics, Boston Children's Hospital (BCH), Harvard

Medical School (HMS), and a former Staff Scientist, Department of Surgery, City of Hope Medical Center (COH). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant T32 HL066987. The questioned research was included in two grant applications submitted for PHS funds, specifically R03 CA270990–01 and R21 CA272364–01 submitted to the National Cancer Institute (NCI), NIH. The administrative actions, including supervision for a period of four (4) years, were implemented beginning on August 21, 2024, and are detailed below.

FOR FURTHER INFORMATION CONTACT:

Sheila Garrity, JD, MPH, MBA, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Arunoday K. Bhan, Ph.D., Boston Children's Hospital, Harvard Medical School and City of Hope Medical Center: Based on the report of an investigation conducted by HMS and COH and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Arunoday K. Bhan (Respondent), former Research Fellow, Department of Pediatrics, BCH, HMS, and a former Staff Scientist, Department of Surgery, COH, engaged in research misconduct in research supported by PHS funds, specifically NHLBI, NIH, grant T32 HL066987. The questioned research was included in two (2) grant applications submitted for PHS funds, specifically R03 CA270990–01 and R21 CA272364–01 submitted to the National Cancer Institute (NCI), NIH.

ORI found that Respondent engaged in research misconduct by intentionally and knowingly falsifying, fabricating, and/or plagiarizing data in the following one (1) published paper and two (2) grant applications:

- Human induced pluripotent stem cell-derived platelets loaded with lapatinib effectively target HER2+ breast cancer metastasis to the brain. *Sci Rep.* 2021 Oct 15;11(1):16866. doi: 10.1038/s41598–021–96351–2 (hereafter referred to as *Sci Rep.* 2021). Retraction in: *Sci Rep.* 2024 Mar 12;14(1):5972. doi: 10.1038/s41598–024–56291–z.
- R03 CA270990–01, ''Human induced pluripotent stem cell derived platelets and platelet derived extracellular vesicles mediated delivery of chemotherapeutics for breast to brain metastasis treatment,'' submitted to NCI, NIH, on June 15, 2021 (hereafter referred to as R03 CA270990–01).
- R21 CA272364–01, ''Off-the-shelf engineered human induced pluripotent stem cell derived platelets mediated delivery of HER2 inhibitors for HER2+ Breast to brain metastasis tumors immunotherapy,'' submitted to NCI, NIH, on September 29, 2021 (hereafter referred to as R21 CA272364–01).

Specifically, ORI found that Respondent intentionally and knowingly falsified, fabricated, and/or plagiarized:

- Figure 2D of *Sci Rep.* 2021, Figure 4A of R03 CA270990–01, and Figure 4A of R21 CA272364–01 by relabeling the transmission electron microscopy (TEM) image as Lapatinib-loaded platelet derived from the commercially available human induced pluripotent stem cell (hiPSC) line DF–19–9–7T when it was actually from a non-drug loaded platelet derived from a human donor sample, without appropriate citation to the researcher who generated the image
- Supplementary Figure SIB of *Sci Rep.* 2021 by relabeling the fluorescence microcopy images as from a culture of the hiPSC line DF–19–9–7T when these were actually from a derivative of the hiPSC line 1157 .2, without appropriate citation to the researcher who generated the image
- Supplementary Figure SlE of *Sci Rep.* 2021 by relabeling the TEM image as from a megakaryocyte on day 6 of maturation obtained directly by differentiation of the hiPSC line DF–19–9–7T when it was actually from an immortalized megakaryocyte cell line (four days after doxycycline-withdrawal induction of differentiation) previously derived from hiPSC line 1156
- Supplementary Figure S1C of *Sci Rep.* 2021 by relabeling the karyotype image as from the hiPSC line DF–19–9–7T when it was actually from the hiPSC line 1156, without appropriate citation to the researcher who generated the image

Respondent entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will have his research supervised for a period of four (4) years beginning with the effective date of the Agreement (the ''Supervision Period''). Prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity in PHS-supported research, Respondent will submit a plan for supervision of Respondent's duties to ORI for approval. The supervision plan must be designed to ensure the integrity of Respondent's research. Respondent will not participate in any PHS-supported research until such a supervision plan is approved by ORI. Respondent will comply with the agreed-upon supervision plan.

(2) The requirements for Respondent's supervision plan are as follows:

i. A committee of 2–3 senior faculty members at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance for a period of four (4) years from the effective date of the Agreement. The committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee meeting dates and Respondent's compliance with appropriate research standards and confirming the integrity of Respondent's research.

ii. The committee will conduct an advance review of each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved. The review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that the data presented in the proposed application, report, manuscript, or abstract are supported by the research record.

(3) During the Supervision Period, Respondent will ensure that any institution employing him submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI and the PHS funding agency that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract.

(4) If no supervision plan is provided to ORI, Respondent will provide certification to ORI at the conclusion of the Supervision Period that his participation was not proposed on a research project for which an application for PHS support was submitted and that he has not participated in any capacity in PHS-supported research.

(5) During the Supervision Period, Respondent will exclude himself voluntarily from serving in any advisory or consultant capacity to PHS including, but not limited to, service on any PHS

advisory committee, board, and/or peer review committee.

Dated: September 10, 2024.

Sheila Garrity,

Director, Office of Research Integrity, Office of the Assistant Secretary for Health.

[FR Doc. 2024–21016 Filed 9–16–24; 8:45 am]

BILLING CODE 4150–31–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 1009 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Cooperative Agreement (U01 Clinical Trial Required).

Date: October 9, 2024.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G56, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Poonam Tewary, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G56, Rockville, MD 20892, (301) 761–7219, *tewaryp@mail.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: October 11, 2024.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G56, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Poonam Tewary, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G56, Rockville, MD 20892, (301) 761–7219 *tewaryp@mail.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: September 11, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–21025 Filed 9–16–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meetings

Pursuant to section 1009 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: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Conference Grant Applications Review.

Date: October 8, 2024.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Blvd., Rockville, MD 20852, 301–402–3587, *rayk@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel NIDCD Clinical Research Center Grant (P50) Review

Date: November 8, 2024.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Blvd., Rockville, MD 20852, 301–402–3587, *rayk@nidcd.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: September 12, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–21120 Filed 9–16–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

Pursuant to section 1009 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: October 10, 2024.

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

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, 3G58, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Anuja Mathew, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G58, Rockville, MD 20892, 301–761–6911, *anuja.mathew@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)