document is immediately in effect, it remains subject to comment in accordance with FDA’s GCP regulation and FDA will consider all comments received and revise the guidance document as appropriate (§ 10.115(g)(3)).

On November 8, 1990, we issued an interim rule that amended, in relevant part, § 320 (21 CFR 320) by adding a requirement to retain reserve samples of drug products (that is, samples of the drug products that were used to conduct BA or BE studies) for a specified period and, when specifically requested, to release the reserve samples to us. The interim rule was intended to help ensure BE between generic drugs and their reference listed drugs and to help us investigate possible fraud in BA and BE testing. After consideration of public comments, we published a final rule in the Federal Register on April 28, 1993 (58 FR 25918).

In the final rule, 21 CFR 320.38 and 320.63 require a new drug application or abbreviated new drug application applicant (or its CRO) to retain reserve samples of the test article and reference standard that were used in conducting any in vivo BA and in vivo or in vitro BE study that supports the approval of an application or supplemental application. Specifically, § 320.38(c) requires these applicants (or their CROs) to retain a quantity of the test article and reference standard that were used in BA or BE testing that is at least five times the amount of product required for release testing.

Section 320.38(c) requires that reserve samples of the test article and reference standard used in a BA or BE study are of a sufficient quantity to perform five times all of the release tests required in the application or supplemental application. Since the final rule was issued in 1993, technological advances in our ability to test these products have led to test methods that are less destructive and more sensitive, allowing us to detect the identity and composition of the test article and reference standard with smaller volumes of samples. Consistent with these developments, FDA has received communications from applicants and CROs requesting to retain a lower quantity of the reserve samples.

In light of these technological advances, this guidance discusses the conditions under which we do not generally intend to take regulatory action against an applicant or CRO that retains an appropriate reduced quantity of reserve samples of the test article and reference standard that were used in its BA or BE testing.

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 “Compliance Policy for the Quantity of Bioavailability and Bioequivalence Samples Retained Under 21 CFR 320.38(c)” 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 guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information in part 320 for “Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans” have been approved under OMB control number 0910–0672. The recordkeeping requirement for CGMP sample retention in 21 CFR 211.170 has been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/drugs/guidance-compliance-information/guidances-drugs or https://www.regulations.gov. Use the FDA website listed in the previous sentence to find the most current version of the guidance.


Lowell J. Schiller,  
Principal Associate Commissioner for Policy.  
[FR Doc. 2020–17798 Filed 8–18–20; 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 Anil K. Jaiswal, Ph.D. (Respondent), former professor, Department of Pharmacology, University of Maryland at Baltimore, School of Medicine (UMB). Dr. Jaiswal engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Cancer Institute (NCI), National Institutes of Health (NIH), grants R01 CA062483 and R01 CA081057; National Institute of Environmental Health Sciences (NIEHS), NIH, grants R01 ES007943, R01 ES012265, and R01 ES021483; and National Institute of General Medical Sciences (NIGMS), NIH, grant R01 GM047466. The administrative actions, including debarment for a period of three (3) years, were implemented beginning on July 21, 2020, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Elisabeth A. Handley, 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:

Anil K. Jaiswal, Ph.D., University of Maryland at Baltimore, School of Medicine: Based on an investigation conducted by UMB and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Anil K. Jaiswal, former professor, Department of Pharmacology, UMB, engaged in research misconduct in research supported by PHS funds, specifically NCI, NIH, grants R01 CA062483 and R01 CA081057; NIEHS, NIH, grants R01 ES007943, R01 ES012265, and R01 ES021483; and NIGMS, NIH, grant R01 GM047466. ORI found that Respondent intentionally, knowingly, or recklessly: (a) Used random blank background sections of film or empty boxes to falsely represent or fabricate western blot analyses; (b) used manipulated images to generate and report falsified data in figures; and (c) used mislabeled images to falsely report data in figures. Respondent’s research misconduct occurred in the following four (4) funded PHS grant applications, four (4) unfunded PHS grant applications, and six (6) PHS-supported published papers:

- NCI, NIH grant application R01 CA061057–11, Mechanisms of Bioreductive Drugs Activation (unfunded)
- NIEHS, NIH grant application R01 ES007943–10, Prevention of Quinone Toxicity and Mutagenicity (funded)
- NIEHS, NIH grant application R01 ES007943–15, Prevention of Quinone Toxicity and Mutagenicity (unfunded)

- NCI, NIH grant application R01 CA061057–11, Mechanisms of Bioreductive Drugs Activation (unfunded)
- NIEHS, NIH grant application R01 ES007943–10, Prevention of Quinone Toxicity and Mutagenicity (funded)
- NIEHS, NIH grant application R01 ES007943–15, Prevention of Quinone Toxicity and Mutagenicity (unfunded).
• NIH, grant application R01 ES007943–15A1, Prevention of Quinone Toxicity and Mutagenicity (funded).
• NIH, grant application R01 ES012265–07, Role of Regulation of Nrf2 (funded).
• NIH, grant application R01 GM047466–20, Regulation of NAD(P)H:Quinone Oxydoreductases (unfunded).
• NIGMS, grant application R01 GM047466–20A1, Regulation of NAD(P)H:Quinone Oxydoreductases (funded).
• Overlapping signal sequences control nuclear localization and endoplasmic reticulum retention of NAD(P)H:Quinone Oxydoreductases (unfunded).


JBC 2004 Sep 1;279(17):5025–8 (hereafter referred to as “JBC 2004”).

Using a vertically flipped image in Figure 9 (top right) in PHS grant application R01 ES012265–07 to falsify reverse immunoprecipitation of Hepa-1 cell extract with anti-Grp58 and anti-PGAM5L antibodies and reusing the same image, after being flipped horizontally, in Figure 12 (top right) of the same application to falsify the same experiment as with anti-Flag and pClNc antibodies.

Falsifying reported results in Figure 9 (upper panel) in PHS grant application R01 ES021483–01 as representing in vitro translation of two proteins (BRCA1 and NQO1), showing that NQO1 stabilizes BRCA1 against 20S proteasomal degradation, by falsifying using bands labeled NQO1 from a cell lysate experiment on the original film, flipping them horizontally, enhancing the contrast to obscure one band (BRCA1+20S), and falsely relabeling the resulting panel as BRCA1.

Using a sample with a molecular weight of 80–85kD to falsify represent P-Akt-Thr308, which should have a molecular weight of 60kD, in PHS grant application R01 GM047466–20A1, Figure 4 (first panel).
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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: National Cancer Institute Special Emphasis Panel; SEP–6: Research Answers to NCI Provocative Questions.

Date: September 28, 2020.
Time: 12:00 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W104, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Byeon-Chel Lee, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W104, Rockville, MD 20850, 240–276–6351, byeon-chel.lee@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–9: Research Answers to NCI Provocative Questions.

Date: October 20, 2020.
Time: 12:00 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W104, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: David G. Ransom, Ph.D., Chief, Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W104, Rockville, MD 20850, 240–276–6351, david.ransom@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–10: Research Projects in Cancer Systems Biology.

Date: October 9, 2020.
Time: 10:30 a.m. to 3:30 p.m.
Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W238, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Klaus B. Piontek, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W116, Rockville, MD 20850, 240–276–5413, klaus.piontek@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–9: Clinical and Translational R21 and Omnibus R03 Review.

Date: October 28, 2020.
Time: 9:30 a.m. to 5:30 p.m.
Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W238, Rockville, MD 20850 (Telephone Conference Call).

Respondent will copy ORI and the Research Integrity Officer at UMB on the correspondence.


Elisabeth A. Handley, Director, Office of Research Integrity; Office of the Assistant Secretary for Health.

[FR Doc. 2020–18137 Filed 8–18–20; 8:45 am]

BILLING CODE 4150–31–P