

electronically, and the paper application will no longer be used for submissions.

A 60-day notice published in the **Federal Register** on March 8, 2023, Vol. 88, No. 45; pp. 14377, received no public comments.

Need and Proposed Use of the Information: PDs of coverage applications are provided in compliance with 42 CFR 6.6 and must address certain specified criteria for coverage determinations to be issued. The application provides the Bureau of Primary Health Care with the information that is essential for

evaluation of compliance with legal requirements and making a deeming determination of coverage under 42 CFR 6.6.

Likely Respondents: Respondents include recipients of Health Center Program funds with deemed PHS employee status under section 224(g)–(n) of the PHS Act (42 U.S.C. 233(g)–(n)).

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time

needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Application for Federally Supported Health Center Assistance Act (FSHCAA)/Federal Tort Claims Act (FTCA) Particularized Determination	12	1	12	2	24
Total	12	1	12	24	24

HRSA specifically requests comments on (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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–13822 Filed 6–28–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted

on the SACHRP website at <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

DATES: The meeting will be held on Wednesday, July 19, 2023 from 11:00 a.m. until 5:00 p.m., and Thursday, July 20, 2023, from 11:00 a.m. until 5:00 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP website as this information becomes available.

ADDRESSES: This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted at least one week prior to the meeting at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: SACHRP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 11:00 a.m., on Wednesday, July 19, 2023, followed by opening remarks from Julie Kaneshiro, Acting Director of OHRP and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with a discussion of IRB effectiveness, topic #4 of the recently published GAO report #GAO–23–104721, Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness. This will be followed by commentary on the FDA draft guidance, Decentralized Clinical Trials for Drugs, Biological Products, and Devices, in addition to discussion of recommendations that address the ethical conduct of decentralized clinical trials in human subjects research more broadly.

Discussion of both topics will continue on July 20, in addition to commentary on the recently released

draft HHS guidance, *Frequently Asked Questions: Limited Institutional Review Board Review and Related Exemptions*. Other topics may be added; for the full and updated meeting agenda, see <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>. The meeting will adjourn by 5:00 p.m. July 20, 2023.

Time will be allotted for public comment on both days of the meeting. The public may submit written public comment in advance to SACHRP@hhs.gov no later than midnight July 12, 2023, ET. Written comments will be shared with SACHRP members and may be read aloud during the meeting. Public comment must be relevant to topics being addressed by the SACHRP.

Dated: June 12, 2023.

Julia G. Gorey,

Executive Director, SACHRP, Office for Human Research Protections.

[FR Doc. 2023–13833 Filed 6–28–23; 8:45 am]

BILLING CODE 4150–36–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 Yiorgos (Georgios) I. Laliotis, M.D. (Respondent), who was a Postdoctoral Fellow, Department of Cancer Biology and Genetics, College of Medicine, The Ohio State University (OSU), and Postdoctoral Fellow, Department of Oncology, Johns Hopkins University (JHU). Respondent 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 CA186729, R01 CA198117, P30 CA016058, K22 CA245487, and R21 CA252530 and included in grant applications submitted for PHS funds, specifically R01 CA186729–07 and R01 CA198117–05 submitted to NCI, NIH. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on June 12, 2023, 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:

Yiorgos (Georgios) I. Laliotis, M.D., The Ohio State University and Johns Hopkins University: Based on the reports of inquiries conducted by OSU and JHU, admissions by Respondent, and analysis conducted by ORI in its oversight review, ORI found that Yiorgos (Georgios) I. Laliotis, M.D., former Postdoctoral Fellow, Department of Cancer Biology and Genetics, College of Medicine, OSU, and former Postdoctoral Fellow, Department of Oncology, JHU, engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically NCI, NIH, grants R01 CA186729, R01 CA198117, P30 CA016058, K22 CA245487, and R21 CA252530 and included in grant applications submitted for PHS funds, specifically R01 CA186729–07 and R01 CA198117–05 submitted to NCI, NIH.

ORI found that Respondent engaged in research misconduct by intentionally and knowingly falsifying and/or fabricating data, methods, results, and conclusions by representing a fabricated Exon 2 splice variant of *U2AF2*, which would translate as a Serine-Arginine-Rich deficient *U2AF65* isoform, leading to the repression of lung adenocarcinomas and by enhancing the role of splicing in mutant *PIK3CA* breast cancer cell lines in the following three (3) published papers, two (2) NIH grant applications, and two (2) unpublished manuscripts:

- AKT3-mediated IWS1 phosphorylation promotes the proliferation of EGFR-mutant lung adenocarcinomas through cell cycle-regulated *U2AF2* RNA splicing. *Nat. Commun.* 2021 Jul 30; 12(1):4624. doi: 10.1038/s41467-021-24795-1 (hereafter referred to as “*Nat. Commun.* 2021”). Retraction in: *Nat. Commun.* 2022 Jun 28; 13(1):3711. doi: 10.1038/s41467-022-31445-7.
- Phosphor-IWS1-dependent *U2AF2* splicing regulates trafficking of CAR-E-positive intronless gene mRNAs and sensitivity to viral infection. *Commun. Biol.* 2021 Oct 11; 4(1):1179. doi: 10.1038/s42003-021-02668-z (hereafter referred to as “*Commun. Biol.* 2021”). Retraction in: *Commun. Biol.* 2021 Dec 15; 4(1):1419. doi: 10.1038/s42003-021-02941-1.
- Overexpression of the SETD2 WW domain inhibits the phosphor-IWS1/SETD2 interaction and the oncogenic AKT/IWS1 RNA splicing program. *bioRxiv* 2021.08.12.454141. doi: 10.1101/2021.08.12.454141 (hereafter referred to as “*bioRxiv* 2021”). Withdrawn. The manuscript also was submitted to *Commun. Biol.* in 2021 but

was withdrawn prior to completion of peer review.

- R01 CA186729–07, “The role of IWS1-dependent alternative RNA splicing in lung cancer,” submitted to NCI, NIH, on November 5, 2020.
 - R01 CA198117–05, “The role of IWS1 in development and tumorigenesis,” submitted to NCI, NIH, on June 3, 2019.
 - The transcriptomic landscape of oncogenic P13K reveals key functions in splicing and gene expression regulation. Manuscript submitted to *Cancer Res.* (hereafter referred to as the “*Cancer Res.* manuscript”).
 - Interpretable deep learning for chromatin-informed inference of transcriptional programs driven by somatic alterations across cancers. Manuscript in preparation (hereafter referred to as “*Manuscript 2021*”).
- Specifically, ORI finds that Respondent knowingly and intentionally:
- falsified the sequencing data in Figure 1g of *Nat. Commun.* 2021 by splicing two sequencing chromatograms together to falsely represent a novel identification of a previously undescribed *U2AF2* RNA transcript lacking Exon 2
 - falsified conclusions about the fabricated *U2AF2* splice variant in RT-PCR results in Figures 1f, 2a, 2b, 2c, 3d, 4a, 4b, 4c, 4e, 5h, 6f, 6i, and 7c of *Nat. Commun.* 2021
 - falsified conclusions about the fabricated *U2AF2* splice variant as the source of two endogenous protein isoforms in immunoblot panels in Figures 5c and 5g of *Nat. Commun.* 2021 and Figure 2 of R01 CA186729–07
 - falsified the experimental conditions of p-ERK1/2 (Y202/T204), p-CDK1 (Y15), CDK1, and Cyclin B1 immunoblot panels in Figure 5g of *Nat. Commun.* 2021 and Figure 2 of R01 CA186729–07 by using shControl or shIWS1 instead of the samples as reported in the figure labels to falsely represent the immunoblots as the result of *U2AF2* containing spliced Exon 2
 - falsified the experimental conditions of the α -actinin immunoblot panel in Figure 1e of *Commun. Biol.* 2021 by using shIWS1 instead of shIWS1/*U2AF65* β -V5 as reported in the figure label
 - in *Commun. Biol.* 2021, *bioRxiv* 2021, R01 CA186729–07, and R01 CA198117–05, reported falsified conclusions highlighting the role of the fabricated *U2AF2* RNA transcript lacking Exon 2 from *Nat. Commun.* 2021