duties: (1) advises the Commissioner regarding recommended classification or reclassification of devices into one of three regulatory categories, (2) advises on any possible risks to health associated with the use of devices, (3) advises on formulation of product development protocols, (4) reviews premarket approval applications for medical devices, (5) reviews guidelines and guidance documents, (6) recommends exemption of certain devices from the application of portions of the FD&C Act, (7) advises on the necessity to ban a device, and (8) responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

II. Criteria for Voting Members

The MDAC with its 18 panels shall consist of a maximum of 159 standing members. Members are selected by the Commissioner or designee from among authorities in clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. Almost all non-Federal members of this committee serve as Special Government Employees. A maximum of 122 members shall be standing voting members and 37 shall be nonvoting members who serve as representatives of consumer interests and of industry interests. FDA is publishing separate documents announcing the Request for Nominations Notification for Nonvoting Representatives on certain panels of the MDAC. Persons nominated for membership on the panels should have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The current needs for each panel are listed in table 2. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on one or more of the advisory panels. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, and email address if available and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must also specify the advisory panel(s) for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: November 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25813 Filed 11–25–22; 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 Douglas D. Taylor, Ph.D. (Respondent), former Professor and Vice Chair for Research, Department of Obstetrics & Gynecology, University of Louisville School of Medicine (UL). 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 R41 CA139802 and R21 CA098166. The administrative actions, including debarment for a period of three (3) years, were implemented beginning on October 17, 2022, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr.P.H., Acting 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:

Douglas D. Taylor, Ph.D., University of Louisville School of Medicine: Based on the evidence and findings of investigations conducted by UL, ORI's oversight review of UL's investigation, and additional evidence obtained and analysis conducted by ORI during its oversight review, ORI found that Dr. Douglas D. Taylor, former Professor and Vice Chair for Research, Department of Obstetrics & Gynecology, UL, engaged in research misconduct under 42 CFR part 93 in research supported by PHS funds, specifically NCI, NIH, grants R41 CA139802 and R21 CA098166.

ORI found based on a preponderance of the evidence that Respondent intentionally, knowingly, or recklessly used falsely labeled images to falsely report data in figures, and in one finding, intentionally, knowingly, or recklessly plagiarized, reused, and falsely labeled an image to falsely report data in a figure. Respondent's research misconduct occurred in one (1) funded PHS grant application, twelve (12) unfunded PHS grant applications, and two (2) PHS-supported published papers. ORI found that these acts constitute a significant departure from accepted practices of the relevant research community. The affected papers and grant applications are:

- Patient-derived tumor-reactive antibodies as diagnostic markers for ovarian cancer. *Gynecol. Oncol.* 2009 Oct;115(1):112–20; doi: 10.1016/j.ygyno.2009.06.031 (hereafter referred to as ''*Gynecol. Oncol.* 2009'').

• MicroRNA signatures of tumor-derived exosomes as diagnostic biomarkers of ovarian cancer. *Gynecol. Oncol.* 2008 Jul;110(1):13–21; doi: 10.1016/j.ygyno.2008.04.033 (hereafter referred to as ''*Gynecol. Oncol.* 2008''). Corrigendum in: *Gynecol. Oncol.* 2010 Jan;116(1):153; doi: 10.1016/j.ygyno.2009.10.045.

• R01 CA152218–01, ''Exosomal noncoding RNA for Lung Cancer Early Detection,'' submitted to NCI, NIH, on 10/05/2009, not funded.

• RC1 HD063778–01, ''Circulating exosomal microRNA in predicting preterm birth,'' submitted to the National Institute of Child Health and Human Development (NICHD), NIH, on 04/29/2009, not funded.

• R41 CA144598–01, ''Use of exosomal miRNA to diagnose pancreatic cancer,'' submitted to NCI, NIH, on 04/10/2009, not funded.

• R01 CA132886–01A2, ''Characterization of circulating lung cancer-derived exosomal miRNA,'' submitted to NCI, NIH, on 03/06/2009, not funded.

• P50 CA142508–01, ''University of Louisville SPORE [Specialized Program of Research Excellence] in Lung Cancer, Project 2: Exosomal MicroRNAs as Biomarkers for Lung Cancer,'' submitted to NCI, NIH, on 01/23/2009, not funded.

• R21 CA135269–01A1, ''miRNA methylation profiling of endometrial cancer-associated exosomes,'' submitted to NCI, NIH, on 11/12/2008, not funded.

• R41 CA139802–01, ''Exosomal microRNA profiles as diagnostic biomarkers of ovarian cancer,'' submitted to NCI, NIH, on 05/28/2009, funded, Project Award Dates: 09/23/2009–08/31/2011.

• R01 CA132886–01A1, ''Characterization of lung circulating lung cancer-derived exosomal miRNA,'' submitted to NCI, NIH, on 03/05/2008, not funded.

• R41 CA135853–01, ''Micro RNA signatures of tumor-derived exosomes as diagnostic biomarkers of cancer,'' submitted to NCI, NIH, on 12/04/2007, not funded.

• R21 CA135269–01, ''Micro RNA methylation in endometrial cancer,'' submitted to NCI, NIH, on 10/16/2007, not funded.

• R21 CA132886–01, ''Characterization of circulating lung cancer-derived exosomal miRNA,'' submitted to NCI, NIH, on 06/04/2007, not funded.

• R41 CA131011–01, ''Circulating exosomal microRNA as an Ovarian Cancer Diagnostic,'' submitted to NCI, NIH, on 01/31/2007, not funded.

• R41 CA130498–01, ''Serologically Defined Diagnostic and Therapeutic Response Markers for Ovarian Cancer,'' submitted to NCI, NIH, on 12/01/2006, not funded.

Specifically, ORI found based on a preponderance of the evidence that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly:

• falsifying and/or fabricating research results by reusing parts of one graph to show quantitation of circulating tumor-derived exosomes from patients with varying stages of:

—NSCLC (lung cancer) in Figure 5 of R21 CA132886–01, R01 CA132886–01A1, R01 CA132886–01A2, P50 CA142508–01, and R01 CA152218–01

—ovarian cancer in Figure 6 of R41 CA135853–01 and R41 CA139802–01

—pancreatic cancer in Figure 4 of R41 CA144598–01

• falsifying and/or fabricating pancreatic cancer research results in Figure 6 of R41 CA144598–01 by omitting the word ''ovarian'' from the label of the same image that was previously labeled as ovarian cancer tumor cells and circulating tumor-derived exosomes in Figure 8 of R41 CA139802–01

• falsifying and/or fabricating pancreatic cancer research results in Figure 7 of R41 CA144598–01 by relabeling and omitting the word ''ovarian'' from the label of the same image that was previously labeled as ovarian cancer tumors and exosomes from these patients in Figure 3 of *Gynecol. Oncol.* 2008 and Figure 9 of R41 CA139802–01

• falsifying and/or fabricating pancreatic cancer research results in Figure 8 of R41 CA144598–01 by relabeling and omitting the word ''ovarian'' from the label of the same image that was previously labeled as benign ovarian disease and ovarian cancer in Figure 4 of *Gynecol. Oncol.* 2008 and Figure 10 of R41 CA139802–01

• falsifying and/or fabricating pancreatic cancer research results in Figure 5 of R41 CA144598–01 by relabeling and omitting the word ''ovarian'' from the label of the same image that was previously used to show data from ovarian cancer patients in Figure 2 of *Gynecol. Oncol.* 2008, Figure 7 of R41 CA139802–01, and Figure 2 of R21 CA135269–01A1

• falsifying and/or fabricating research results by reusing a graph, first claiming to show the isolation of the miRNA fraction associated with circulating tumor-derived exosomes from an unnamed cancer in a grant application focused on ovarian cancer (Figure 6 of R41 CA131011–01) and to show the isolation of the miRNA fraction associated with circulating tumor exosomes in a subsequent grant application on endometrial cancer (Figure 6 of R21 CA135269–01); this graph was then paired with a gel image showing the RNA distribution from tumor-derived exosomes from ovarian cancer (Figure 6 of R01 CA132886–01); the figure containing the graph paired with the gel image was then used to also represent exosomes derived from:

— unnamed cancer tumors in a grant application on ovarian cancer (Figure 7 of R41 CA135853–01)

—lung cancer tumors (Figure 6 of R01 CA132886–01A1, R01 CA132886–01A2, and P50 CA142508–01)

—placentas from preterm births (Figure 3 of RC1 HD063778–01)

• falsifying and/or fabricating research results by reusing a single image to show miRNAs expressed in circulating exosomes from:

—ovarian cancer patients in five grant applications (Figure 7 of R41 CA131011–01, Figure 7 of R21 CA135269–01, Figure 10 of R41 CA135853–01, Figure 4 of R21 CA135269–01A1, and Figure 11 of R41 CA139802–01)

—lung cancer patients in four grant applications (Figure 8 of R21 CA132886–01 and Figure 10 of R01 CA132886–01A1, R01 CA132886–01A2, and P50 CA142508–01)

• falsifying and/or fabricating research results by reusing a single image from a non-PHS-supported paper that claimed to demonstrate the presence of antibodies that recognize normal endometrium and endometrial tumors, from the sera of women with recurrent pregnancy loss (Figure 2A and 2B in a paper published in *Fertil Steril.* 2000 [1]), to represent the presence of antibodies that recognize antigens from normal epithelium and ovarian tumor cell lines from patients with:

—stage II or IV ovarian cancer in Figure 4 of R41 CA130498–01

—stage I and stage IIIc ovarian cancer in Figure 1 of *Gynecol. Oncol.* 2009

• plagiarizing, reusing, and relabeling an electron micrograph of melanoma derived exosomes created by a scientist and published in *Lancet* [2] in 2002 to falsely represent exosomes from patients with:

—ovarian cancer in Figure 4B of R41 CA135853–01, Figure 1B of *Gynecol.*

[1] *Fertil Steril.* 2000 Feb;73(2):305–13; doi: 10.1016/s0015–0282(99)00505–1 (hereafter referred to as ''*Fertil Steril.* 2000'').

[2] *Lancet* 2002 Jul 27;360(9329):295–305; doi: 10.1016/S0140–6736(02)09552–1 (hereafter referred to as ''*Lancet* 2002'').

Oncol. 2008, Figure 1B of R21 CA135269–01A1, Figure 4B of R41 CA139802–01, and Figure 2B of R41 CA144598–01

—NSCLC (lung cancer) in Figure 11B of R01 CA132886–01A1, R01 CA132886–01A2, P50 CA142508–01, and R01 CA152218–01

The following administrative actions have been implemented:

(1) For a period of three (3) years, beginning on October 17, 2022, Respondent is debarred from participating in ''covered transactions'' as defined in 42 CFR § 180.200 and procurement transactions covered under the Federal Acquisition Regulation (48 CFR chapter 1).

(2) Respondent is prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on October 17, 2022.

(3) In accordance with 42 CFR 93.407(a)(1) and 93.411(b), HHS will send to the pertinent journal a notice of ORI's findings and the need for retraction or correction of:

- *Gynecol. Oncol.* 2009 Oct;115(1):112–20; doi: 10.1016/j.ygyno.2009.06.031
- *Gynecol. Oncol.* 2008 Jul;110(1):13–21; doi: 10.1016/j.ygyno.2008.04.033

Dated: November 22, 2022.

Wanda K. Jones,

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

[FR Doc. 2022–25866 Filed 11–25–22; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request;

NIH Information Collection Forms To Support Genomic Data Sharing for Research Purposes (Office of Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

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

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Julia Slutsman, Ph.D. Director, Genomic Data Sharing Policy Implementation, OER, OD, NIH, Natcher Building, Room 3AN–44D, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892, or call non-toll-free number (301) 594–7783 or email your request, including your address to: *slutsmaj@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on September 21, 2022, pages 57705–57707 (87 FR 57705) 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 Office of the Director (OD), National Institutes of Health, 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 November 30, 2022, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: NIH Information Collection Forms to Support Genomic Data Sharing for Research Purposes—0925—REVISION—expiration date 11/30/2022, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Sharing research data supports the National Institutes of Health (NIH) mission and is essential to facilitate the translation of research results into knowledge, products, and procedures that improve human health. NIH has longstanding policies to make a broad range of research data, including genomic data, publicly available in a timely manner from the research activities that it funds. Genomic research data sharing is an integral element of the NIH mission as it facilitates advances in our understanding of factors that influence health and disease, while also providing opportunities to accelerate research through the power of combining large and information-rich datasets. To promote robust sharing of human and non-human data from a wide range of large-scale genomic research and provide appropriate protections for research involving human data, the NIH issued the NIH Genomic Data Sharing Policy (NIH GDS Policy). Human genomic data submissions and controlled access are managed through a central data repository, the database of Genotypes and Phenotypes (dbGaP) which is administered by the National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH. Under the NIH GDS Policy, all investigators who receive NIH funding to conduct large-scale genomic research are expected to register studies with human genomic data in dbGaP, no matter which NIH-designated data repository will maintain the data. As part of the registration process, investigators must provide basic study information such as the type of data that will be submitted to dbGaP, a description of the study, and an institutional assurance (*i.e.* Institutional Certification) of the data submission which delineates any limitations on the secondary use of the data (*e.g.,* data cannot be shared with for-profit companies, data can be used only for research of particular diseases). Investigators interested in using controlled-access data for secondary research must apply through dbGaP and be granted permission from the relevant NIH Data Access Committee(s). As part of the application process, investigators and their institutions must provide information such as a description of the proposed research use of controlled access datasets that conforms to any data use limitations, agree to the Genomic Data User Code of Conduct, and agree to the terms of access through a Data Use Certification agreement. Requests to renew data access and reports to close out data use are similar to the initial data access request, requiring sign-off by both the requestor and the institution, but also ask for information about how the data have been used, and about publications, presentations, or intellectual property based on the research conducted with the accessed data as well as any data security issues or other data management incidents. NIH has developed online forms, available through dbGaP, in an effort to reduce the burden for researchers and their