number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 8, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams, at *Annmarie.Williams@fda.hhs.gov,* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 24, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–12641 Filed 5–27–16; 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: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Ricky Malhotra, Ph.D., University of Michigan and University of Chicago: Based on the Respondent's admission to committing research misconduct at the University of Michigan (UM) and subsequently at the University of Chicago (UC), the reports of separate investigations conducted by UM and UC, and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Ricky Malhotra, former Research Assistant Professor, Department of Internal Medicine, UM, from 2005–2006, and Research Assistant Professor, Department of Surgery, UC, from 2007–2011, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants K08 HL081472 and R01 HL107949.

ORI found that falsified and/or fabricated data were included in the following three (3) NIH grant applications, one (1) NIH grant progress report, one (1) publication, seven (7) presentations, and one (1) image file:

- R03 AG029508–01
- R21 AG030361–01
- R01 HL102405–01
- K08 HL081472–05 Progress Report
- *J Biol Chem.* 285(18):13748–60, 2010 Apr 30 (hereafter referred to as ''*JBC* 2010'')
- Presentation: Autophagy Pathway.ppt, MKK4 expression after UV.ppt, Oct PPt.ppt, RicDec.ppt, Ricky Presentation 06.ppt, Ricky STC.ppt, and RM.ppt
- Image file: Final LC 3.jpg

ORI found that Respondent reused and falsely relabeled Western blot gel images, falsified the related densitometry measurements based on the falsified Western blots, and falsified and/or fabricated data for experiments that were not performed. Respondent continued this falsification at UC, after the UM research misconduct investigation was completed. Specifically:

• While at UM, Respondent falsified and/or fabricated images in R03 AG029508–01 and three (3) presentations, where:

▪ R03 AG029508–01, Figure 2, represented Western blots for phosphorylated p53 (Ser15) and β-actin expression in normal and Snell dwarf mice fibroblasts (mN/SF) treated with the DNA alkylating agent methyl methanesulfonate (MMS), when the same images were duplicated to represent different proteins and treatments in the presentations Autophagy Pathway.ppt and RM.ppt.

▪ R03 AG029508–01, Figure 3, represented Western blots for $p16^{Ink4a}$ and β-actin expression in mN/SF, when the same images were duplicated to represent different proteins and treatments in the presentations Autophagy Pathways.ppt, RicDec.ppt, and RM.ppt.

• While at UM, Respondent fabricated data in R21 AG030361–01 and supporting data for the grant application in the research record, where:

▪ R21 AG030361–01, Figure 2, represented a Western blot for phosphorylated c-Jun-N-terminal kinase (JNK) expression in mN/SF exposed to cadmium, when the experiment was not performed.

▪ The research record contained ninety (90) Western blot images and ninety (90) densitometry measurement files for 45 experiments that examined phosphorylated JNK or Mitogen-activated protein kinase 4 (MMK4) expression in mN/SF exposed to UV light, H_2O_2, cadmium, or anisomycin, when the experiments were not performed.

▪ The research record contained densitometric analyses for an additional twenty-eight (28) experiments that examined phosphorylated JNK or MMK4 expression in mN/SF exposed to UV light, H_2O_2, cadmium, or anisomycin, when the quantifications were based on experiments that were not performed.

• While at UM, Respondent falsified and/or fabricated Western blots for phosphorylated and total Rac1/cdc42 expression in mN/SF, total JNK expression in mN/SF treated with anisomycin, phosphorylated JNK expression in Snell dwarf mice fibroblasts treated with cadmium, β-actin expression in mN/SF, β-actin expression in Snell dwarf mice fibroblasts treated with or without MMS, β-actin expression in normal mice fibroblasts treated with cadmium, and β-actin expression in mN/SF treated with H_2O_2 in the presentations Autophagy Pathway.ppt, Oct PPt.ppt, RicDec.ppt, Ricky Presentation 06.ppt, Ricky STC.ppt, and RM.ppt, and the image file Final LC 3.jpg, when the images were duplicated and falsely relabeled Western blots of unrelated experiments.

• While at UM, Respondent falsified twenty-four (24) Western blots for phosphorylated JNK or MMK4 expression in mN/SF exposed to UV light, H_2O_2, cadmium, or anisomycin in the seven (7) presentations and twenty-six (26) data files in the research record, when the images were duplicated and falsely relabeled Western blots of unrelated experiments.

• While at UC, Respondent falsified and/or fabricated Western blots by using images from unrelated experiments and the related densitometric analyses that were based on falsified Western blots in the following:

▪ R01 HL102405–01 for:

—Figure 1A for phosphorylated Rhodopsin (Rho) expression in neonatal rat ventricular cardiac myocytes (NRVCM) subjected to stimulation with Angiotension II (Ang II)

—Figure 1A for G protein-coupled receptor kinase-2 (GRK2) expression in NRVCM subjected to cyclical mechanical stretch
—Figure 1B for densitometric analysis of GRK2 activity
—Figure 2A for phosphorylated Rho and GRK2 expression in NRVCM subjected to mechanical stretch
—Figure 2B for densitometric analysis of GRK2 activity
—Figure 3A for phosphorylated Rho expression in NRVCM after mechanical stretch and treatment with protein kinase C (PKC) inhibitor chelerythrine (lanes 5 and 6)
—Figure 3B for densitometric analyses of GRK2 activity after PKC inhibition via chelerythrine treatment

▪ K08 HL081472–05 Progress Report for:
—Figure 1A for phosphorylated Rho and GRK2 expression in NRVCM subjected to mechanical stretch
—Figure 1B for densitometric analyses of GRK2 activity after PKC inhibition via chelerythrine treatment

▪ *JBC* 2010 for:
—Figure 1B for phosphorylated Rho expression in NTVCM subjected to stimulation with Ang II
—Figure 1B for GRK2 expression in NRVCM subjected to cyclical mechanical stretch panel
—Figure 1C for densitometric analysis of GRK2 activity
—Figure 2A for phosphorylated Rho expression in NRVCM after mechanical stretch and treatment with the Ang II type 1 (AT_1) receptor antagonist Irbesartan (lanes 5 and 6)
—Figure 2B for densitometric analyses of GRK2 activity after PKC inhibition via Irbesartan treatment
—Figure 4C for phosphorylated Rho and GRK2 expression in NRVCM subjected to mechanical stretch
—Figure 4D for densitometric analysis of GRK2 activity after RNAi treatment

Dr. Malhotra has entered into a Voluntary Settlement Agreement with ORI, in which he voluntarily agreed to the administrative actions set forth below:

(1) Respondent agreed that he had no intention in applying for or engaging in U.S. Public Health Service (PHS)-supported research or otherwise working with PHS. However, if within five (5) years of the effective date of the Agreement (May 6, 2016), Respondent receives or applies for PHS support, Respondent agreed to have his research supervised for a period of ten (10) years beginning on the date of his employment in a position in which he receives or applies for PHS support and to notify his employer/institution(s) of the terms of this supervision.

(2) Respondent certified that he is not currently engaged in or receiving PHS support. Respondent agreed that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to the Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval. The supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution as outlined below. Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI. Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan.

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

i. A committee of senior faculty members and officials 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 ten (10) years. The committee will review primary data for Respondent's PHS-supported research on a quarterly basis setting forth the committee meeting dates, Respondent's compliance with appropriate research standards, and confirming the integrity of Respondent's research.

ii. The committee will conduct an advance review of any PHS grant application (including supplements, resubmissions, etc.), manuscripts reporting PHS-funded research submitted for publication, and abstracts. The review will include a discussion with Respondent of the primary data represented in those documents and will include a certification that the data presented in the proposed application/publication is supported by the research record.

(4) If within five (5) years from the effective date of the Agreement, Respondent receives or applies for PHS support, Respondent agreed that for a period of ten (10) years beginning on the date of his employment that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a report and certification to ORI at six (6) month intervals 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.

(5) If no supervisory plan is provided to ORI, Respondent agreed to provide certification to ORI on a quarterly basis for a period of five (5) years, beginning on May 6, 2016, that he has not engaged in, applied for, or had his name included on any application, proposal, or other request for PHS funds made available through grants, subgrants, cooperative agreements, contracts, subcontracts, supplements, awards, fellowships, projects, programs, small business technology transfer (STTR) and small business innovation research (SBIR) programs, conferences, meetings, centers, resources, studies, and trials, without prior notification to ORI.

(6) Respondent agreed to exclude himself voluntarily 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 five (5) years, beginning on May 6, 2016.

(7) As a condition of the Agreement, Respondent agreed to the retraction of *JBC* 2010.

FOR FURTHER INFORMATION CONTACT: Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

Kathryn M. Partin,

Director, Office of Research Integrity.

[FR Doc. 2016–12800 Filed 5–27–16; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

AGENCY: National Committee on Vital and Health Statistics (NCVHS), HHS

ACTION: Notice of full committee and subcommittee meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

DATES: Tuesday, June 14, 2016: 9 a.m.–5:40 p.m.—Full Committee Meeting.

Wednesday, June 15, 2016: 8 a.m.–2:25 p.m.—Full Committee Meeting.

Thursday, June 16, 2016: 8:30 a.m.–5 p.m.—Privacy Subcommittee Meeting on ''Minimum Necessary and the Health Insurance Portability and Accountability Act (HIPAA)''.

Friday, June 17, 2016: 8:15 a.m.–4 p.m.—NCVHS Meeting on Claims-based Databases for Policy Development and Evaluation.