



(Billing Code: 4150-31)

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 Alexander Neumeister, M.D. (Respondent), who was a Professor of Psychiatry and Radiology, Department of Psychiatry, New York University School of Medicine, Langone Medical Center (NYUSOM). Dr. Neumeister engaged in research misconduct in psychiatric clinical research supported by National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grants R01 MH096876, R01 MH102566, R21 MH094763, R21 MH096105, R21 MH102035, and R34 MH102871. The administrative actions, including debarment for a period of two (2) years, followed by supervision for a period of two (2) years, were implemented beginning on December 13, 2019, and are detailed below.

FOR FURTHER INFORMATION CONTACT:

Elisabeth A. Handley
Interim 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:

Alexander Neumeister, M.D., New York University School of Medicine, Langone Medical Center:

Based on the report of an investigation conducted by NYUSOM and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Alexander Neumeister, Professor of Psychiatry and Radiology, Department of Psychiatry, NYUSOM, engaged in research misconduct in psychiatric clinical research supported by NIMH, NIH, grants R01 MH096876, R01 MH102566, R21 MH094763, R21 MH096105, R21 MH102035, and R34 MH102871.

Respondent neither admits nor denies ORI's findings of research misconduct. The settlement is not an admission of liability on the part of the Respondent. The parties entered into a Voluntary Exclusion Agreement (Agreement) to conclude this matter without further expenditure of time, finances, or other resources.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, and/or recklessly falsifying and/or fabricating data in the clinical records of research supported by six (6) NIMH grants, resulting in the inclusion of falsified and/or fabricated research methods and results in four (4) published papers:

- Association of in vivo k-opioid receptor availability and the transdiagnostic dimensional expression of trauma-related psychopathology. *JAMA Psychiatry* 2014 Nov;71(11):1262-70. *Erratum* in: *JAMA Psychiatry* 2014 Nov 7;71(11):1301.

- Cannabinoid type 1 receptor availability in the amygdala mediates threat processing in trauma survivors. *Neuropsychopharmacology* 39(11):2519-28, 2014 Oct.
- Linking plasma cortisol levels to phenotypic heterogeneity of posttraumatic stress symptomatology. *Psychoneuroendocrinology* 2014 Jan;39:88-93.
- Association of posttraumatic stress disorder with reduced in vivo norepinephrine transporter availability in the locus coeruleus. *JAMA Psychiatry* 2013 Nov;70(11):1199-205.

Specifically, the Respondent misrepresented the characteristics of the subjects entered in the research record by:

- combining data from multiple subjects to represent single subjects to justify financial payments
- changing and/or instructing his staff to change, omit, or ignore clinical and psychiatric assessment data contained in the electronic and/or written research records
- failing to conduct and/or document screening tests (i.e. pregnancy tests, urine toxicology, electrocardiograms, blood alcohol levels) to determine eligibility for each protocol
- using outdated clinical and/or psychiatric assessments to determine eligibility for experimental and control groups

- reporting the utilization of trained and/or licensed personnel to perform clinical and psychiatric assessments, when the specific training, certification, and/or licensing had not been obtained
- including in subsequent clinical research trials and their associated publications, human research subjects' data that were previously reported in:
 - Positron emission tomography shows elevated cannabinoid CB1 receptor binding in men with alcohol dependence. *Alcohol Clin. Exp. Res.* 2012 Dec;36(12):2104-9

This resulted in the inclusion of subjects in experimental and control groups who did not meet the criteria for entry, as specified in the protocols of the Respondent's funded grants, rendering the data and/or published results invalid in the four (4) papers. The grants are:

- R01 MH096876, "CB1 Receptor PET Imaging Reveals Gender Differences in PTSD," project dates July 1, 2012-June 30, 2015
- R01 MH102566, "KOR Depression," project dates June 1, 2014-June 30, 2015
- R21 MH094763, "CB1 Receptor Imaging in Anorexia," project dates April 1, 2012-March 31, 2014
- R21 MH096105, "Kappa Opioid Receptor Imaging in PTSD," project dates April 1, 2012-March 31, 2015

- R21 MH102035, “Kappa Opioid Receptor Imaging in Anorexia,” project dates August 20, 2013-June 30, 2015
- R34 MH102871, “A mGlu2/3 agonist in the treatment of PTSD,” project dates July 9, 2014-June 30, 2015

Dr. Neumeister entered into an Agreement and agreed:

- (1) to exclude himself voluntarily for a period of two (2) years, beginning on December 13, 2019, from any contracting or subcontracting with any agency of the United States Government and from eligibility for or involvement in nonprocurement programs of the United States Government referred to as “covered transactions” pursuant to HHS’ Implementation (2 C.F.R. Part 376) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the “Debarment Regulations”); at the conclusion of the period of voluntary exclusion, Respondent agreed to have his research supervised for a period of two (2) years; Respondent agreed that prior to submission of an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent’s participation is proposed and prior to 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; 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 agrees to maintain responsibility for compliance with the agreed supervision plan;

- (2) 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 four (4) years, beginning on December 13, 2019.
- (3) as a condition of the Agreement, Respondent will utilize information provided by ORI to request that the following papers be corrected or retracted in accordance with 42 C.F.R. § 93.407(a)(1):

- *JAMA Psychiatry* 2014 Nov;71(11):1262-70.
- *Neuropsychopharmacology* 2014 Oct;39(11):2519-38.
- *Psychoneuroendocrinology* 2014 Jan;39:88-93.
- *JAMA Psychiatry* 2013 Nov;70(11):1199-205.

Respondent will copy ORI and the Research Integrity Officers at NYUSOM and Yale University on the correspondence.

Elisabeth A. Handley,

Interim Director,

Office of Research Integrity.

[FR Doc. 2020-00036 Filed: 1/6/2020 8:45 am; Publication Date: 1/7/2020]