

<b>POLICY: Ethics Advisory Board</b>	Date: January 4, 2018
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## **A. ETHICS ADVISORY BOARD: RESPONSIBILITIES**

NYSPI has established the Ethics Advisory Board (EAB) as the committee responsible for developing, communicating, and implementing policies and standards with respect to financial and non-financial conflict of interest (COI) and commitment, and providing consultation and advisory opinions on ethical matters related to administrative, academic, research and clinical policies, as needed. Its charge includes, but is not limited to, the following:

- Developing policies, standards and providing guidance to NYSPI leadership and staff on financial and non-financial conflicts of interest and commitment in accordance with applicable New York State (NYS) laws, NYS and agency regulations, and the advisory opinions of the Joint Commission on Public Ethics.
- Developing processes for the disclosure, review, management and reporting of financial conflict of interest in research at NYSPI, conducted under the auspices of the Research Foundation for Mental Hygiene (RFMH) or the Columbia University Department of Psychiatry under their policies, respectively, and in accordance with obligations under 42 CFR Part 50 (Subpart F), 45 CFR Part 94 and relevant NYS law, regulation and advisory opinions.
- Reviewing applications for consulting agreements under the RFMH Consulting Policy for Investigators; and
- Acting as an *ad hoc* ethics committee for Institute and departmental matters relating to clinical and research ethics consultation, authorship and other academic disputes.

### **1. NYS Ethics Rules, Guidance and Policy**

The EAB, its leadership, members, and coordinator, consult with and advise Institute leadership and staff on the applicability of NYS law and regulations governing ethics, the determinations and advisory opinions of the NYS Joint Commission on Public Ethics (JCOPE), and relevant Office of Mental Health (OMH) and Institute policy. These matters include, but are not limited to, outside financial interests, conflicts of interest and commitment in the conduct of funded and unfunded research, education and training, and restrictions on the use of NYS time, personnel, and resources.

## 2. Financial Conflict of Interest Review in Research

### a) RFMH Financial Conflict of Interest Policy

The EAB is the conflict of interest in research review committee for NYSPI in accordance with the RFMH Financial Conflict of Interest Policy. This policy applies to all activities supported by funds administered through RFMH, regardless of source, and incorporates the provisions of U.S. Public Health Service Policy, Department of Health and Human Services, 42 CFR Part 50, 45 CFR Part 94 and FDA regulations under 21 CFR Part 54.

### b) NYS Ethics Law and Rules

As an agency of the New York State Office of Mental Health, RFMH and NYSPI officers, directors, employees and staff activities are governed by New York Public Officers Law §73 and §74 and the determinations and advisory opinions issued by the JCOPE as they apply to outside financial interests and research.

### c) Columbia University Department of Psychiatry Financial Conflict of Interest in Research

Researchers at NYSPI who have appointments as faculty or research scientists in the Columbia University Department of Psychiatry may conduct research sponsored by Columbia University. All such sponsored research is governed by the Columbia University Policy on Financial Conflicts of Interest and Research and is reviewed by the Columbia University Financial Conflict of Interest Committee.

### d) Principles and Practice of Integrated Review

Research activities are integrated across NYSPI and the Columbia Department of Psychiatry to a significant extent. An IRB inter-institutional reliance agreement between Columbia and NYSPI cedes to the NYSPI IRB review of all human subject research involving psychiatric and behavioral disorders emerging from the Department of Psychiatry. There is no inter-institutional agreement between Columbia and NYSPI for animal research. All research involving animal care and use at NYSPI is subject to review by the NYSPI IACUC. Animal research performed at NYSPI and funded through Columbia University requires CU IACUC review in addition to NYSPI IACUC review. NYSPI is responsible, in whole or in part, for all human and animal research activities reviewed by the IACUC and IRB, regardless of funding or funding source. Moreover, research conducted by NYS employees in part or in whole in their capacity as Columbia University faculty or employees may occur alongside NYSPI/RFMH research, or make use of the NYSPI facilities and resources, its staff or its students. As such, outside financial and non-financial interests of NYSPI or Columbia Psychiatry researchers that present real or apparent conflicts of interest require EAB review.

The EAB reviews and applies a single set of standards for the disclosure, review and management of conflicts for all research conducted by employees of the NYSPI, RFMH, and the Department of Psychiatry, regardless of funding status or funding source. The most restrictive elements of NYS, RFMH and CU policy, as applicable, are determinative.

### 3. RFMH Consulting Policy

The EAB is responsible for review and approval of proposals under which RFMH will contract with industry (such as pharmaceutical companies) and other commercial entities and their closely affiliated entities for the participation of NYSPI employees in scientific and/or professional consulting activities. Such interaction and collaboration between OMH and industry is necessary to maximize the value of public investment in research and the transfer of science to practice. Nonetheless, it is important to conduct such activities in a manner that does not create a conflict of interest or commitment for the employee and promotes public confidence in the appropriate use of NYS resources. When reviewing applications, the EAB shall ensure that the proposed activity is consistent with the New York Public Officers Law §73 and §74 and serves the interests and mission of OMH. Examples of activities that would be disapproved in almost every case include, but are not limited to, acting as an expert witness or public advocate for private industry or engaging in or advising on marketing, advertising or other promotional activities for private industry.

### 4. *Ad Hoc* Ethics Review

The EAB, or a committee of persons it may designate, will provide consultation and advisory opinions to the Institute and Department on matters involving administrative and educational policies and clinical research. The EAB may be asked to assist in the evaluation or resolution of academic disputes, such as those related to authorship or academic credit. The EAB may also be asked by the IRB to assist in policy development, or by the clinical services, to offer guidance on matters such as treatment over objection. The EAB will advise Institute and Department administration on policy development related to ethics issues.

## B. EAB COMPOSITION

- a. **Voting Members:** The EAB consists of at least five and up to nine members, including a chair, two co-chairs, or a chair and vice-chair appointed by the Director of Research Operations and Compliance, who also serves as a committee member. At least one Member of the EAB must also be a member of the NYSPI IRB.
- b. ***Ex-Officio* Members:** The Director of the Research Foundation for Mental Hygiene at NYSPI, the Director for Administrative Services and the Coordinator of the Ethics Advisory Board are *Ex-Officio* members of the EAB. *Ex-Officio* members of the EAB are not voting members.
- c. **Term:** Members on the EAB sit for a renewable term of three years. There are no term limits for these positions.
- d. **Disclosure:** All Members and *Ex-Officio* Members of the EAB are required to submit Financial Disclosures annually and update disclosures within thirty (30) days of discovering or acquiring a Financial Interest. Any Member or *Ex-Officio* Member who

reports a conflict of interest with any EAB agenda item must recuse himself or herself from review of that issue.

- e. Confidentiality: To the extent possible and as allowed by law, all Financial Disclosures and all information and written materials provided to or produced by the EAB shall be kept confidential. Members of the EAB sign a non-disclosure agreement to this effect upon appointment.
- f. Meetings: The EAB meets monthly when there are issues requiring its review, or as needed.
- g. Agenda: Agenda items are scheduled for EAB review by the Coordinator. The EAB Coordinator is responsible for the collection and review of Financial Disclosures in accordance with RFMH FCOI Policy. All potential Significant Financial Interests identified through this process are referred to the EAB for further evaluation. Additionally, any RFMH or Columbia Investigator may present an issue to the EAB Coordinator and request EAB review and an Advisory Opinion. The NYSPI EAB will also conduct conflict of interest review for the Nathan Kline Institute upon their request.
- h. Quorum: A quorum exists when a majority of the voting members are present.
- i. Decisions: A recommendation can be made by the EAB only by a vote of a majority of the voting members present. Recommendations may also be made after discussion by phone or email, as circumstances require, provided that a majority of the voting members participate.
- j. Minutes: The minutes will document comments or concerns that support the Board's determinations, a summary of issues discussed and their resolution. Additionally, the minutes shall reflect attendance and the number of votes in favor, against or abstaining from a Board decision.
- k. Recommendations: In addition to the monthly minutes, the EAB Coordinator shall prepare memoranda for all final recommendations of the EAB. The memoranda shall contain a brief description of topic, a summary of materials reviewed by the Board, comments and concerns raised during open discussion and the final recommendations of the Board. The Memorandum shall be reviewed and approved by the Co-Chairs, who shall direct its dissemination.

### **C. PROCEDURES FOR REVIEW**

See NYSPI-FCOI Policy  
Policy on RFMH Consulting  
NYSPI/CU Psychiatry Ethics Committee

### **D. AUTHORITY**

- 1.1 RFMH Financial Conflict of Interest Policy, revised December 14, 2012;
- 1.2 By-Laws of the Research Foundation for Mental Hygiene, Inc. (Oct. 2006);
- 1.3 NYSPI Program for Human Subjects Research: Policies and Procedures of the Institutional Review Board (IRB);
- 1.4 Institutional Authorization Agreement (IAA) between Columbia University Department of Psychiatry and NYSPI;

- 1.5 21 CFR Part 50.604 – all institutions carrying out PHS-funded research are required to maintain and enforce policies on Financial Conflicts of Interest;
- 1.6 45 CFR Part 46 – Protection of Human Subjects;
- 1.7 42 CFR 50.601–50.607 - Promoting Objectivity in Research;
- 1.8 New York Public Officers Law §73 and §74;
- 1.9 Columbia University Policy on Financial Conflicts of Interest and Research, Revised, effective as of August 24, 2012.