NEW YORK STATE OF OPPORTUNITY | Department of Health

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HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

August 20, 2019

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Jeffrey J. Conklin, Esq.
NYS Department of Health
Corning Tower Room 2517
Empire State Plaza
Albany, New York 12237

Brandon Porter, M.D.
c/o Michael S. Kelton, Esq.
Abrams, Fensterman, et. al.
1 Metrotech Center, Suite 1701
Brooklyn, New York 11201

Michael S. Kelton, Esq.
Abrams, Fensterman, et. al.
1 Metrotech Center, Suite 1701
Brooklyn, New York 11201

RE: In the Matter of Brandon Porter, M.D.

Dear Parties:

Enclosed please find the Determination and Order (No. 19-213) of the Hearing Committee in the above referenced matter. This Determination and Order shall be deemed effective upon the receipt or seven (7) days after mailing by certified mail as per the provisions of §230, subdivision 10, paragraph (h) of the New York State Public Health Law.

Five days after receipt of this Order, you will be required to deliver to the Board of Professional Medical Conduct your license to practice medicine together with the registration certificate. Delivery shall be by either certified mail or in person to:

Office of Professional Medical Conduct
New York State Department of Health
Office of Professional Medical Conduct
Riverview Center
150 Broadway - Suite 355
Albany, New York 12204

If your license or registration certificate is lost, misplaced or its whereabouts is otherwise unknown, you shall submit an affidavit to that effect. If subsequently you locate the requested items, they must then be delivered to the Office of Professional Medical Conduct in the manner noted above.

As prescribed by the New York State Public Health Law §230, subdivision 10, paragraph (i), (McKinney Supp. 2015) and §230-c subdivisions 1 through 5, (McKinney Supp. 2015), "the determination of a committee on professional medical conduct may be reviewed by the Administrative Review Board for professional medical conduct." Either the licensee or the Department may seek a review of a committee determination.

Request for review of the Committee's determination by the Administrative Review Board stays penalties other than suspension or revocation until final determination by that Board. Summary orders are not stayed by Administrative Review Board reviews.

All notices of review must be served, by certified mail, upon the Administrative Review Board and the adverse party within fourteen (14) days of service and receipt of the enclosed Determination and Order.

The notice of review served on the Administrative Review Board should be forwarded to:

James F. Horan, Esq., Chief Administrative Law Judge
New York State Department of Health
Bureau of Adjudication
Riverview Center
150 Broadway – Suite 510
Albany, New York 12204

The parties shall have 30 days from the notice of appeal in which to file their briefs to the Administrative Review Board. Six copies of all papers must also be sent to the attention of Mr. Horan at the above address and one copy to the other party. The stipulated record in this matter shall consist of the official hearing transcript(s) and all documents in evidence.

Parties will be notified by mail of the Administrative Review Board's Determination and Order.

Sincerely,

James F. Horan
Chief Administrative Law Judge
Bureau of Adjudication

JFH: nm
Enclosure

STATE OF NEW YORK : DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER OF BRANDON PORTER, M.D.	DETERMINATION AND ORDER 19-213

A Notice of Hearing and Statement of Charges dated April 24, 2018 were duly served upon Brandon Porter, M.D. (Respondent.) [Exhibits 2a-2c; Appendix I.] Pursuant to Public Health Law (PHL) § 230(10)(e), Airlie A.C. Cameron, M.D., Chairperson, David F. Irvine, DHSc, P.A. and C. Deborah Cross, M.D., duly designated members of the State Board for Professional Medical Conduct, served as the Hearing Committee in this matter. Dawn MacKillop-Soller served as the Administrative Law Judge. The Department of Health, Bureau of Professional Medical Conduct (Department), appeared by Richard J. Zahnleuter, General Counsel, Jeffrey J. Conklin, Associate Counsel, and Lee A. Davis, Associate Counsel. The Respondent was represented by Michael S. Kelton, Esq. and Jordan Fensterman, Esq.

The Department charged the Respondent with 25 specifications of professional misconduct, as defined in Education Law (Educ. Law) § 6530. The Respondent denied the factual allegations and specifications of misconduct. The Department withdrew factual allegations A.10, A.11, A.12, C.9 and the twenty fifth specification of misconduct. The Hearing Committee examined documents from the Department [Exhibits 1, 2a-c, 3, 4, 6, 8a, 9, 10B, 10b, 11, 12, 13, 14, 19a, 20a, 21a, 22, 34a, 39] and the Respondent [Exhibits A, J2, Q, R, V, W, Y] and a transcript of the proceeding was made [Transcript, p. 1-2472.] The Hearing Committee votes 3-0 to sustain the first through twenty-fourth specifications of misconduct and determines to revoke the Respondent's medical license pursuant to PHL § 230-a.

Procedural History

Pre-Hearing Conference:	June 12, 2018
Hearing Dates:	June 27, 2018 July 12, 18 and 24, 2018 August 9, 2018 October 2, 10, 25 and 29, 2018 November 13 and 28, 2018 December 4 and 17, 2018 January 15, 2019 April 10, 2019
Witnesses for Petitioner:	Elmer Streeter Thea Dalfino, M.D. Steven Hanks, M.D. Brandon Porter, M.D. Subject A.5 Ariella Cepelinski Michael Menashy Bruce F. Farber, M.D. Robert L. Klitzman, M.D.
Witnesses for Respondent:	Julia Berry Subject A.7 Lucas Roberts Robert Younis Subject A.10 Dolores Wilson Sean Craney Evan Horowitz Subject A.9 Respondent's spouse Roxane Cohen Silver, Ph.D. Brandon Porter, M.D.
Written Submissions dated:	April 10, 2019
Deliberations held:	May 8, 2019 June 11, 2019 June 20, 2019

Applicable Law

1. A researcher is "any person licensed under title VIII of the education law to perform diagnosis, treatment, medical services, prescription or therapeutic exercises with regard to or upon human beings." PHL § 2441(6).

2. Only a researcher is permitted to conduct human research. PHL § 2443.

3. Human subject is defined as:

> any individual who may be exposed to the possibility of injury, including physical, psychological or social injury, as a consequence of participating as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs or which increases the ordinary risk of daily life. PHL § 2441(1).

4. Human research consists of:

> any medical experiments, research or scientific or psychological investigation, which utilizes human subjects and which involves physical or psychological intervention by the researcher upon the body of the subject and which is not required for the purposes of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of medical condition for the direct benefit of the subject. PHL § 2441(2).

5. Each public or private institution or agency which "conducts, or which proposes to conduct or authorize, human research, shall establish a human research review committee" pursuant to the following requirements:

> Such committee shall be composed of not less than five persons, approved by the commissioner, who have such varied backgrounds as to assure the competent, complete and professional review of human research activities conducted or proposed to be conducted or authorized by the institution or agency. No member of a committee shall be involved in either the initial or continuing review of an activity in which he has a conflicting interest, except to provide information required by the committee. PHL § 2444(1).

6. A person conducting human research "shall affiliate himself with an institution or agency having a human research review committee, and such human research as he conducts or proposes to conduct shall be subject to review by such committee." PHL § 2444(3).

7. The human research review committee (HRRC) for each institution or agency shall "promulgate a statement of principle and policy in regard to the rights and welfare of human subjects in the conduct of human research, and the committee and the commissioner shall approve that statement prior to its taking effect." It is the responsibility of a HRRC to determine the following with regard to a proposed human research project:

> (1) its necessity;
> (2) that the rights and welfare of the human subjects involved are adequately protected,
> (3) that the risks to the human subjects are outweighed by the potential benefits to them or by the importance of the knowledge to be gained;
> (4) that the voluntary informed consent is to be obtained by methods that are adequate and appropriate, and
> (5) that the persons proposed to conduct the particular medical research are appropriately competent and qualified.

The HRRC is required to "periodically examine each existing human research project with regard to the proper application of the approved principles and policies which the institution or agency has promulgated." PHL § 2444(2).

8. Human research shall not be conducted "in the absence of the voluntary informed consent subscribed to in writing by the human subject." PHL § 2442.

9. Voluntary informed consent is defined as:

> (t)he legally effective knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion. With regard to the conduct of human research, the basic elements of information necessary to such consent include:

(a) a fair explanation to the individual of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;
(b) a description of any attendant discomforts and risks reasonably to be expected;
(c) a description of any benefits reasonably to be expected;
(d) a disclosure of any appropriate alternative procedures that might be advantageous for the individual;
(e) an offer to answer any inquiries by the individual concerning the procedures; and
(f) an instruction that the individual is free to withdraw his consent and to discontinue participation in the human research at any time without prejudice to him. PHL § 2441(5).

10. Physicians' reporting obligations for communicable or unusual disease outbreaks are:

> It shall be the duty of every physician to report to the city, county or district health officer, within whose jurisdiction such patient resides, the full name, age and address of every person with a suspected or confirmed case of a communicable disease, any outbreak of communicable disease, any unusual disease or unusual disease outbreak and as otherwise authorized in section 2.1 of this Part, together with the name of the disease if known, and any additional information requested by the health officer in the course of an investigation pursuant to this part, within 24 hours from the time the case is first seen by him, and such report shall be by telephone, facsimile transmission or other electronic communication if indicated, and shall also be made in writing, except that the written notice may be omitted with the approval of the State Commissioner of Health. 10 NYCRR 2.10.

11. Any "disease outbreak or unusual disease" shall be reported to the Department of Health. Unusual disease is defined as:

> a newly apparent or emerging disease or syndrome of uncertain etiology that a health care provider or the State Commissioner of Health has reason to believe could possibly be caused by a transmissible infectious agent or microbial toxin. 10 NYCRR 2.1(c).

12. Under 10 NYCRR 2.27, a physician has a duty to isolate a patient with a highly communicable disease "as defined in section 2.1 of this Part" until "official action by the health officer." This requirement also applies to diseases deemed by the State Commissioner of Health (Commissioner) to be "communicable, rapidly emergent or a significant threat to public safety." 10 NYCRR 2.1(a).

Findings of Fact

1. Brandon Porter, M.D. was authorized to practice medicine in New York State on June 12, 2009, by the issuance of license number 253486. The Respondent's background includes M.D. and Ph.D. graduate degrees from the University of Iowa as part of a Medical Science Training Program. [Exhibit 1; Transcript, p. 2386.]

2. Beginning in 2001, the Respondent became a member of NXIVM, a corporation based in Albany, New York and founded by Keith Raniere, with the "goal to do research," specifically to evaluate whether the NXIVM curriculum produced measurable results. The Respondent relocated for NXIVM in 2009 to Albany, New York, from Iowa to "measure the program and see how well it's working." The Respondent alleged the purpose of NXIVM was to help people build more joy in their lives and achieve self-improvement goals through its programs, which included Executive Success Programs, of which Nancy Salzman was president, the Ethical Science Foundation, funded by Clare Bronfman as president, and the Ethicist, overseen by Daniella Padilla and Lauren Saltzman. NXIVM targeted individuals willing to pay for courses to improve themselves personally and professionally. [Transcript, p. 122-124, 130, 134-35, 142, 158, 361, 2089-2090, 2357-2358.]

3. Between 2009 and 2017, the Respondent was employed as a hospitalist at St. Peter's Hospital in Albany. His job duties included providing care and treatment to hospital patients and making referrals to specialists. In September of 2017, the Respondent met with Steven Hanks, M.D., Chief Medical Officer, and his supervisor, Thea Dalfino, M.D., Chief of Hospital Medicine, to discuss his employment amid "reputational concerns" after articles emerged that he was showing videos to people. The Respondent admitted to the physicians that he was conducting human subject research without IRB approval. One month later, Dr. Hanks provided the Respondent with the opportunity to resign from this position and the Respondent accepted. [Transcript, p. 55-56, 91, 93-94, 99, 121, 309, 2083.]

4. Within the period of 2010 through 2017, the Respondent performed human subject research on approximately 200 subjects, including A.7 and A.10, participating in courses through NXIVM's Executive Success Program (ESP study). As part of the study, he used an electroencephalogram (EEG) to record the subjects' brain activity, galvanic skin resistance (GSR) to measure their physiological responses and a video camcorder or audio tape to record their facial or auditory reactions. The Respondent claimed his purpose in using these devices was to evaluate subjects' brainwave and emotional responses to the curriculum. [Transcript, p. 128-129, 133, 324-325, 328, 366, 857, 2175.]

5. Between 2012 and 2017, as part of NXIVM's Executive Success Program, the Respondent performed human subject research on ten subjects diagnosed with Tourette's Syndrome, including C.1, when he counted their tics and instructed them to complete Yale Global Tic Severity Scale surveys to determine the severity of their Tourette's symptoms. He also used the EEG, GSR and video camcorder to record their tics and the results of Nancy Saltzman working with them over the course of four to 20 sessions. The Respondent alleged the purpose in the Tourette's study was to measure improvement or changes of the subjects' Tourette's symptoms. [Transcript, p. 132, 292, 295-299, 303, 832, 2136-2141.]

6. Following completion of the Tourette's study, on behalf of NXIVM, five out of the ten subjects participated in a documentary film, *My Tourette's,* which was made available online and identified the Respondent as "lead researcher." [Exhibit Q; Transcript, p. 2141, 2147, 2153.]

7. Within the period 2012 to 2017, on behalf of NXIVM Executive Success Programs, the Respondent performed human subject research on two subjects diagnosed with Obsessive-Compulsive Disorder (OCD), including B-1, when he administered Yale-Brown Obsessive-Compulsive Scale surveys to measure the severity of their OCD symptoms (OCD study) and used a video camcorder to record the results of Nancy Saltzman working with B.1. [Transcript, p. 314, 844, 2162-2163, 2170.]

8. Between 2016 through August of 2017, as part of NXIVM's Ethicist program, the Respondent performed human subject research on approximately 40 human subjects, including A.1, A.2, A.5, A.6, A.7, A.9 and A.10, by showing them happy or inspirational and disturbing or graphically violent scenes from commercials, short films and movie clips (video clips study). These clips included a video depicting the actual murders and dismemberment of five women and movie scenes showing a gang rape and a racially motivated murder of an African American male. The Respondent used the EEG and GSR to record their brainwaves and physiological responses to watching the clips. He also used a video camcorder to record their facial expressions. [Exhibits 19a, 20a, 21a, 22, Y; Transcript, p. 158-61, 170-74, 177-179, 252-255, 365-366, 806.]

9. The Respondent's conduct in performing the video clips, Tourette's, OCD and ESP human research studies on the subjects, including A.1, A.2, A.5, A.6, A.7, A.9, A.10, B.1 and C.1, constituted the practice of medicine. The Respondent also practiced medicine when he prescribed Wellbutrin to subject B-1 on two occasions, which he completed without documenting a clinical record or communicating with the subject's treating psychiatrist. [Transcript, p. 318-320, 390, 2384.]

10. The Respondent collected the data from the EEGs, galvanic skin responses and video camcorder and downloaded it to a computer. The data, hard drive and equipment used for the studies, lists containing names of study participants and OCD and Tourette's surveys are located in the locked room of a building used by the Ethical Science Foundation and beyond the Respondent's control. [Transcript, p. 171-73, 177, 218, 301, 303, 321, 328, 2146.]

11. The Respondent labeled the data by assigning non-random numerical values to the subjects based on the order in which they "joined the study." This number and the subjects' names were placed on a list, which was saved to the computer. The video data shows the subjects' unmasked faces. [Transcript, p. 367-368, 1451, 2133, 2165.]

12. It was a deviation from the standard of care for the Respondent not to maintain the data from the studies himself. The Respondent was obligated to safeguard the data to prevent its improper use. [Transcript, p. 852, 1261.]

13. In performing the human research studies, the Respondent exposed the subjects, including A.1, A.2, A.5, A.6, A.7, A.9, A.10, B.1 and C.1 to risks of harm, including psychological and physical anguish, pain and suffering and data breaches of their confidential and sensitive information. The subjects' responses from the EEGs and other recording devices were never analyzed, resulting in studies without results or benefits to science, medicine or humankind. [Transcript, p. 816-818, 822, 828, 848, 861, 864.]

14. Prior to performing human research on the subjects, including A.1, A.2, A.5, A.6, A.7, A.9, A.10, B.1 and C.1, the Respondent was required to apply to the Commissioner to establish a HRRC or affiliate himself with an institution or agency having a HRRC to review the studies in accordance with New York State laws, neither of which he accomplished. A HRRC is equivalent to an Institutional Review Board (IRB) as an entity that reviews human subject research not in compliance with, or subject to, federal regulations. PHL § 2444(1); PHL § 2444(3). [Transcript, p. 153, 165, 186, 309, 329, 748, 753.]

15. The Respondent very seriously deviated from the standard of care by performing human subject research without approval from the Commissioner to establish a HRRC or affiliation with an institution or agency having a HRRC. The purpose of a HRRC is to assess risks, protect subjects and avoid abuse. [Transcript, p. 747, 752-753, 755-758, 763, 811-812, 835, 839, 854, 862.]

16. Prior to performing human research on the subjects, including A.1, A.2, A.5, A.6, A.7, A.9, A.10, B.1 and C.1, the Respondent was required to obtain their voluntary, written informed consent. The Respondent failed to obtain this consent from the subjects. PHL § 2442. [Transcript, p. 157.]

17. The Respondent very seriously deviated from the standard of care by performing human subject research on the subjects without obtaining their written, informed consent. It is essential to obtain

initial written informed consent and written reconsent to inform subjects of the human research details, risks, benefits, the right to withdraw and plans for confidentiality protection and minimization of risks. PHL § 2442. [Transcript, p. 747, 769-771, 811-812, 835, 839, 854, 862.]

18. Prior to performing human research on subjects, including A.1, A.2, A.5, A.6, A.7, A.9, A.10, B.1 and C.1, the Respondent was required to complete human subject research training to confirm his competency and qualifications to engage in such research. The Respondent never completed this training. [Transcript, p. 156-157.]

19. The Respondent very seriously deviated from the standard of care in performing human subject research without completing human subject research training. The purpose of the training is to ensure research staff adhere to rules, laws and standards applicable to human subject research. [Transcript, p. 772, 811, 835, 839, 854, 862, 1934.]

20. Prior to performing human research on subjects, including A.1, A.2, A.5, A.6, A.7, A.9, A.10, B.1 and C.1, the Respondent was required to submit a research protocol, informed consent templates certificates of human subject research training and plans for data interpretation and statistical methods to an HRRC for review. The Respondent never submitted these documents. The protocol would identify research details, including its necessity, purpose, benefits and risks, the research team and plans for minimizing risks and protecting confidentiality. PHL § 2444(2). [Transcript, p. 149, 154, 737, 742, 1258.]

21. The Respondent very seriously deviated from the standard of care by performing human subject research without submitting any of these documents to a HRRC. The purpose of this requirement is to ensure human subject research respects persons by protecting their rights and autonomy. PHL § 2440. [Transcript, p. 745-748, 750-756, 811, 835, 839, 854, 862.]

22. Between August and into the beginning of September of 2016, the Respondent participated in an annual corporate retreat for NXIVM at the Silver Bay YMCA Family and Retreat Center, located in

Silver Bay, New York. The Respondent alleged that the goal of the event was for NXIVM members to "be joyful" and celebrate "humanity." Approximately 400 to 450 NXIVM members attended this event. [Exhibit 12; Transcript, p. 331, 334, 430.]

23. While attending this event, the Respondent became aware that many of the attendees, including a pregnant woman, infants and young children, became ill with a wide-spread gastrointestinal illness and suffered symptoms of nausea, vomiting, diarrhea and abdominal pain. The Respondent suspected the cause of the illness was a virus, possibly Norovirus. Norovirus is contagious and can lead to large, quick outbreaks of the disease. [Transcript, p. 334, 337-338, 342, 350, 430, 625.]

24. This illness constituted an unusual disease outbreak. It included a group of people who developed symptoms that they otherwise would not have had. Physicians are legally obligated to report any disease outbreak or unusual disease to public health officials and pending a response, isolate infected individuals. The Respondent failed to satisfy these obligations. 10 NYCRR 2.10; 10 NYCRR 2.1(c); 10 NYCRR 2.27. [Transcript, p. 350, 352, 620, 640, 688, 700.]

25. It was a moderate departure from the standard of care for the Respondent not to report the disease outbreak. The attendees and public were placed at risk for harm, including preterm labor for pregnant women, dehydration for neonates and infants and morbidity for the immunosuppressed or renal compromised. [Transcript, p. 621, 626, 632, 639, 651-653, 658, 697.]

Witness credibility

The Hearing Committee based its conclusions on whether the Department met its burden of establishing that the allegations contained in the Statement of Charges were more probable than not. PHL § 230(10)(f). The Respondent claims his research does not constitute human subject research requiring IRB oversight and involves "personal conduct outside the practice of medicine, specifically during self-improvement courses and events." [Respondent's brief, p. 2.] In support of these arguments, the

Respondent provided the expert testimony of a psychologist, Roxane Cohen Silver, Ph.D. Although Dr. Silver's background includes 40 years' experience as a research psychologist studying individuals and communities coping with traumatic events and community disasters, academic appointments at the University of California, Irvine, fellow to many organizations and awards, including from the American Psychological Association for "distinguished contributions to society," the Hearing Committee discredited her testimony based on her unfamiliarity with the applicability of PHL Article 24-A to human subject research. She based her opinions solely on her background in the federal regulations or "common rule" and limited review of the Department of Health Institutional Review Board (DOH IRB) guidelines, both of which are inapplicable to this case. 45 CFR 46.101(a); New York State Department of Health Institutional Review Board, IRB Guidelines for Researchers, Version 4, May 2015, p. 2. [Exhibit W; Transcript, p. 1707-1891, 1897-2045.]

Dr. Silver's opinion that all "research that is conducted in the state of New York falls under the (c)ommon rule" demonstrated her unawareness of the requirements for human subject research performed in New York State that is not in compliance with and/or subject to federal regulations. [Transcript, p. 1862.] This opinion disregards the circumstances when the federal regulations apply, which is only to human research "conducted, supported or otherwise subject to regulation by any federal department or agency." 45 CFR 46.101(a). She also misunderstood that equally inapplicable are the NYS DOH guidelines, which specifically pertain to research conducted within the jurisdiction of the Department of Health by Department and Health Research Inc. employees or agents in accordance with the federal regulations. IRB Guidelines for Researchers, p. 2. The only applicable requirements to the Respondent's human research studies are under PHL Article 24-A. *See also* PHL § 2445; 45 CFR 46.101(f).

Further noted by the Hearing Committee was Dr. Silver's failure to review most of the evidence, including the videos, the complete testimony from the Respondent and Department witness A.5 and

transcripts from many of the other fact witnesses. Dr. Silver's level of unpreparedness and steady refusal to recognize the applicability of PHL Article 24-A to the Respondent's human subject research raised credibility concerns for the Hearing Committee. The Hearing Committee found the testimony of the Department's psychiatry expert witness, Dr. Klitzman, on the other hand, more credible and convincing than Dr. Silver's in his opinion that the Respondent's studies constituted human subject research and required HRRC oversight and approval. Dr. Klitzman's opinions were based on his decades of experience specializing in research ethics and human research studies in accordance with New York State requirements and his thorough understanding of PHL Article 24-A.

Dr. Klitzman's opinions are not "unsupportable under commonly accepted standards for human subject research," as suggested by the Respondent. [Respondent's brief, p. 3.] To the contrary, his testimony was consistent with the evidence, which confirmed "the accepted standards throughout the country and world at this point for human research" mandate review by an IIRRC or similar entity to ensure human research protects subjects from harm. PHL § 2444(1); PHL § 2444(3); 45 CFR 46.101(a); DOH IRB guidelines, p. 2. [Transcript, p. 747.] The Hearing Committee noted Dr. Klitzman's background also includes clinical practice, journals, chapters in medical books, lectures, academic positions, publications and interviews with major media outlets on human subject research and related ethical issues. He is the author of a book on IRBs and human subject research, The Ethics Police?: The Struggle to Make Human Research Safe, which was published in 2015, and director of the Master's of Bioethics Program at Columbia University, which explores ethical medical research issues. [Exhibit 4; Transcript, p. 717-937, 1170-1294, 1467-1517.]

The Department also produced infectious disease expert Bruce Frederick Farber, M.D. to testify in support of its charges against the Respondent involving violations of the New York State Sanitary Code. Dr. Farber has over 30 years' experience as an infectious disease specialist and his background includes

Chief, Division of Infectious Diseases, at North Shore University Hospital, in Manhasset, New York, and Long Island Jewish Medical Center, in New Hyde Park, New York, hospital epidemiologist and author of numerous journal articles on hospital acquired infections. His current academic appointments include Hofstra Northwell Medical School, in Uniondale, New York. The Hearing Committee found Dr. Farber's testimony, which the Respondent failed to refute, credible and consistent with the evidence. [Exhibit 6; Transcript, p. 607-710.]

The Department's additional witnesses included Elmer Streeter, Director of Communications, St. Peter's Hospital [Transcript, 31-45], Dr. Dalfino [Transcript, p. 45-84] and Dr. Hanks. [Transcript, p. 85-118.] These witnesses testified regarding the Respondent's employment tenure at St. Peter's Hospital, his reputation and character and admissions he made regarding human subject research and IRB approval. The Department also presented testimony from witness A.5 [Transcript, p. 405-537], who described his personal experience with the video clips study and as a NXIVM member. The Department also presented as witnesses Ariella Cepelenski [Transcript, p. 543-584] and Michael Menashy [Transcript, p. 584-597], both of whom testified regarding their attendance at NXIVM's annual retreat at the Silver Bay YMCA to discuss the outbreak of an infectious illness at the facility. The Hearing Committee found these witnesses credible and gave great weight to their testimony because it was consistent with the other evidence.

The Respondent testified as a witness for the Department [Transcript, p. 120-399] and provided testimony on his own behalf. [Transcript, p. 2059-2395.] The Hearing Committee noted his obvious stake in the outcome of this proceeding and evaluated his testimony accordingly. There were inconsistencies in his testimony regarding fundamental facts in this case, such as what constitutes human subject research and when IRB oversight is required. The Respondent also produced as witnesses A.7 [1075-1162], A.9 [1297-1355], A.10 [1359-1409], Robert Younis [1019-1075], Sean Craney [1409-1459], Julia Berry [944-1019], Delores Wilson [Transcript, p. 1520-1588], his spouse [Transcript, p. 1589-1609] and Evan

Horowitz [Transcript, p. 1610-1699], all of whom described the Respondent's character and their knowledge of his studies. The Hearing Committee found them knowledgeable but attributed their unrealistic expectations regarding the confidentiality of their data and potential harm from the studies to their strong ties to the Respondent and NXIVM.

Conclusions of Law

The vote of the Hearing Committee on whether the factual allegations contained in the Statement of Charges were proven by a preponderance of the evidence is as follows:

Paragraph	A – A.1	Sustained
	A – A.2	Sustained
	A – A.3	Sustained
	A – A.4	Sustained
	A – A.5	Sustained
	A – A.6	Sustained
	A – A.7	Sustained
	A – A.8	Sustained
	A – A.9	Sustained
	A – A.13	Sustained
	A – A.14	Sustained
	A – A.15	Sustained
	A – A.16	Sustained
Paragraph	B – B.1	Sustained
	B – B.2	Sustained
	B – B.3	Sustained
	B – B.4	Sustained
	B – B.5	Sustained
	B – B.6	Sustained
	B – B.7	Sustained
	B – B.8	Sustained
	B – B.9	Sustained
Paragraph	C – C.1	Sustained
	C – C.2	Sustained
	C – C.3	Sustained
	C – C.4	Sustained
	C – C.5	Sustained
	C – C.6	Sustained
	C – C.7	Sustained
	C – C.8	Sustained

Paragraph	D – D.1	Sustained
	D – D.2	Sustained
	D – D.3	Sustained
	D – D.4	Sustained
	D – D.5	Sustained
	D – D.6	Sustained
	D – D.7	Sustained
	D – D.8	Sustained
Paragraph	E – E.1	Sustained
	E – E.2	Not sustained[1]
	E – E.3	Sustained

Practice of the profession of medicine

The Respondent's claim that his conduct was "personal" and "outside the practice of medicine" because "no clinical care and treatment was rendered" to "any of the individuals identified in the Statement of Charges" is not supported by the evidence. [Respondent's brief, p. 1-2, 16-17.] The practice of the profession of medicine is defined as "diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition." Educ. Law § 6521. This definition includes evaluating, treating or prescribing in a non-traditional medical or therapeutic setting and outside a formal physician-patient relationship. Matter of Emanuel Falcone, M.D., 2008 NY Phys. Dec. Lexis 331, p. 24. Whether a physician's conduct occurred in the course of the practice of medicine is a factual issue for the Hearing Committee to resolve. Addei v. State Bd. For Professional Med. Conduct, 278 AD2d 551, 552 (3d Dept. 2000); Educ. Law § 6504.

The Respondent concedes he used his authority as a physician to provide medical treatment when he issued Wellbutrin prescriptions to subject B.1, but he denies rendering any other medical care to B.1 or the other study subjects. [Respondent's brief, p. 1.] The evidence confirmed, however, that the

1 The Department presented no evidence to support the allegation that food poisoning caused the gastrointestinal illness. Dr. Farber's testimony as to the basis for diagnosing food poisoning could not clearly connect the outbreak of the unusual disease with a food borne illness. As such, the Hearing Committee declined to sustain factual allegation E-E.2.

Respondent practiced medicine when he evaluated the subjects and hooked them up to an EEG machine and GSR, which are medical devices, and collected their EEG readings and emotional responses for measurement purposes as part of the video clips, Tourette's and ESP studies. The Respondent also practiced medicine during the Tourette's study when he gained clinical information from C.1 about her medical illnesses, psychiatric treatment and medications and performed therapy or counseling. He also engaged in the practice of medicine when he administered surveys to B.1, C.1 and the other Tourette's and OCD study subjects to measure their symptoms related to their medical diagnoses. [Transcript, p. 57, 131-132, 160, 243, 870-873, 1334, 2280, 2335, 2383.]

Although some of these tasks can be performed by technicians, the record establishes that the Respondent used his status as licensed physician to obtain the trust and participation of the individuals subjected to these human research studies. The Respondent acknowledged his ongoing responsibilities as a physician in his testimony that his goal in "doing science" and "being a physician" was to "help people," which he seeks to achieve "in everything (he does)." In fact, he acknowledged that his status as a physician was well-known in the NXIVM community, which is consistent with his testimony that he "(o)ftentimes" responded to questions from members about "colds and things like that." Dr. Klitzman's testimony confirmed that the Respondent's ongoing physician duties applied to all his interactions with the subjects even though he never engaged them in a formal physician-patient relationship. [Transcript, p. 251, 380-381, 437, 872, 1060, 1114, 1346, 2280.]

The Respondent attempts to support his claim that his studies constituted research "outside" the practice of medicine by pointing to his extensive, respected clinical experience as a hospitalist at St. Peter's Hospital and his reputation as kind and considerate among staff and patients, evidence the Department does not dispute. [Respondent's brief, p. 5-6.] Indeed, Dr. Hanks and Dr. Thea Dalfino consistently testified to the Respondent's stellar reputation in that position for his clinical work, patient care and

professionalism. This testimony is also consistent with A.7's characterization of him as "a man of integrity and a doctor" and A.10's description of him as honorable and trustworthy. The Respondent's reputation, however, does not disprove the evidence establishing he practiced medicine as part of his human subject research studies. The Respondent's status as a physician entitled him to conduct human subject research and in doing so, he was required to adhere to applicable laws, rules and regulations, which the evidence established he failed to do. PHL § 2441(6). [Exhibit J2; Transcript, p. 78-80, 113, 1367-1368, 1383-1386.]

The Hearing Committee unanimously determined that the Respondent's conduct in issuing Wellbutrin prescriptions for B.1 without maintaining a record constituted professional misconduct as defined in Educ. Law § 6530(32), failing to maintain a record for a patient which accurately reflects the evaluation and treatment. Physicians are required to maintain records for each patient that "accurately reflect the evaluation and treatment of the patient," including prescription details. Mucciolo v. Fernandez, 195 AD2d 623, 625 (3d Dept. 1993). The Respondent's issuance of these prescriptions without documenting them or any discussions with B.1's treating psychiatrist represented to the Hearing Committee his disregard for recording meaningful clinical information for other providers' follow-up or contemporaneous care. [Transcript, p. 318-320, 2383-2384.]

Human subject research

In September of 2017, the Respondent conceded to Dr. Hanks and Dr. Dalfino that he performed human subject research without IRB approval, but he backpedaled on that admission at the hearing to claim his studies did not constitute human subject research requiring such oversight. [Respondent's brief, p. 2, 9, 17.] In support of this claim, the Respondent relies on the same inapplicable NYS DOH guidelines used by Dr. Silver that define human subject research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge," which mirrors the definition under the federal regulations. IRB Guidelines for Researchers, p. 9-10; *See*

45 CFR 46.102(d). [Respondent's brief, p. 8, 17.] This definition only applies to research under a "Federalwide Assurance" completed in accordance with "the federal regulations" that is "conducted by or under the direction of any employee or agent of the NYS DOH or Health Research, Inc. (IIRI)." IRB Guidelines for Researchers, p. 2; *See* 45 CFR 46.101. None of these elements apply to the Respondent's studies on behalf of NXIVM, a private corporation. [Transcript, p. 56, 93, 131-132, 1753-1754, 1819, 1984, 2002.]

The Department correctly claims that the Respondent's studies are "subject to the provisions of Public Health Law Article 24-A," which define human subject research as "medical experiments, research or scientific or psychological investigation, which utilizes human subjects and which involves physical or psychological intervention." PHL § 2441(2). [Department's brief, p. 17.] Dr. Silver conceded her confusion on the applicability of this law to this case and unfamiliarity with any of its provisions. Dr. Klitzman, however, testified consistent with the definition of human subject research under PHL Article 24-A that human subject research is a psychological intervention with human subjects to gain knowledge that has risks. All human subject research conducted in New York State not subject to, or in compliance with, "policies and regulations promulgated by any agency of the federal government," is subject to PHL Article 24-A. PHL § 2445. [Transcript, p. 785, 791, 806, 1923, 1929.]

Generalizable

Even considering the definition of human subject research under the DOH IRB guidelines and federal regulations, the Hearing Committee decided that the Respondent's studies would still constitute human subject research that would require IRB approval. IRB Guidelines for Researchers, p. 9; 45 CFR 46.102(d). [Respondent's brief, p. 8, 17, 45.] It is undisputed that the studies are systematic based on the Respondent's interventions with the subjects, including EEGs and surveys, which he performed to gather information. The Hearing Committee disagreed with Dr. Silver's opinion that the Respondent's studies

are not generalizable because they are "internal to an organization" and done with "the intent of only improving the program." IRB Guidelines for Researchers, p. 10; 45 CFR 46.101(b). This opinion lacked any credibility for the Hearing Committee because in the past three decades, all of Dr. Silver's human subject research studies have been deemed generalizable and subject to IRB approval and review, which means none of them have ever been exempt from this form of oversight. The Hearing Committee concluded that the Respondent's studies contribute to generalizable knowledge by having implications or relevance for at least one other person, which is consistent with Dr. Klitzman's description of generalizable as reaching "beyond the individual." [Transcript, p. 806, 833, 844, 857, 891, 1204-1208, 1754, 1757, 1765, 1780, 1832, 1857.]

Dr. Silver's opinion that the Respondent's studies do not contribute to generalizable knowledge because his intent was not to "publish or present the findings" is contrary to the evidence. The Respondent admitted his intent in performing the Tourette's evaluations was to "help people" and maybe "publish" the results. Dr. Hanks also credibly testified that the Respondent admitted that in performing the Tourette's study, his intent was "to do something" with the outcomes to help others. Indeed, the Respondent is identified as "lead researcher" in the credits of a promotional NXIVM movie, *My Tourette's,* made available online to document the Tourette's study results. His testimony that his "goal" was to "have a legitimate, like, human research study with controls" – an objective shared by subjects that their EEGs would lead to scientifically reproducible results – evinces an intent to contribute to generalizable knowledge. [Exhibit Q; Transcript, p. 93, 132-133, 168, 259, 301, 389, 930, 1370, 1765-1768, 1832, 1857.]

The Hearing Committee also considered that the Respondent's generalizable argument lacked any merit because it hinges on his activities qualifying as exempt, a status the evidence showed they fail to meet. [Respondent's brief, p. 9, 17.] IRB Guidelines for Researchers, p. 10; 45 CFR 46.101(b), p. 5-6.

Activities that do not contribute to generalizable knowledge include those intended for "internal improvements to an educational program and/or intended to be for quality assurance purposes." IRB Guidelines for Researchers, p. 10; 45 CFR 46.101(b). In support of his argument, the Respondent relies on the testimony of A.5 to claim that "NXIVM ESP courses were promoted as a university program," yet this witness never mentioned such a program. [Respondent's brief, p. 9.] The only "university" information for NXIVM referenced at this hearing was from Ms. Wilson, who merely mentioned the possibility of "a credit course" taught by Nancy Saltzman in Mexico, which hardly meets the criteria for the Respondent's studies to qualify as exempt. The Respondent's studies would not be exempt because they neither follow customary educational practices, such as their use in schools nationwide, nor serve a public benefit evaluative process, like Medicare or Medicaid. They also would not qualify because they have risks and involved subjects with medical diagnoses, such as Tourette's Syndrome and OCD. [Transcript, p. 524-525, 780-783, 786, 791, 1526, 1756-57.]

The Hearing Committee also rejected the Respondent's attempt to shift responsibility from himself, as a "researcher," to a "principal investigator" to decide whether the studies contribute to generalizable knowledge. [Respondent's brief, p. 9.] The evidence established that regardless of the Respondent's research role, the burden was on him, as part of the research team, to submit this issue to an IRB to decide. Dr. Silver incorrectly delegates this task to "the researcher, him or herself, by evaluating the intent of the activity." The Hearing Committee recognizes that researchers have an implicit bias in determining what is generalizable and have conflicts of interest in evaluating the safety of their own research. [Transcripts, p. 1212, 1237, 1271, 1766, 1781.]

Video clips study

The Hearing Committee determined that the Respondent's video clips study constituted human subject research. This decision was based on the Respondent's performance of a psychological

investigation in which he intervened with people for the purpose of seeking knowledge that exposed them to risks of harm. PHL § 2441(1) and (2). The Respondent's purpose in performing this study was to show the subjects happy, inspirational, disturbing and violent video clips and evaluate which of them evoked emotions in the subjects. His interventions included measuring an "integration" or "new meaning" they experienced while watching the clips by using EEGs to monitor their brainwaves, GSR to measure their physiological reactions and a video camcorder to record their facial expressions. He also selected the subjects and designed the sequencing of the video clips. [Exhibits 19a, 20a, 21a, 22, Y; Transcript, p. 159, 170, 173, 236-238, 247-248, 325, 363, 382, 398, 806-807, 816, 2247, 2263, 2349.]

Tourette's and OCD studies

The Hearing Committee found these studies constituted human subject research. This conclusion was made because the Respondent psychologically intervened with the subjects to seek knowledge that placed them at risk for harm. PHL § 2441(1) and (2). His interventions included videotaping the subjects and administering them Yale Global Tic Severity Scale and Yale-Brown Obsessive-Compulsive Scale questionnaires to measure the severity of their symptoms. He also performed EEG procedures on the Tourette's subjects. The subjects' medical diagnoses of Tourette's Syndrome and OCD also automatically qualified these studies as human subject research. The Hearing Committee rejected the Respondent's attempts to distance himself from these studies in his claim that his role was "minimal" due to the level of Nancy Saltzman's involvement. [Respondent's brief, p. 2.] As part of the research team, he remained responsible for performing human subject research. [Transcript, p. 292, 295, 312, 786, 791, 793, 844.]

ESP study

The Hearing Committee concluded that this study constituted human subject research. This determination was based on the Respondent's psychological intervention with the subjects to gain knowledge that placed them at risk for harm. PHL § 2441(1) and (2). The Respondent's purpose in

performing this study was to evaluate their emotional responses by measuring the subjects' brainwaves in connection with how frequently they experienced integrations during the curriculum. The Respondent's interventions included performing EEGs and GSR and using a video camcorder on the subjects during the coursework. [Transcript, p. 133, 144-145, 324-328, 857, 1329, 2174-2175, 2177.]

HRRC

The Respondent claims his studies do not "require oversight from an IRB." [Respondent's brief, p. 17.] In New York, however, a person conducting human research is required to apply to the Commissioner to establish a HRRC or affiliate himself with an institution or agency having a HRRC. PHL § 2444(1); PHL § 2444(3). A human researcher's responsibilities also include submitting documents to a HRRC for approval, including an application for the research project, proposed surveys, certificates of human subject research training, plan for data interpretation and protocol identifying the research hypothesis, necessity, benefits, risks, templates for informed consent and identification of the research team. PHL § 2444(2). Enforcement of these mandatory rules is required to ensure human subject research is completed justly and avoids harm. These principles are consistent with the Legislature's "vital concern" in "(s)afeguarding the rights and welfare of individual human subjects" as part of its policy and purpose as stated in Article 24-A. PHL § 2440. The Respondent concedes that he did not adhere to these laws, which Dr. Klitzman deemed a serious deviation from the standard of care. [Transcript, p. 153, 156, 244, 727, 746, 754, 811, 835, 839, 854, 862.]

Voluntary informed consent must be without undue influence or coercion, which the evidence established as missing in this case. The purpose of this rule is to confirm subjects fully understand study procedures, risks, benefits, withdrawal options and to guard against undue influence. PHL § 2441(5). The Respondent's alleged ongoing, verbal consent is no substitute for written informed consent, and even reconsent, as required. PHL § 2442. The Hearing Committee rejected the Respondent's attempts to cast

blame on the subjects for not discontinuing the video clips study. The evidence established the deference they had for the Respondent, as a trusted physician and friend, in their continued participation despite its harmful content. The Hearing Committee noted these factors impinged on the voluntariness of the subjects' consent and their ability to withdraw at any time, highlighting the importance of the informed consent process. [Transcript, p. 256, 260, 473, 491, 746, 755, 767, 771, 797, 812.]

The Hearing Committee unanimously voted that the Respondent's performance of the video clips, Tourette's, OCD and ESP studies without adhering to the requirements under PHL Article 24-A constituted professional misconduct as defined in Educ. Law § 6530(21), a willful failure to file a report required by law, and professional misconduct as defined in Educ. Law § 6530(16), a willful or grossly negligent failure to comply with substantial provisions of state laws governing the practice of medicine.

The Hearing Committee considered the importance in following these laws to confirm subjects are protected against risks of harm. The video clips study subjected subjects to potential mental anguish, nightmares, suffering and exacerbation of prior psychiatric conditions, such as PTSD. The Respondent psychologically shocked the subjects by surprising them with a graphic, violent film clip depicting the real-life beheading and dismemberment of a group of defenseless women in Mexico, a scene described by Dr. Klitzman as "truly gruesome" and "deeply disturbing." He also showed the subjects other disturbing film clips from movies, including *Hannibal*, where Hannibal removed a person's skull, cut out parts of the brain and cooked them and fed them to the victim, *The Accused*, involving a violent gang rape and *American History X*, depicting a white male as a neo-Nazi stomping the face of an African American male and killing him. The risks of harm were not diminished because the Respondent also chose to show the subjects happy or inspirational videos. [Exhibit 19a, 20a, 21a, 22, Y; Transcript, p. 246, 254, 262, 267, 435, 800, 807, 824 1141, 1377.]

The Respondent does not dispute that most subjects experienced strong emotions, such as horror, revulsion and deep sadness from the violent and disturbing clips. He specifically recalled A.1 physically shaking and gasping, crying and screaming in response to watching the murder scene in *American History X* and crying during the gang rape scene in *The Accused* and A.5 as "very emotional" from the real-life murders and dismemberment video and "shocked" from the gang rape scene. A.10 testified he felt "horror, revulsion" from the gang rape scene and cried from the murders and dismemberment video, emotions he recalled as common among the subjects. [Transcript, p. 252, 256, 273, 277-282, 442, 822, 828, 1307, 1338, 1395, 1446, 1448.]

Dr. Klitzman described this study as grossly unethical and characterized the Respondent's performance of it as a very serious deviation from the standard of care. Such reactions are not "pure fantasy," as suggested by the Respondent. [Respondent's summation, p. 14.] Dr. Klitzman described them as actual psychological and physical anguish, suffering and pain; responses that the Respondent recognized, yet chose to ignore. The Hearing Committee further noted that the Respondent failed to discontinue this study even after A.1 and others exhibited strong adverse reactions, perpetuating harm to other subjects. The Hearing Committee found Dr. Silver's dismissive testimony that the subjects' reactions were not "harm" but "distress" resulting from a mere "single exposure" to such media, disregards the emotional trauma some subjects experienced in the aftermath of this study. [Transcript, p. 156, 243, 256, 807, 814, 822.]

The Hearing Committee unanimously voted that the Respondent's performance of this study without meeting the requirements under PHL Article 24-A constituted professional misconduct as defined in Educ. Law § 6530(4), practicing the profession with gross negligence on a particular occasion, and professional misconduct as defined in Educ. Law § 6530(6), practicing the profession with gross incompetence. Gross negligence involves a significant deviation from acceptable medical standards that

creates the risk of grave consequence to the patient. Such conduct may result in a single act of negligence in egregious proportions or multiple acts of negligence that cumulatively are egregious. Post v. NYS Dept. of Health, 245 AD2d 985, 986 (3d Dept. 1997). Gross incompetence involves an unmitigated lack of the skill or knowledge necessary to perform an act undertaken by the licensee in the practice of medicine. This conduct may consist of a single act of incompetence of egregious proportions or multiple acts of incompetence that cumulatively amount to egregious conduct. Post, 245 AD2d at 986; Minielly v. Commissioner of Health, 222 AD2d 750, 751-752 (3d Dept. 1995).

The Respondent's obligations under PHL Article 24-A also included a plan for minimizing risks of harm from the studies, an effort he never made. In performing all the studies, the Respondent never had any treatment plans in place in the event of illness or injury, such as a backup psychiatrist, or for prescreening subjects for medical or psychological histories, which placed those with preexisting PTSD, anxiety, insomnia or depression at risk for exacerbation of those conditions. His failures also included not creating a plan for referrals or medication for the Tourette's and OCD subjects should their symptoms worsen or not improve. [Transcript, p. 481, 785, 792, 818, 839, 849, 912, 1337.]

The Respondent's claim that "there's no chance" for "EEG injury" and description of the EEG cap as "non-invasive," represented to the Hearing Committee his failure to recognize the risks associated with EEGs, none of which he attempted to minimize. In never disclosing EEG results to subjects, the Respondent risked them missing a diagnosis of a serious condition, such as a seizure disorder or possible brain tumor, and the opportunity to receive prompt follow-up care. These subjects were also at risk for mistakenly believing their brain is normal when the EEG results were abnormal or for catastrophizing the results. The Hearing Committee rejected the Respondent's excuse for never evaluating EEGs for medical purposes that the machine was a "research device," unapproved by the "federal government" and not for "clinical" purposes because it lacked any meaning in medical practice. Dr. Klitzman determined these

treatment failures constituted serious deviations from the standard of care. [Transcript, p. 144, 366-368, 783, 812, 839, 854, 860-862, 2175, 2177.]

The Respondent also failed to mitigate ongoing harm to subjects in not adequately protecting the confidentiality of their data, as required. The subjects were unaware that participating in the studies placed them at risk for blackmail or reputational harm from publishing of their identifying and potentially stigmatizing personal information from the videos, EEG results and Tourette's and OCD surveys. Dr. Silver and Dr. Klitzman agree that all human subject research data must be kept confidential and deidentified, neither of which the Respondent completed. Instead of using a computer program to generate random numbers and to mask personal identifiers, the Respondent insufficiently labeled the data by assigning each person a number in the order in which they joined the study and saving it to a document in the computer that also contained their name, a key personal identifier. His videos also exposed a face, another personal identifier. The Hearing Committee did not find credible the Respondent's claim that he maintained the password to the computer because he acknowledged others "with ESF," such as Claire Bronfman, had access to it. As such, the Respondent failed to maintain control of the data contrary to the subjects' expectations. Dr. Klitzman deemed these data breaches very serious deviations from the accepted standards of care. [Transcript, p. 367, 394, 757, 783, 812, 838, 849, 853, 861, 1451, 1940, 2134, 2170, 2332, 2346.]

The Hearing Committee unanimously voted that the Respondent's performance of the studies without authorization under PHL Article 24-A constituted professional misconduct as defined by Educ. Law § 6530(3), practicing the profession with negligence on more than one occasion, and professional misconduct as defined by Educ. Law § 6530(5), practicing the profession with incompetence on more than one occasion. Negligence on more than one occasion involves the "failure to exercise the care that would be exercised by a reasonably prudent licensee under the circumstances." Bogdan v. State Bd. For

Professional Med. Conduct, 195 AD2d 86, 88 (3d Dept. 1993). The Department is not required to prove harm to a patient. Youssef v. State Bd. For Professional Med. Conduct, 89 AD3d 824, 825 (3d Dept. 2004). Incompetence on more than one occasion involves a lack of knowledge necessary to practice the profession. This includes a lack of the requisite knowledge or skill in the practice of the profession but does not require a showing of an act or omission constituting a breach of the duty of due care. Dhabuwala v. State Bd. For Professional Med. Conduct, 225 AD2d 209, 213 (3d Dept. 1996).

The Respondent was also required under Article 24-A to perform studies with benefits, a basic element of informed consent. PHL § 2441(5). Dr. Klitzman and Dr. Silver consistently acknowledged as unethical enrolling human subjects in research studies that collected data and produced no results. In addition to creating a written protocol, the Respondent was obligated to define a plan for data analysis and statistical methods for his research, key ethical research principles he failed to follow. These subjects trusted the Respondent to collect, analyze and store their data for the purpose of interpreting their "brainwaves" to contribute to "science," yet none of the studies produced results. The Respondent never took any steps to interpret and analyze the EEG data he collected. Although he "planned" to hire a company or use a mathematician and MATLAB, a computer program, to analyze the EEG data, he never made any successful attempts to complete this process. [Respondent's brief, p. 10.] The Hearing Committee was not persuaded by his attempt to blame other NXIVM members for not having the EEGs interpreted because as the physician who performed these procedures, this process was his responsibility. [Transcript, p. 366, 370, 1069, 1138, 1155-1160, 1258, 1263, 1265, 1352, 1375, 1398, 2028, 2182, 2347.]

The Respondent claims that during the period he was performing the studies, he lacked any awareness of the proper requirements of the profession under PHL Article 24-A. This excuse for not complying with PHL Article 24-A was rejected by the Hearing Committee. The Hearing Committee found it more likely that the Respondent was familiar with these laws that governed his human research studies

based on his background, which includes employment at a New York hospital with an IRB, his move to Albany to conduct research and his Ph.D. that involved research. In addition, his admissions to Dr. Dalfino in September of 2017 that his studies were not subject to IRB review because an IRB would be "too restrictive" and limit his ability to "change things," combined with his expression of deep "regret" at the hearing for not bringing these studies "in front of an IRB," demonstrated to the Hearing Committee his awareness that oversight of his studies under PHL Article 24-A was required. Despite having this knowledge, the Respondent proceeded with the studies without informing the subjects of these laws, which deprived them of advance notice of the risks of harm the studies entailed. The concealment of this information was especially troubling to the Hearing Committee considering the Respondent's acknowledgment that someone who is not "psychologically balanced" could have "difficulties" from the video clips study. [Transcript, p. 71, 149, 154, 165, 219, 221-222, 737, 742, 745, 760, 768, 829, 840, 854, 863, 2068.]

In deliberately subjecting these subjects to meaningless studies that involved risks of psychological and physical harm without apprising them of the requirements of PHL Article 24-A, the Hearing Committee unanimously voted that the Respondent's conduct constituted practicing the profession fraudulently, as defined in Educ. Law § 6530(2). Fraudulent practice requires "proof of either an intentional misrepresentation or concealment of a known fact" and "intent or knowledge" can be inferred. Matter of Patin v. State Bd. For Professional Med. Conduct, 77 AD3d 1211, 1214 (3d Dept. 2010). The Hearing Committee infers the Respondent's intent to conceal his knowledge that his human subject research required HRRC approval based on the Respondent's background and his admissions to Dr. Dalfino regarding the restrictions an IRB would place on the type of research he wanted to perform. This conduct also evidences moral unfitness to practice medicine, as defined in Educ. Law § 6530(20). This conduct "violat[es] the trust the public bestows on the medical profession and/or violat[es] the medical

profession's moral standards." Such conduct is suggestive or, or would tend to prove, moral unfitness. Matter of Patin, 77 AD3d at 1215 *citing* Matter of Prado v. Novello, 301 AD2d 692, 694 (3d Dept. 2003).

Silver Bay/YMCA

The Department also charges the Respondent with failing to report a communicable disease or an unusual outbreak of a disease and isolate infected individuals during the annual NIXVM retreat at the Silver Bay YMCA. Physicians are required to report an outbreak of an unusual disease to public health officials and pending a response, isolate affected individuals. 10 NYCRR 2.10; 10 NYCRR 2.27. The evidence established this illness involved a gastrointestinal virus, possibly Norovirus, that affected a massive group of people who developed contagious symptoms, which constitutes an outbreak of an unusual disease that triggered the Respondent's reporting and isolating responsibilities under the regulations. 10 NYCRR 2.10; 10 NYCRR 2.27; *See also* 10 NYCRR 2.1(c); 10 NYCRR 2.1(a). The Hearing Committee agreed with Dr. Farber's testimony that the purpose in enforcing these rules is to prevent the "potential widespread propagation of the organism." [Transcript, p. 621.]

The Respondent admits that he failed to report the outbreak of the illness to public health officials even after he became aware that it affected many of the 400-450 attendees and that he failed to isolate infected individuals. He attempts to justify his failure to comply with the regulations, however, by claiming that he was unaware of them and not practicing medicine when the outbreak occurred. [Respondent's brief, p. 15-16.] The Hearing Committee rejected these excuses. The Hearing Committee regarded the Respondent as having the requisite knowledge of the applicable regulations based on his extensive experience working as a hospitalist, a position that involves the handling and isolation of patients with infectious diseases, and from a course in infection control that he would have had to complete for license re-certification every four years. These regulatory obligations apply to physicians in all settings and include any outbreak of a disease. 10 NYCRR 2.10; 10 NYCRR 2.27; *See also* 10 NYCRR 2.1(c); 10

NYCRR 2.1(a). Dr. Farber characterized the Respondent's failure to report this illness a moderate and even "more severe" deviation from accepted standards of care based on the risks of harm, particularly involving preterm labor for pregnant women, dehydration for neonates and children and morbidity for the elderly and other vulnerable individuals. The public was also placed at risk for ongoing harm from secondary outbreaks. [Transcript, p. 350-352, 620, 626, 633, 639, 641, 651-652, 688, 695.]

The Hearing Committee unanimously voted that the Respondent's failure to report the outbreak of an unusual disease and isolate infected individuals constituted professional misconduct as defined in Educ. Law § 6530(21), a willful failure to file a report required by law, professional misconduct as defined in Educ. Law § 6530(16), a willful or grossly negligent failure to comply with substantial provisions of state laws governing the practice of medicine, professional misconduct as defined in Educ. Law § 6530(3), practicing the profession with negligence on more than one occasion, and professional misconduct as defined in Educ. Law § 6530(5), practicing the profession with incompetence on more than one occasion.

Determination as to penalty

The Hearing Committee considered the spectrum of penalties available pursuant to PHL §230-a, including censure and reprimand, suspension of the license, wholly or partially, limitations of the license, revocation of license, annulment of license or registration, fine, public service hours, probation and continued medical education training and determined that revocation of the Respondent's medical license is appropriate.

The Respondent betrayed the trust and confidence the subjects placed in him based on his status as a respected physician when he abandoned his oath by taking inadequate care of them. The Hearing Committee considered the effect this trust had on the subjects' willingness to comply with the Respondent's performance of the studies without any advance notice of the potential risks. Some of the NXIVM members expressed vulnerabilities when joining the organization, such as "rough" times and

periods of "high stress" in their lives, which they hoped would be addressed through NXIVM's programs aimed at achievement of their self-betterment goals. A.5, who advanced within the program to a "two-stripe coach," detailed the time-consuming and expensive process towards meeting such goals to include payment of between $50,000 and $60,000 for coursework and membership fees, many unreimbursed trips to Monterrey, Mexico; San Francisco, California; London, England; and New York, New York to facilitate ESP classes, and ongoing recruitment obligations, which included signing up friends to NXIVM. Such intense personal and financial efforts represented to the Hearing Committee the subjects' trust that at the completion of the program, they would have achieved their self-improvement objectives. [Transcript, p. 410-412, 415, 417-420, 425, 946, 1020-1022, 1038, 1133, 1362, 1367, 1383-1386.]

The Hearing Committee deems the Respondent at risk for repeated misconduct due to his profound indifference to the consequences of his actions that continued over the course of several years and until his conduct was under investigation. The Hearing Committee noted the Respondent's deep committment to NXIVM, as evidenced by his relocation from Iowa to further its goal of communicating "what they do" to "encourage people to take the program" and his high ranking coach status and is concerned that he may again be enticed to use his medical license to engage in similar conduct. His claim that he can continue to safely practice medicine is undermined by the lack of insight he exhibited in his failure to respond to clear signs of harm, such as by stopping the video clips study when A.1 exhibited symptoms of severe distress. It is also weakened by his failure to recognize his responsibility as a physician in the well-being of these subjects, which is evidence of his lack of the knowledge or skill required to safely practice the profession. [Transcript, p. 130, 2357.]

The Hearing Committee concluded that by not obtaining proper informed consent from the subjects prior to performing the studies, the Respondent exploited them to further his research agenda for NXIVM and in doing so, violated ethical research principles mandating respect for persons. The

Respondent's personal statement at the close of this case even failed to show sincere remorse or understanding of the severity of the misconduct and harm associated with the studies which might have suggested the possibility of rehabilitation to justify the imposition of a lesser penalty. [Transcript, p. 744, 2411.]

ORDER

Based upon the foregoing, IT IS HEREBY ORDERED THAT:

1. The first through twenty-fourth specifications of professional misconduct, as set forth in the Statement of Charges, are sustained.

2. The Respondent's license to practice medicine in the State of New York is revoked under PHL 230-a(4).

3. This Determination and Order shall be effective upon service on the Respondent. Service shall be either by certified mail or upon the Respondent at his last known address and such service shall be effective upon receipt or seven days after mailing by certified mail, whichever is earlier, or by personal service and such service shall be effective upon receipt.

DATED: Albany, New York
August 16, 2019

[redacted]
Airlie A.C. Cameron, M.D., M.P.H. (CHAIR)

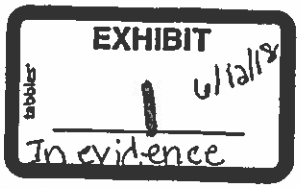
C. Deborah Cross, M.D.
David F. Irvine, DHSc, P.A.

TO: Jeffrey J. Conklin, Esq.
Associate Counsel
New York State Department of Health
Bureau of Professional Medical Conduct
Corning Tower Building, Room 2517
Empire State Plaza
Albany, New York 12237-0032

Michael S. Kelton, Esq.
Abrams, Fensterman, Fensterman, Eisman, Formato, Ferrara, Wolf & Carone, LLP
Attorneys for Respondent
1 Metrotech Center, Suite 1701
Brooklyn, New York 11201

Brandon Porter, M.D.
c/o Michael S. Kelton, Esq.
Attorneys for Respondent
Abrams, Fensterman, Fensterman, Eisman, Formato, Ferrara, Wolf & Carone, LLP
1 Metrotech Center, Suite 1701
Brooklyn, New York 11201

APPENDIX I



NEW YORK STATE DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER

OF

BRANDON PORTER, M.D.

NOTICE

OF

HEARING

TO: Brandon Porter, M.D.
c/o Mr. Michael Kelton, Esq.
Abrams, Fensterman, Fensterman,
Eisman, Formato, Ferrara, Wolf & Carone, LLP
1 Metrotech Center, Suite 1701
Brooklyn, New York 11201

PLEASE TAKE NOTICE:

A hearing will be held pursuant to the provisions of N.Y. Pub. Health Law §230 and N.Y. State Admin. Proc. Act §§301-307 and 401. The hearing will be conducted before a committee on professional conduct of the State Board for Professional Medical Conduct on June 27, 2018, at 10:00 a.m., at the Offices of the New York State Department of Health, Riverview Center, 150 Broadway, Suite 510, Albany, New York 12204-2719, and at such other adjourned dates, times and places as the committee may direct.

At the hearing, evidence will be received concerning the allegations set forth in the Statement of Charges, which is attached. A stenographic record of the hearing will be made and the witnesses at the hearing will be sworn and examined. You shall appear in person at the hearing and may be represented by counsel who shall be an attorney admitted to practice in New York state. You have the right to produce witnesses and evidence on your behalf, to issue or have subpoenas issued on your behalf in order to require the production of witnesses and documents, and you may cross-examine witnesses

and examine evidence produced against you. A summary of the Department of Health Hearing Rules is enclosed.

YOU ARE HEREBY ADVISED THAT THE ATTACHED CHARGES WILL BE MADE PUBLIC FIVE BUSINESS DAYS AFTER THEY ARE SERVED.

Department attorney: Initial here [redacted]

The hearing will proceed whether or not you appear at the hearing. Please note that requests for adjournments must be made in writing and by telephone to the New York State Department of Health, Division of Legal Affairs, Bureau of Adjudication, Riverview Center,150 Broadway - Suite 510, Albany, NY 12204-2719, ATTENTION: HON. JAMES HORAN, DIRECTOR, BUREAU OF ADJUDICATION, (henceforth "Bureau of Adjudication"), (Telephone: (518-402-0748), upon notice to the attorney for the Department of Health whose name appears below, and at least five days prior to the scheduled hearing date. Adjournment requests are not routinely granted as scheduled dates are considered dates certain. Claims of court engagement will require detailed Affidavits of Actual Engagement. Claims of illness will require medical documentation.

Pursuant to the provisions of N.Y. Pub. Health Law §230(10)(c), you shall file a written answer to each of the charges and allegations in the Statement of Charges not less than ten days prior to the date of the hearing. Any charge or allegation not so answered shall be deemed admitted. You may wish to seek the advice of counsel prior to filing such answer. The answer shall be filed with the Bureau of Adjudication, at the address indicated above, and a copy shall be forwarded to the attorney for the Department of Health whose name appears below. Pursuant to §301(5) of the State Administrative Procedure Act, the Department, upon reasonable notice, will provide at no charge a qualified interpreter of the

deaf to interpret the proceedings to, and the testimony of, any deaf person. Pursuant to the terms of N.Y. State Admin. Proc. Act §401 and 10 N.Y.C.R.R. §51.8(b), the Petitioner hereby demands disclosure of the evidence that the Respondent intends to introduce at the hearing, including the names of witnesses, a list of and copies of documentary evidence and a description of physical or other evidence which cannot be photocopied.

At the conclusion of the hearing, the committee shall make findings of fact, conclusions concerning the charges sustained or dismissed, and in the event any of the charges are sustained, a determination of the penalty to be imposed or appropriate action to be taken. Such determination may be reviewed by the Administrative Review Board for Professional Medical Conduct.

THESE PROCEEDINGS MAY RESULT IN A DETERMINATION THAT YOUR LICENSE TO PRACTICE MEDICINE IN NEW YORK STATE BE REVOKED OR SUSPENDED, AND/OR THAT YOU BE FINED OR SUBJECT TO OTHER SANCTIONS SET OUT IN NEW YORK PUBLIC HEALTH LAW §§230-a. YOU ARE URGED TO OBTAIN AN ATTORNEY TO REPRESENT YOU IN THIS MATTER.

DATE: April 24, 2018
Albany, NY

[redacted]
MICHAEL A. HISER, ESQ.
Deputy Counsel
Bureau of Professional Medical Conduct

Inquiries should be directed to:
Jeffrey J. Conklin, Associate Counsel
Bureau of Professional Medical Conduct
Rm 2512, Corning Tower, ESP
Albany, New York 12237
518-473-4219

NEW YORK STATE DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER OF BRANDON PORTER, M.D.

STATEMENT

OF

CHARGES

BRANDON PORTER, M.D., the Respondent, was authorized to practice medicine in New York State on or about June 12, 2009, by the issuance of license number 253486 by the New York State Education Department.

FACTUAL ALLEGATIONS

A. At all times hereinafter mentioned, Respondent's medical license permitted him to act as a human subject researcher, to the extent he complied with state law, and state and federal rules and guidelines. From on or about 2012 through 2017, the Respondent, either individually or in association with a public or private institution or agency, conducted a human subject research study (hereinafter "Fright Study"). Among other things, the Fright Study involved showing human subjects an actual video of the horrific and brutal murders and dismemberment of four women by machetes; and violent film clips, including a male African American being viciously stomped by a Nazi; a conscious male being forced to eat a portion of his own brain matter; and a graphic gang rape. A list of the known human subjects who participated in the Fright Study is annexed hereto and made a part hereof as Appendix "A". Individuals not specifically known by name are listed as "Other human

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subject participants". The Fright Study conducted by the Respondent violated state law, and/or state and federal rules and guidelines, and deviated from accepted professional standards as follows:

1. Violations of Section 2444 of the Public Health Law of the State of New York (hereinafter "P.H.L."), and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to submit required documents, including, but not limited to, a protocol review request form, written consent template, and human subject training certificates to the New York State Department of Health Institutional Review Board (hereinafter "DOH IRB") for authorization of a human research review committee, and/or for an appropriate federal and/or independent Institutional Review Board, in connection with initiating the Fright Study.

2. Violations of Section 2444 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to obtain authorization from the DOH IRB for a human research review committee, and/or a federal and/or independent Institutional Review Board, prior to commencing the Fright Study.

3. Violations of Sections 2441(5) and 2442 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to obtain appropriate and voluntary informed written consents from the human subjects who participated in the Fright Study.

4. Violations of Section 2444(3) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent engaged in the conduct of human research (Fright Study) without having affiliated himself with an institution or agency having a DOH IRB authorized human research review committee, and/or a federal and/or independent Institutional Review Board.

5. Department of Health Institutional Review Board Guidelines of Human Subject Researchers, and/or federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to obtain a mandated human subjects protection training certificate prior to conducting the Fright Study.

6. Violations of Sections 2441(5) and 2442 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent caused videos to be taken while human subjects participated in the Fright Study were viewing, among other things, an actual video of the horrific and brutal murders and dismemberment of four women by machetes; and violent film clips, including a male African American being viciously stomped by a Nazi, a conscious male being forced

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to eat a portion of his own brain matter, and a graphic gang rape, without their prior appropriate and voluntary informed written consent, and without having obtained authorization from a DOH IRB human research review committee, and/or federal and/or independent Institutional Review Board.

7. Violations of Sections 2441(5) and 2442 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to advise the human subjects who participated in the Fright Study that they would be viewing, among other things, an actual video of the horrific and brutal murders and dismemberment of four women by machetes; and violent film clips, including a male African American being viciously stomped by a Nazi, a conscious male being forced to eat a portion of his own brain matter, and a graphic gang rape.

8. Violations of Sections 2440 and 2441(1) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent, prior to conducting the Fright Study, knew or should have known that viewing the disturbing and violent actual video and film clips could cause the human subjects mental pain and suffering, and/or psychological injury.

9. Violations of Sections 2440 and 2441(1) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent, who knew or should have known that human subjects participating in the Fright Study could have been caused mental pain and suffering, and/or psychological injury while viewing the disturbing and violent actual video and film clips, failed to terminate such study.

10. Violations of Sections 2441(5)(e) and 2442 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent, during the course of the Fright Study, failed to answer inquiries of some of the human subjects concerning the procedures being used during such study.

11. Violations of Sections 2440, 2441(f) and 2442 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent, during the course of the Fright Study, impeded the rights of some of the human subjects to withdraw from such study.

12. Violations of Section 2442 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent required some of the human subjects who participated in the Fright Study to sign non-disclosure forms, thereby inappropriately attempting to compel such human subjects to waive their statutory rights.

13. Violations of Section 2444(3) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent

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failed to submit mandated reports and/or documents, including, but not limited to, one year continuing review and adverse event reports to a DOH IRB authorized human research review committee, and/or a federal and/or independent Institutional Review Board, regarding the Fright Study.

14. Violations of Section 2440 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to appropriately minimize the potential risks of harm to the human subjects who participated in the Fright Study.

15. Violations of Section 2440 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to prepare and maintain appropriate records of the Fright Study, to ensure the safety of the human subjects, and/or provide adequate protection of their privacy and to maintain the confidentiality of the data.

16. Prior to and/or during the course of the Fright Study, Respondent made false representations to the human subjects, by words, conduct and/or the concealment that such study was not in compliance with Article 24-A of the P.H.L., and/or state and federal rules and guidelines; Respondent knew the representations were false; and Respondent intended to mislead the human subjects through the false representations.

B. At all times hereinafter mentioned, Respondent's medical license permitted him to act as a human subject researcher, to the extent he complied with state law, and state and federal rules and guidelines. During on or about 2012 and 2017, Respondent, either individually and/or in association with a public or private institution or agency, conducted a human subject research study involving obsessive compulsive disorder (hereinafter "OCD Study"). From on or about January 2016 through on or about December 2016, Respondent provided medical care and treatment to Patient B, who was also a participant in the OCD Study. A list of the human subjects in the OCD Study is annexed hereto and made a part hereof as Appendix "B". Individuals not specifically known by name are listed as "Other patient/human subject participants".

The OCD Study conducted by the Respondent violated state law, and/or state and federal rules and guidelines, and deviated from accepted professional standards; and Respondent's medical care of Patient B deviated from accepted standards of care as follows:

1. Violations of Section 2444 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to submit required documents, including, but not limited to, a protocol review request form, written consent template, proposed questionnaires, and human subject training certificates to the DOH IRB for authorization of a human research review committee, and/or for an appropriate federal and/or independent Institutional Review Board, in connection with in initiating the OCD Study.

2. Violations of Section 2444 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to obtain authorization from the DOH IRB for a human research review committee, and/or federal and/or independent Institutional Review Board, prior to commencing the OCD Study.

3. Violations of Sections 2441(5) and 2442 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to obtain appropriate and voluntary informed written consent from the human subjects who participated in the OCD Study.

4. Department of Health Institutional Review Board Guidelines of Human Subject Researchers, and/or federal rules and guidelines, and deviations from accepted professional standards – Respondent failed to obtain a mandated human subjects protection training certificate prior to commencing the OCD Study.

5. Violations of Section 2444(3) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent engaged in the conduct of human research (OCD Study) without having affiliated himself with an institution or agency having a DOH IRB authorized human research review committee, and/or a federal and/or independent Institutional Review Board.

6. Violations of Section 2444(3) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to submit mandated reports and/or documents, including, but not limited to, one year continuing review and adverse event reports to a DOH IRB authorized human research review committee, and/or a federal and/or independent Institutional Review Board, regarding the OCD Study.

7. Violations of Sections 2440 and 2441(1) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to prepare and maintain detailed records of the OCD Study, to ensure the safety of the human subjects, and provide adequate protection of their privacy and to maintain the confidentiality of the data.

8. Prior to and/or during the course of the OCD Study, Respondent made false representations to the human subjects, by words, conduct and/or the concealment that such study was not in compliance with Article 24-A of the P.H.L., and/or state and federal rules and guidelines; Respondent knew the representations were false; and Respondent intended to mislead the human subjects through the false representations.

9. Respondent failed to keep and maintain appropriate medical records for Patient B.

C. At all times hereinafter mentioned, Respondent's medical license permitted him to act as a human subject researcher, to the extent he complied with state law, and state and federal rules and guidelines. During on or about 2012 and 2017, Respondent either individually and/or in association with a public or private institution or agency, conducted a human subject research study involving Tourette's Syndrome (hereinafter "Tourette's Study"). From some time during 2012 through 2017, Respondent provided medical care and treatment to Patient C, who was also a participant in the Tourette's Study. A list of the human patients/participants in the Tourette's Study is annexed hereto and made a part hereof as Appendix "C". Individuals not specifically known by name are listed as "Other patient/human subject participants". The Tourette's Study conducted by the Respondent violated state law, and/or state and federal rules and guidelines, and deviated from accepted professional standards; and

Respondent's medical care of Patient C deviated from accepted standards of care as follows:

1. Violations of Section 2444 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to submit required documents, including, but not limited to, a protocol review request form, written consent template, questionnaires, and human subject training certificates to the DOH IRB for authorization of a human research review committee, and/or a federal and/or independent Institutional Review Board, in connection with initiating the Tourette's Study.

2. Violations of Section 2444 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to obtain authorization from the DOH IRB for a human research review committee, and/or a federal and/or independent Institutional Review Board, prior to commencing the Tourette's Study.

3. Violations of Sections 2441(5) and 2442 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to obtain appropriate and voluntary informed written consent from the human subjects who participated in the Tourette's Study.

4. Department of Health Institutional Review Board Guidelines of Human Subject Researchers, and/or federal rules and guidelines, and deviations from accepted professional standards – Respondent failed to obtain a mandated human subjects protection training certificate prior to conducting the Tourette's Study.

5. Violations of Section 2444(3) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent engaged in the conduct of human research (Tourette's Study) without having affiliated himself with an institution or agency having a DOH IRB authorized human research review committee, and/or a federal and/or independent Institutional Review Board.

6. Violations of Section 2444(3) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to submit mandated reports and/or documents, including, but not limited to, one year continuing review and adverse event reports to a DOH IRB authorized human research review committee, and/or a federal and/or independent Institutional Review Board, regarding the Tourette's Study.

7. Violations of Section 2440(1) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent

failed to prepare and maintain detailed records of the Tourette's Study, to ensure the safety of the human subjects, and provide adequate protection of their privacy and to maintain the confidentiality of the data.

8. Prior to and/or during the course of the Tourette's Study, Respondent made false representations to the human subjects by words, conduct and/or the concealment that such study was not in compliance with Article 24-A of the P.H.L., and/or state and federal rules and guidelines; Respondent knew the representations were false; and Respondent intended to mislead the human subjects through the false representations.

9. Respondent failed to maintain a record for Patient C which accurately reflected the evaluation and treatment of said patient.

D. At all times hereinafter mentioned, Respondent's medical license permitted him to act as a human subject researcher, to the extent he complied with state law, and state and federal rules and guidelines. During on or about 2015 and 2016, Respondent, either individually and/or in association with a public or private institution or agency, engaged in human subject research studies (hereinafter "ESP Studies") which involved monitoring the brain waves of participants attending training and coaching sessions, intensive classes, and other professional advancement courses sponsored by NXIVM and/or the Executive Success Program (ESP) and/or other entities. A list of the human participants in the ESP Studies is annexed hereto and made a part hereof as Appendix "D". Individuals not specifically known by name are listed as "Other human subject participants". The ESP Studies conducted by the Respondent violated state law, and/or state and federal rules and guidelines, and deviated from accepted professional standards; as follows:

1. Violations of Section 2444 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent

(14)

failed to submit required documents, including, but not limited to, protocol review request forms, written consent templates, and human subject training certificates to the DOH IRB for human research review committees, and/or federal and/or independent Institutional Review Boards, in connection with initiating the ESP Studies.

2. Violations of Section 2444 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to obtain authorization from the DOH IRB for human research review committees, and/or federal and/or independent Institutional Review Boards, prior to commencing the ESP Studies.

3. Violations of Sections 2441(5) and 2442 of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to obtain appropriate and voluntary informed written consents from the human subjects who participated in the ESP Studies.

4. Department of Health Institutional Review Board Guidelines of Human Subject Researchers and deviations from accepted professional standards – Respondent failed to obtain mandated human subjects protection certificates prior to conducting the ESP Studies.

5. Violations of Section 2444(3) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent engaged in the conduct of human research (ESP Studies) without having affiliated himself with an institution or agency having DOH IRB authorized human research review committees, and/or a federal and/or independent Institutional Review Boards.

6. Violations of Section 2444(3) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to submit mandated reports and/or documents, including, but not limited to, one year continuing review and adverse event reports to a DOH IRB authorized human research review committee, and/or a federal and/or independent Institutional Review Board, regarding the ESP Studies.

7. Violations of Sections 2440 and 2441(1) of the P.H.L., and/or state and federal rules and guidelines, and deviations from accepted professional standards -- Respondent failed to prepare and maintain detailed records of the ESP Studies, to ensure the safety of the human subjects, and provide adequate protection of their privacy and to maintain the confidentiality of the data.

8. Prior to and/or during the course of the ESP Studies, Respondent made false representations to the human subjects, by words, conduct and/or the

concealment that such studies were not in compliance with Article 24-A of the P.H.L., and/or state and federal rules and guidelines; Respondent knew the representations were false; and Respondent intended to mislead the human subjects through the false representations.

E. From on or about August 2016 through September 2016, NXIVM and/or the Executive Success Program (ESP), and/or another entity, conducted a conference and/or meeting at the Silver Bay YMCA Conference and Family Retreat Center, located in Silver Bay, New York. The Respondent and approximately 300 to 400 other individuals attended the conference, which included 50 to 60 children. During the course of the conference, many of the attendees and most of the children became ill with an undetermined infectious disease. The individuals who became ill suffered, inter alia, flu-like symptoms, vomiting and diarrhea. The Respondent had knowledge of the fact that many individuals at the conference had become ill. The Respondent knew or should have known that the illness suffered by the attendees at the conference was a communicable disease, outbreak of a communicable disease, and/or an unusual disease or outbreak. Respondent violated provisions of the State of New York Sanitary Code as follows:

1. Violation of Title 10 N.Y.C.R.R. Section 2.10 (Reporting cases or suspected cases of communicable diseases by physicians). Respondent failed to report the suspected or confirmed case of communicable disease, outbreak of communicable disease, and/or the unusual disease or outbreak to the city, county, or district health officer.

2. Violation of Title 10 N.Y.C.R.R. Section 2.15 (Reporting of food poisoning). Respondent, as a physician, failed to report by telephone, facsimile, or other electronic communication, or in person the illness of the attendees at the conference suspected or confirmed to have been caused due to the consumption of spoiled or poisonous food to the city, county, or district health officer.

3. Violation of Title 10 N.Y.C.R.R. Section 2.27 (Physician to isolate person with highly communicable disease and give instructions regarding prevention of spread of disease). Upon being made aware of the fact that attendees at the conference might have been suffering from a communicable disease, the Respondent failed to cause such individuals to be isolated in an appropriate environment, pending official action by the health officer.

SPECIFICATIONS OF CHARGES

FIRST THROUGH FIFTH SPECIFICATIONS
CONDUCT IN THE PRACTICE OF MEDICINE WHICH EVIDENCES MORAL UNFITNESS TO PRACTICE MEDICINE

Respondent is charged with committing professional misconduct as defined by New York Education Law §6530(20) engaging in conduct in the practice of medicine which evidences moral unfitness to practice medicine as alleged in the facts of the following:

1. A and A.1, and/or A and A.2, A and A.3, A and A.4, A and A.5, A and A.6, A and A.7, A and A.8, A and A.9, A and A.10, A and A.11, A and A.12, A and A.13, A and A.14, A and A.15, and/or A and A.16.
2. B and B.1, and/or B and B.2, B and B.3, B and B.4, B and B.5, B and B.6, B and B.7, and/or B and B.8.
3. C and C.1, and/or C and C.2, C and C.3, C and C.4, C and C.5, C and C.6, C and C.7, and/or C and C.8.
4. D and D.1, and/or D and D.2, D and D.3, D and D.4, D and D.5, D and D.6, D and D.7, and/or D and D.8.
5. E and E.1, and/or E and E.2, and/or E and E.3.

SIXTH THROUGH TENTH SPECIFICATIONS
WILLFULLY FAILING TO FILE A REPORT REQUIRED BY LAW
BY THE DEPARTMENT OF HEALTH OR THE EDUCATION DEPARTMENT

Respondent is charged with committing professional misconduct as defined by New York Education Law §6530(21) by willfully failing to file a report required by law or by the Department of Health, or the Education Department as alleged in the facts of the following:

6. A and A.1, and/or A and A.2, A and A.3, A and A.11, A and A.12, A and A.14 and/or A and A.15.
7. B and B.1, and/or B and B.2, B and B.3, and/or B and B.5.
8. C and C.1, and/or C and C.2, C and C.3, and/or C and C.5.
9. D and D.1, and/or D and D.2, D and D.3, and/or D and D.5.
10. E and E.1, and/or E and E.2.

ELEVENTH THROUGH FIFTEENTH SPECIFICATIONS
WILLFULLY OR GROSSLY NEGLIGENTLY FAILING TO COMPLY WITH SUBSTANTIAL PROVISIONS OF FEDERAL, STATE, OR LOCAL LAWS RULES OR REGULATIONS GOVERNING THE PRACTICE OF MEDICINE

Respondent is charged with committing professional misconduct as defined by New York Education Law §6530(16) by willfully or grossly negligently failing to comply with substantial provisions of federal, state, or local laws, rules, or regulations governing the practice of medicine as alleged in the facts of the following:

11. A and A.1 and/or A and A.2, A and A.3, A and A.4, A and A.5, A and A.6, A and A.7, A and A.8, A and A.9, A and A.10, A and A.11, A and A.12, A and A.13, A and A.14, and/or A and A.15.

12. B and B.1, and/or B and B.2, B and B.3, B and B.4, B and B.5, B and B.6, and/or B and B.7.

13. C and C.1, and/or C and C.2, C and C.3, C and C.4, C and C.5, C and C.6, and/or C and C.7.

14. D and D.1, and/or D and D.2, D and D.3, D and D.4, D and D.5, D and D.6, and/or D and D.7.

15. E and E.1, and/or E and E.2, and/or E and E.3.

SIXTEENTH SPECIFICATION
PRACTICING THE PROFESSION WITH GROSS NEGLIGENCE

Respondent is charged with committing professional misconduct as defined by New York Education Law §6530(4) by practicing the profession with gross negligence as alleged in the facts of the following:

16. A and A.1, and/or A and A.2, A and A.3, A and A.4, A and A.5, A and A.6, A and A.7, A and A.8, A and A.9, A and A.10, A and A.11, A and A.12, A and A.13, A and A.14, and/or A and A.15.

SEVENTEENTH SPECIFICATION
PRACTICING THE PROFESSION WITH NEGLIGENCE ON MORE THAN ONE OCCASION

Respondent is charged with committing professional misconduct as defined by New York Education Law §6530(3) by practicing the profession with negligence on more than one occasion as alleged in the facts of the following:

17. A and A.1, and/or A. and A.2, A and A.3, A and A.4, A and A.5, A and A.6, A and A.7, A and A.8, A and A.9., A and A.10. A and A.11., A and A.12., A and A.13., A and A.14, and/or A and A.15; and/or B and B.1, and/or B and B.2, B and B.3, B and B.4, B and B.5, B and B.6, B and B.7, and/or B and B.9; and/or C and C.1, and/or C and C.2, C and C.3, C and C.4, C and C.5, C and C.6, C and C.7, and/or C and C.9; and/or D and D.1, and/or D and D.2, D and D.3, D and D.4, D and D.5, D and D.6, and/or D and D.7; and/or E and E.1, and/or E and E.2, and/or E and E.3.

EIGHTEENTH SPECIFICATION
PRACTICING THE PROFESSION WITH GROSS INCOMPETENCE

Respondent is charged with committing professional misconduct as defined by New York Education Law §6530(6) by practicing the profession with gross incompetence as alleged in the facts of the following:

18. A and A.1, and/or A and A.2, A and A.3, A and A.4, A and A.5, A and A.6, A and A.7, A and A.8, A and A.9, A and A.10, A and A.11, A and A.12, A and A.13, A and A.14, A and A.15.

NINETEENTH SPECIFICATION
PRACTICING THE PROFESSION WITH
INCOMPETENCE ON MORE THAN ONE OCCASION

Respondent is charged with committing professional misconduct as defined by New York Education Law §6530(5) by practicing the profession with incompetence on more than one occasion as alleged in the facts of the following:

19. A and A.1, and/or A and A.2, A and A.3, A and A.4, A and A.5, A and A.6, A and A.7, A and A.8, A and A.9, A and A.10, A and A.11, A and A.12, A and A.13, A and A.14 and/or A and A.15; and/or B and B.1, and/or B and B.2, B and B.3, B and B.4, B and B.5, B and B.6, B and B.7, and/or B and B.9; and/or C and C.1, and/or C and C.2, C and C.3, C and C.4, C and C.5, C and C.6, C and C.7; and/or C and C.9 and/or D and D.1, and/or D and D.2, D and D.3, D and D.4, D and D.5, D and D.6, and/or D and D.7; E and E.1, and/or E and E.2, and/or E and E.3.

TWENTIETH THROUGH TWENTY-THIRD SPECIFICATIONS
PRACTICING THE PROFESSION FRAUDULENTLY

Respondent is charged with committing professional misconduct as defined by New York Education Law §6530(2) by practicing the profession fraudulently as alleged in the facts of the following:

20. A and A.16.

21. B and B.8.

22. C and C.8.

23. D and D.8.

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TWENTY-FOURTH AND TWENTY-FIFTH SPECIFICATIONS
FAILURE TO MAINTAIN RECORDS

Respondent is charged with committing professional misconduct as defined in New York Education Law § 6530(32) by failing to maintain a record for each patient which accurately reflects the evaluation and treatment of the patient, as alleged in the facts of:

24. Paragraphs B and B.9.

25. Paragraphs C and C.9

DATE: April 24, 2018
Albany, New York

[redacted]

MICHAEL A. HISER, ESQ.
Deputy Counsel
Bureau of Professional Medical Conduct

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