ATTORNEY GENERAL OF THE STATE OF NEW YORK
CIVIL RIGHTS BUREAU
HEALTH CARE BUREAU

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In the Matter of:

The New York and Presbyterian Hospital

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ASSURANCE OF DISCONTINUANCE PURSUANT TO EXECUTIVE LAW SECTION 63, SUBDIVISION 15

Pursuant to the provisions of Executive Law § 63(12), the Attorney General of the State of New York caused an inquiry to be made into certain practices of The New York and Presbyterian Hospital ("NYPH").

I.
PARTIES

1. NYPH is a New York hospital licensed by the State of New York pursuant to Article 28 of the New York Public Health Law.

2. NYPH currently operates one laboratory that conducts genetic tests: the New York Hospital Laboratory, located in New York City. This laboratory is licensed by the New York State Department of Health to perform genetic tests.

II.
DEFINITIONS

3. As used throughout this Assurance of Discontinuance ("Assurance"), the terms set forth below shall mean as follows:

a. "Biological Sample" shall have the definition set forth in N.Y. Civil

Rights Law § 79-l(1)(c).

b. "Effective Date" means the date this Assurance of Discontinuance is fully executed by the parties.

c. "Genetic Test" shall have the definition set forth in N.Y. Civil Rights Law § 79-l(1)(a).

d. "NYPH Laboratory" means any laboratory operated by NYPH under a license issued by the New York State Department of Health that conducts one or more Genetic Tests.

e. "NYPH Attending Physician" means any attending physician with privileges in the NYPH departments of Obstetrics/Gynecology or Medicine who is a faculty employee of Weill Cornell Medical Center.

f. "Laboratory Staff" means any NYPH Laboratory employee who processes requests for Genetic Tests or performs Genetic Tests.

III.
BACKGROUND

4. Section 79-l of the New York Civil Rights Law ("Section 79-l"), enacted in 1996, prohibits any person from performing a Genetic Test on a Biological Sample taken from an individual without the prior written informed consent of such individual, except where such Genetic Test is for purposes of research or newborn testing conducted in accordance with applicable laws and regulations or is court-ordered. Accordingly, before a laboratory conducts a Genetic Test, it is necessary that the patient give written informed consent to that test.

5. Section 79-l further provides that written informed consent to a Genetic Test must include at least the following elements of informed consent:

a. a general description of the test;

b. a statement of the purpose of the test;

c. a statement indicating that the individual may wish to obtain professional genetic counseling prior to signing the informed consent;

d. a statement that a positive test result is an indication that the individual may be predisposed to or have the specific disease or condition tested for and may wish to consider further independent testing, consult his or her physician or pursue genetic counseling;

e. a general description of each specific disease or condition tested for;

f. the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease (not required if no level of certainty has been established);

g. the name of the person or categories of persons or organizations to whom the test results may be disclosed, and the fact that disclosure will be made if court-ordered;

h. a statement that no tests other than those authorized shall be performed on the Biological Sample and that the sample shall be destroyed at the end of the testing process or not more than 60 days after the sample was taken, unless a longer period of retention is expressly authorized in the consent; and

i. the signature of the individual subject of the test or, if that individual lacks the capacity to consent, the signature of the person authorized to consent for such individual.

IV.
ATTORNEY GENERAL'S INVESTIGATION AND FINDINGS

6. In September 2005, the Office of the Attorney General ("OAG") received a complaint alleging that NYPH was not in full compliance with Section 79-l.

7. In November 2005, the OAG initiated an investigation, which included a review

of NYPH's' policies and procedures regarding informed consent in genetic testing; its standardized genetic testing informed consent forms; and its standardized genetic testing requisition forms. The OAG also had discussions with staff of NYPH regarding its Laboratories' procedures and practices in this area. NYPH cooperated fully with the OAG throughout the inquiry.

8. The OAG's investigation identified certain standardized genetic testing informed consent forms employed by one of NYPH's Laboratories that did not contain every element set forth in Section 79-l.

9. Based on the findings set forth in this Assurance, the OAG has determined that NYPH has violated the informed consent provisions of Section 79-l as well as Section 63(12) of the New York Executive Law.

THEREFORE, without admitting or denying those contentions, NYPH offers this Assurance of Discontinuance in settlement of the violations alleged by the OAG, and the OAG accepts the specific assurances made herein pursuant to Executive Law § 63(15) in lieu of commencing a civil action.

V.
PROSPECTIVE RELIEF

A. COMPLIANCE WITH THE LAW

10. NYPH shall comply fully with the obligations, terms and conditions set forth in Section 79-l, including any revisions enacted after the Effective Date of this Assurance.

B. GENETIC TESTS PERFORMED BY NYPH'S LABORATORIES

11. Within 90 days of the Effective Date, NYPH shall prepare and provide to the OAG a standardized informed consent form for each Genetic Test currently performed by

NYPH's Laboratories ("Informed Consent Forms"). Each Informed Consent Form shall comply fully with Section 79-l and shall contain all the elements of informed consent set forth therein. The Informed Consent Forms shall be submitted to the OAG for review within 7 days of their introduction.

12. NYPH shall update the Informed Consent Forms as needed to ensure their accuracy and compliance with the law and this Assurance. If NYPH's Laboratories undertake to perform additional Genetic Tests in the future, NYPH shall ensure that an Informed Consent Form that complies with Section 79-l is prepared for that additional Genetic Test and that such form is submitted to the OAG for review within 10 business days of its introduction.

13. Within 60 days of the Effective Date, NYPH shall prepare and provide to the OAG any forms used by health care providers to requisition the performance of a Genetic Test by NYPH's Laboratories ("Requisition Forms"). Each Requisition Form shall contain a method by which the referring health care provider can state that he or she has obtained the consent of either the patient on whose Biological Sample the Genetic Test is to be conducted (or the patient's authorized representative) using the applicable Informed Consent Form, and that such Informed Consent Form is maintained in the patient's medical records.

14. If NYPH changes the method by which referring health care providers requisition the performance of Genetic Tests by NYPH's Laboratories (e.g. to a paperless, internet or email system), any new system of requisition shall include a method by which the referring health care provider may state that he or she has obtained the consent of either the patient on whose Biological Sample the Genetic Test is to be conducted (or the patient's authorized representative) using the applicable Informed Consent Form, and that such Informed Consent

Form is maintained in the patient's medical records. NYPH shall advise the OAG of any proposed changes to such system prior to their implementation.

15. NYPH's Laboratories shall make their Informed Consent Forms and Requisition Forms available to any health care provider who requisitions the performance of a Genetic Test. NYPH's Laboratories shall not perform a Genetic Test without receiving from the referring health care provider either (i) a copy of the applicable Informed Consent Form signed by the patient whose Biological Sample is to be tested (or the patient's authorized representative) ("Signed Informed Consent Form") or (ii) a signed Requisition Form in which the referring health care provider has stated that he or she has obtained the consent of the patient on whose Biological Sample the Genetic Test is to be conducted or the patient's authorized representative using the applicable Informed Consent Form, and that such Informed Consent Form is maintained in the patient's medical records ("Signed Requisition Form"). For patients for whom the medical record containing the result of the Genetic Test is maintained by NYPH, the Signed Informed Consent Forms that authorized such Genetic Test shall also be retained in such NYPH medical record.

16. NYPH's Laboratories shall retain all Signed Informed Consent Forms and/or Signed Requisition Forms, as applicable, consistent with Part 58-1.11 of Chapter 10 of the New York State Laws and Regulations.

17. All records, findings and results of any Genetic Test performed by NYPH's Laboratories and maintained by NYPH shall be deemed confidential and shall be disclosed only as allowed by law.

C. GENETIC TESTING INFORMED CONSENT POLICIES

18. Within 60 days of the Effective Date, NYPH shall: (a) adopt a written Genetic Testing Informed Consent Policy that explains the requirements of Section 79-l and this Assurance ("Genetic Testing Policy"); and (b) revise any existing policies that address Genetic Testing to conform to the requirements of applicable law and this Assurance. The Genetic Testing Policy and any such revised policies shall be submitted to the OAG for review within 7 days after final adoption. Within 15 days of their adoption, the Genetic Testing Policy and any such revised policies shall be distributed to Laboratory Staff and NYPH Attending Physicians.

D. TRAINING

19. Within 100 days of the Effective Date, NYPH shall train all Laboratory Staff and NYPH Attending Physicians on the requirements of applicable law and this Assurance. NYPH shall maintain attendance records for all training sessions. Furthermore, the transmittal of the Genetic Testing Policy to NYPH Attending Physicians as set forth in paragraph 18 above shall include directions and procedures to be followed by NYPH Attending Physicians for assuring compliance with the policy. The transmittal will also explain the requirements of this Assurance.

20. All new Laboratory Staff shall receive training on the policies and procedures required by applicable law and this Assurance within 7 days of commencing employment with NYPH.

21. All new NYPH Attending Physicians shall receive a copy of the Genetic Testing Policy, a summary of the requirements of this Assurance, and the procedures required for compliance within 30 days of becoming NYPH Attending Physicians.

E. MONITORING

22. NYPH shall conduct compliance reviews of Genetic Tests performed by NYPH's Laboratories to determine the extent to which Laboratory Staff and NYPH Attending Physicians are complying with the informed consent procedures set forth in this Assurance. NYPH shall develop written protocols and methodologies for such reviews which shall be conducted over three Reporting Periods. The first Reporting Period shall begin four months after the Effective Date and end six months thereafter. The second Reporting Period shall begin at the close of the first Reporting Period and end six months thereafter. The third Reporting Period shall begin at the close of the second Reporting Period and end one year thereafter.

23. At the end of each Reporting Period, NYPH shall generate a random sample of no fewer than 35 tests from each of NYPH's Laboratories that are the type of tests that are commonly performed as Genetic Tests but may not necessarily be requested for predictive purposes ("Sample Laboratory Tests"). The Sample Laboratory Tests shall be drawn solely from the universe consisting of patients for whom NYPH maintains medical records.

24. NYPH shall review the Laboratory records associated with the Sample Laboratory Tests to determine whether a Signed Informed Consent Form or Signed Requisition Form exists for each test.

25. NYPH shall also review the medical records for those patients on whose Biological Samples the Sample Laboratory Tests were conducted but no Signed Informed Consent Form was submitted to the NYPH Laboratory to determine whether a Signed Informed Consent Form exists. Following the review of those medical records, for each NYPH Laboratory, NYPH shall calculate the percentage of Sample Laboratory Tests where no Signed

Informed Consent Form exists.

26. If, at the end of the first Reporting Period, NYPH finds that the percentage of missing Informed Consent Forms pertaining to the Sample Laboratory Tests exceeds 15 percent for a particular NYPH Laboratory, NYPH shall generate a second random sample of no fewer than 50 tests from that Laboratory that are the type of tests that are commonly performed as Genetic Tests but may not necessarily be requested for predictive purposes ("Additional Sample Laboratory Tests"). NYPH shall conduct a review of the Additional Sample Laboratory Tests as set forth in paragraphs 24 and 25 of this Assurance. If the review of Additional Sample Laboratory Tests finds that the percentage of missing Informed Consent Forms pertaining to the Additional Sample Laboratory Tests exceeds 10 percent, NYPH shall develop and implement appropriate corrective measures, including but not limited to, retraining, additional monitoring and discipline.

27. If, at the end of the second Reporting Period, NYPH finds that the percentage of missing Informed Consent Forms pertaining to the Sample Laboratory Tests exceeds 10 percent for a particular NYPH Laboratory, NYPH shall generate a second random sample of no fewer than 50 Additional Sample Laboratory Tests. NYPH shall conduct a review of the Additional Sample Laboratory Tests as set forth in paragraphs 24 and 25 of this Assurance. If the review of the Additional Sample Laboratory Tests finds that the percentage of missing Informed Consent Forms pertaining to the Additional Sample Laboratory Tests for a particular NYPH Laboratory exceeds 10 percent, NYPH shall develop and implement appropriate corrective measures, including but not limited to, retraining, additional monitoring and discipline. Furthermore, if the NYPH Laboratory exceeded the ten percent threshold in the second stage monitoring undertaken

pursuant to paragraph 26 of this Assurance, NYPH shall undertake additional training focused on those NYPH Attending Physicians whose records lacked the necessary Informed Consent Forms.

28. If, at the end of the third Reporting Period, NYPH finds that the percentage of missing Informed Consent Forms pertaining to the Sample Laboratory Tests exceeds 10 percent for a particular NYPH Laboratory, NYPH shall generate a second random sample of no fewer than 50 Additional Sample Laboratory Tests. NYPH shall conduct a review of the Additional Sample Laboratory Tests as set forth in paragraphs 24 and 25 of this Assurance. If the review of Additional Laboratory Tests finds that the percentage of missing Informed Consent Forms pertaining to the Additional Sample Laboratory Tests for a particular NYPH Laboratory exceeds 10 percent, NYPH shall conduct a root cause analysis of the reasons for non-compliance and shall develop a written corrective action plan. The root cause analysis and corrective action plan shall be shared with the OAG within 14 days of their development. The OAG may request that additional corrective actions be undertaken and may direct that the provisions of this Assurance be extended for an additional six months, including an additional sample review under the terms of this paragraph 28.

VI.
RECORD KEEPING AND REPORTING TO OAG

29. Within 90 days after the end of each Reporting Period, a report shall be prepared (the "Genetic Testing Informed Consent Monitoring Report") and provided to the OAG, to the attention of the Bureau Chief, Civil Rights Bureau. Such report shall include:

a. a description of the protocols and methodologies used for conducting the record reviews;

b. a description of the reviews and their findings, including the results contemplated in paragraph 24-28 of this Assurance and the raw numbers on which those results are based;

c. a detailed description of any corrective measures taken, or planned to be taken, by NYPH, and when such remedial steps will be completed;

d. a description of any proposed revisions to the method by which Genetic Tests are requisitioned from NYPH Laboratories; and

e. copies of any revised or new Informed Consent Forms, revised or new Requisition Forms, and/or any revised genetic testing policies.

30. The OAG shall have access to review any NYPH document relating to the implementation of this Assurance. Patient-identifying information, other than patient signatures required under Section 79-l(2)(b)(8) to be included in the written informed consent, shall be redacted from any document produced, and a method shall be maintained by which patient-identifying information can be retrieved, if necessary.

VII.
MISCELLANEOUS

31. This Assurance shall expire two years and seven months after the Effective Date unless it is extended for an additional six months pursuant to paragraph 28.

32. Notwithstanding any provision of this Assurance to the contrary, the OAG may, in its sole discretion, grant written extensions of time for NYPH to comply with any provision of this Assurance.

33. The signatories to this Assurance warrant and represent that they are duly authorized to execute this Assurance and that they have the authority to take all appropriate

action required or permitted to be taken pursuant to the Assurance to effectuate its terms.

34. The parties may seek to enforce this Assurance through enforcement proceedings, including a civil action in federal or state court, as appropriate, seeking specific performance of the provisions of this Assurance. Pursuant to New York Executive Law § 63(15), evidence of a violation of the Assurance will constitute prima facie proof of a violation of the applicable statutes in any civil action or proceeding hereafter commenced by the OAG. In the event of a dispute among the parties regarding any issue arising hereunder, the parties will attempt in good faith to resolve the dispute before seeking judicial intervention.

35. Any failure by the OAG to enforce this entire Assurance or any provision thereof with respect to any deadline or any other provision herein shall not be construed as a waiver of the OAG's right to enforce other deadlines and provisions of this Assurance.

36. If any provisions, terms, or clauses of this Assurance are declared illegal, unenforceable, or ineffective in a legal forum, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Assurance shall remain valid and binding on the parties. If Section 79-l is repealed, this Assurance shall terminate on the effective date of such repeal.

37. This Assurance constitutes the entire agreement between NYPH and the OAG on the matters raised herein, and no other statement, promise or agreement, either written or oral, made by any party or agents of any party that is not contained in this Assurance shall be enforceable.

38. Nothing in this Assurance is intended to confer any right, remedy, obligation, or liability upon any person or entity other than the parties hereto.

39. Nothing in this Assurance is intended to, nor shall, limit the OAG's investigatory

or compliance review powers otherwise provided by law or this Assurance.

40. This Assurance may be executed in multiple counterparts, each of which shall be deemed a duplicate original.

41. This Assurance is final and binding on the parties, including principals, agents, representatives, successors in interest, assigns, and legal representatives thereof. No assignment by any party hereto shall operate to relieve such party of its obligations herewith.

IN WITNESS THEREOF, the undersigned subscribe their names:

Dated: New York, New York
March 26, 2007

THE NEW YORK AND PRESBYTERIAN HOSPITAL

By: _____
Maxine Fass, Esq.
General Counsel

CONSENTED TO:

Dated: New York, New York
March 28, 2007

ANDREW M. CUOMO
Attorney General of the State of New York

By: Dianne E. Dix
Dianne E. Dixon
Chief, Civil Rights Bureau
120 Broadway
New York, New York 10271
Tel. (212) 416-8905
Fax (212) 416-8074