STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
FACILITY LICENSING AND INVESTIGATIONS SECTION

CONSENT ORDER

The Stamford Hospital
License #0059
One Hospital Plaza
Stamford, CT 06904

The Stamford Health Laboratory
Registration No. HP-0364
29 Hospital Plaza
Room 503
Stamford, CT 06904

The Stamford Hospital Laboratory
Registration No. HP-0243
One Hospital Plaza
Stamford, CT 06904

WHEREAS, in January of 2018, the Facility Licensing and Investigations Section ("FLIS") of the Connecticut Department of Public Health ("Department") commenced an investigation regarding The Stamford Hospital and The Stamford Laboratories ("Respondents");

WHEREAS, the Department alleges:

1. Stamford Hospital has been issued license number 0059 to maintain and operate a hospital.

2. Stamford Hospital is registered to maintain and operate an Approved Public Health Laboratory (Registration No. HP-0364) located at 29 Hospital Plaza, Room 503, Stamford, Connecticut 06904.

3. Stamford Hospital is registered to maintain and operate an Approved Public Health Laboratory (Registration No. HP-0243) located at One Hospital Plaza, Stamford, Connecticut 06904.

4. On or about January 26, 2018, the Department conducted a Blood Collection Facility inspection at Feel Well Health Center, 710 Main Street, Building 4, in Plantsville, Connecticut ("FWHC") for an initial certificate attached to the Stamford Health Laboratory License No. HP-0364.

5. At the time of this inspection, an individual phlebotomist who had contracted with Boston Heart Diagnostics in Massachusetts ("Boston Heart") had been performing venipuncture at

this site prior to Stamford Hospital or either of its Approved Public Health Laboratories had obtained a written certificate of approval to operate a blood collection facility.

6. The phlebotomist who had contracted with Boston Heart was collecting and sending the specimens to Boston Heart in Massachusetts for laboratory analysis.

7. The contract phlebotomist was paid by Boston Heart for per venipuncture performed.

8. Neither Stamford Hospital nor either of its Approved Public Health Laboratories had obtained a written certificate of approval issued by the Department to operate a blood collection facility at the FWHC prior to performing venipuncture at said location.

9. Between approximately October 4, 2017 and January 26, 2018, Stamford Hospital paid a phlebotomist to perform venipuncture at FWHC prior to obtaining a written certificate of approval to operate a blood collection facility.

10. The Stamford Hospital blood collection facility located at the FWHC violated Connecticut State Statutes and/or the Regulations of Connecticut State Agencies by:

    a) Failing to possess and/or display a State of Connecticut blood collection facility certificate with a gold seal of approval;

    b) Failing to possess and/or display emergency procedures for a distressed patient;

    c) Failing to have a supervisor visit the facility on at least a monthly basis;

    d) Failing to maintain the area in that the arms of the chair used for blood collection were torn creating an unsafe environment in terms of infection control; and/or,

    e) Failing to have the centrifuge calibrated annually in that the last calibration date for the centrifuge was January 2016.

11. The above referenced conduct violates Section 19a-36-D29(d), (e) and (f) of the Regulations of Connecticut State Agencies.

WHEREAS, in September of 2018, the Department received a comprehensive plan of correction from Respondents which, upon the effective date of this Consent Order, is hereby accepted by the Department; and,

NOW THEREFORE, the Department acting herein and through Barbara Cass, FLIS Branch Chief, and the Respondents, acting herein and through Ruth Cardiello, RN, MSN, CPHRM, hereby stipulate and agree as follows:

1. Stamford Hospital ("Licensee") and its Approved Public Health Laboratories HP-0364 and HP-0243 and their blood collection facilities approved under such approvals (collectively, with the Licensee, referred to herein as the "Respondents") shall be subject to the following requirements for a period of one year from the effective date of this Consent Order:
    a. Respondents shall submit a comprehensive plan of correction to address the violations detailed above. Such plan of correction must include a plan for training all laboratory staff at Respondents' Approved Public Health Laboratories and blood collection facilities. A plan for such training must be submitted to the Department for approval prior to its implementation.
    b. During the first six months following the effective date, the Department shall have sole and absolute discretion regarding whether to issue Respondents any Approved Public Health Laboratory registrations and any additional certificates of approval for any blood collection facilities in Connecticut. Respondents waive any right it may have to challenge such decision in any forum, and agree that the Department is under no obligation to issue any certificates of approval for blood collection facilities during this six month time period.
    c. Respondents agree that any clinical laboratory or blood collection facility which is granted a license or certificate of approval by the Department during the one-year period following the effective date shall be subject to the terms of this Consent Order.
    d. After the six month period, if Respondents plan to submit any new applications to the Department for an Approved Public Health Laboratory or a blood collection facility, Respondents must notify, and receive approval from, their Corporate Compliance Officer prior to such application.
    e. During the first six months following the effective date, Respondents must submit monthly reports to the Department indicating that they have conducted a monthly review of the practices of the laboratories and blood collection facilities, and such report must indicate whether the laboratories and blood collection facilities are in substantial compliance with federal and state law and regulation. Such monthly report must be signed by the Corporate Compliance Officer of The Stamford Hospital in addition to appropriate representatives from the laboratories and blood collection

facilities. The monthly report shall identify methods utilized for the analysis, areas reviewed, process, findings and any recommendations for improvement.

f. In addition, Respondents' Phlebotomy Supervisor described below shall have the responsibility for:

1. Assessing, monitoring, and evaluating the delivery of direct patient care with particular emphasis and focus on the delivery of services by phlebotomists implementing prompt training and/or remediation in any area in which a staff member demonstrated a deficit. Records of said training and/or remediation shall be maintained by the Licensees for review by the Department;
2. Assessing, monitoring, and evaluating the coordination of the collection and proper storage of specimens by phlebotomists providing services;
3. Assessing, monitoring, and evaluating environmental conditions which include but are not limited to; cleanliness of equipment, work surfaces, refrigerator and freezer temperature, and storage of biomedical wastes;
4. Assessing, monitoring, and evaluating the infection control program;
5. Assessing, monitoring, and evaluating to ensure the necessary equipment and specimen collection supplies are available and maintained within manufacturer's specifications and expiration date;
6. Assessing, monitoring and evaluating the specimen transportation and delivery procedures;
7. Reviewing all pre-analytical quality issues;
8. Providing the facility with oversight and resources to implement a responsible and responsive QAPI program; and,
9. Attending Quality Assurance Performance Improvement ("QAPI") meetings.

g. Within one month of the effective date of this Consent Order, Respondents shall appoint a Phlebotomy Supervisor who holds a minimum of an Associate's Degree in biological, physical or chemical science with a phlebotomy certification or a certification as a medical laboratory scientist, technician or technologist. The Phlebotomy Supervisor's primary responsibility is the assessment of phlebotomy procedures and practices provided by phlebotomy staff. The Phlebotomy Supervisor

shall be responsible to supervise no more than twenty-five (25) blood collection facilities. The Phlebotomy Supervisor shall visit each blood collection facility every other week for a minimum of six (6) months from the effective date unless the Department identifies through inspections or any other evidence it deems relevant that a longer time period is necessary to ensure substantial compliance with applicable federal and state statutes and regulations. The Phlebotomy Supervisor shall maintain a record of any visit and related issue(s) or problem(s) identified and documentation as to the subsequent action taken to resolve the problem(s). Said records shall be made available to the Department upon request and shall be retained for a minimum of five (5) years. The Phlebotomy Supervisor shall be supervised and monitored by The Stamford Hospital's Administrative Director of Laboratory Services to ensure the Supervisor is functioning in accordance with this Consent Order and state and federal statutes and regulations and in accordance with standards of practice. Said administrative supervision and oversight shall be provided on a randomized schedule of visits. The Respondents shall provide the Phlebotomy Supervisor with the following:

1. A job description, which clearly identifies the supervisor's day-to-day duties and responsibilities; and,
2. An in-service training program, which clearly delineates each Phlebotomy Supervisor's responsibilities and duties with respect to patient and staff observations, interventions and staff remediation.

h. A QAPI Program shall be instituted by the Respondents, which shall identify a QAPI Phlebotomy and Laboratory Committee ("Committee"), consisting of, at least, the Clinical Director of Core Laboratory Services, Administrative Director of Laboratory Services, Supervisor, Point of Care Coordination and Regulation, Manager, Regulatory Affairs, Phlebotomy Supervisor, and any other necessary phlebotomy staff. The Committee shall meet at least once every thirty (30) days to review all reports or complaints relating to patient care and compliance with federal and state laws and regulations and standards of practice. The activities of the QAPI Committee shall include, but not be limited to, determination and adoption of new policies to be implemented by Respondents' staff to improve patient care practices, and pre-analytical procedures. The Committee shall implement a QAPI program

that will measure, track and report on compliance with the requirements of this Consent Order. The Committee shall measure and track the implementation of any changes in the Respondents' policies, procedures, and allocation of resources recommended by the Committee to determine compliance with and effectiveness of such changes. A record of QAPI Committee meetings and subject matter discussed shall be documented and available for review by the Department and the Consultant. Minutes of all such meetings shall be maintained by Respondents for a minimum period of five (5) years.

i. The Respondents' Clinical Director of Core Laboratory Services, Administrative Director of Laboratory Services, Supervisor, Point of Care Coordination and Regulation, Manager, Regulatory Affairs, Phlebotomy Supervisor and the Corporate Compliance Officer shall meet with the Department quarterly during the first six months following the effective date of this Consent Order and at a frequency to be determined after six months by the Department, in its sole and absolute discretion, for the remainder of the one-year period. The meetings shall include discussions of issues related to the care and services provided by the Respondents and the Respondents' compliance with applicable federal and state statutes and regulations.

j. Any records maintained in accordance with any state or federal law or regulation or as required by this Consent Order shall be made available to the Department, upon request. Any rights of Respondents to claim and exert privilege to quality assurance or peer review documents under state and/or federal law are preserved and not limited or waived by this Consent Order.

k. Effective upon the execution of this Consent Order, The Stamford Hospital's Governing Body, through the Clinical Director of Core Laboratory Services, Administrative Director of Laboratory Services, Supervisor, Point of Care Coordination and Regulation, Manager, Regulatory Affairs and Phlebotomy Supervisor, shall ensure substantial compliance with the following:

    1. Sufficient and qualified personnel are available to meet the needs of the patients;
    2. The Phlebotomy Supervisor is notified in a timely manner of any significant incidents and concerns,

3. Infection Control, emergency and safety practices are assessed in accordance with current regulations and standards of practice;
4. Necessary supervision and phlebotomy monitoring is provided to ensure quality care;
5. Policies and procedures related to the pre-analytical process will be reviewed and revised as necessary; and,
6. Equipment and supplies are adequate to meet the needs of the patients.

l. Effectively immediately and upon execution of this Consent Order, the Licensees will notify the Department immediately, if any of the following positions became vacant:
   a. Medical Director, Laboratory Services
   b. Administrative Director, Laboratory Services
   c. Clinical Director of Core Laboratory Services
   d. Phlebotomy Supervisor

m. Respondents, with the Department's approval, have designated the Manager, Regulatory Affairs, Maggie Zurita, RN, BSN, CPHRM to monitor the requirements of this Consent Order. If this person is unable to fulfill this duty for any reason, Respondents shall designate another individual to fulfill this duty, and the Department must pre-approve this designation in writing prior to that person assuming these responsibilities.

n. The Respondents shall pay a civil penalty to the Department at the time of signing this Consent Order in the amount of Fifty-five Thousand Dollars ($55,000.00), by money order or bank check payable to "Treasurer, State of Connecticut". The civil penalty and any reports required by this Consent Order shall be directed to:

Kim Hriceniak, RNC, BSN.
Public Health Services Manager
Facility Licensing and Investigations Section
Department of Public Health
410 Capitol Avenue, P.O. Box 340308, MS #12 HSR
Hartford, CT 06134-0308

2. All parties agree that this Consent Order is an Order of the Department with all of the rights and obligations pertaining thereto and attendant thereon. Nothing herein shall be construed as limiting the Department's available legal remedies against the Licensee for violations of the Consent Order or of any other statutory or regulatory requirements, which may be sought in lieu of or in addition to the methods of relief listed above, including all options for the

issuance of a statement of charges, the imposition of civil penalties calculated and assessed in accordance with Conn. Gen. Stat. § 19a-30, or any other administrative and judicial relief provided by law.

3. The execution of this Consent Order has no bearing on any criminal liability without the written consent of the Director of the MFCU or the Bureau Chief of the Department of Criminal Justice's Statewide Prosecution Bureau.
4. The Respondents agree that this Consent Order applies only to Respondents' Connecticut operations, and it resolves this matter only on behalf of the Department. The Respondents agree that this Consent Order does not limit any other agency or entity in any manner.
5. The Respondents agree that this Consent Order and the terms set forth herein are not subject to reconsideration, collateral attack or judicial review under any form or in any forum including any right to review under the Uniform Administrative Procedure Act, Chapter 368a of the Statutes, Regulations that exists at the time the agreement is executed or may become available in the future, provided that this stipulation shall not deprive the Respondents of any other rights that it may have under the laws of the State of Connecticut or of the United States.
6. The Respondents agree that the allegations identified above shall be deemed true in any subsequent proceeding in which the Respondents' compliance with this Consent Order or state and federal statutes and regulations related to the operation of clinical laboratories and/or blood collection facilities are at issue.
7. The Respondents agree that they must comply with its plan of correction approved by the Department pursuant to this Consent Order. The Respondents agree that failure to comply with its plan of correction constitutes a violation of this Consent Order. The Respondents agree that the provisions of this Consent Order are in addition to its plan of correction. The Respondents agree that they must comply with this Consent Order and implement its plan of correction.
8. The Respondents have consulted with their attorney prior to the execution of this Consent Order.
9. This Consent Order is a public document, and it will be reported in accordance with state and federal law and regulation and consistent with Department policy. The Consent Order may be posted on the Department's website.

10. This Consent Order is effective on the date it is signed by the Commissioner of Public Health or his designee.

WITNESS WHEREOF, the parties hereto have caused this Consent Order to be executed by their respective officers and officials. Ruth Cardiello, RN, MSN, CPHRM, represents that she is authorized to sign this Consent Order on behalf of the Respondents.

The Respondents

By: _____
Ruth Cardiello, RN, MSN, CPHRM
Vice President
Enterprise Risk Management &
Corporate Compliance Officer

On this 7th day of September, 2018, before me, personally appeared Ruth Cardiello, RN, MSN, CPHRM, and that she, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained.

My Commission Expires: 5-31-19 _____
(If Notary Public)

Notary Public [✓]
Commissioner of the Superior Court [ ]

KAREN S BELL
Notary Public, State of Connecticut
My Commission Expires May 31, 2019

CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

By: _____
Barbara Cass, R.N.
Branch Chief
Facility Licensing and Investigations Section

September 30th, 2018