

MEMORANDUM

To: NYC Health + Hospitals/Kings County All Departments;
Research Community; and
Facility Research Review Committee (FRRC)

From: Rich Sinert, DO, Professor of Emergency Medicine; Chair, Facility Research Review
Committee, NYC Health + Hospitals/Kings County

CC: Imah Jones, Senior Director, NYC Health + Hospitals/Research Administration

Date: 12/20/2016

Re: NYC Health + Hospitals/Kings County – Clinical Research Office

In the last few years, I have worked with the NYC Health + Hospitals Research Administration office and local hospital administrators to develop a Clinical Research Office at NYC Health + Hospitals/Kings County. The Clinical Research Office is in the Emergency Department Offices (C-Bldg., Ground Floor, Room #54). We provide oversight of all research via STAR (System to Track and Approve Research), the same system used by Principal Investigators (PIs) to obtain NYC Health + Hospitals approval of a research study. For funded studies, we offer accounting services to invoice and track all budgeted items. We have pooled Research Coordinators who can help with all the regulatory requirements (e.g., protocol development, IRB submission, etc.) of human research. In addition, I am very familiar with all the intricacies of research at NYC Health + Hospitals/Kings County and am available for help in both funded and unfunded studies.

Listed below are the most relevant sections for starting new studies, summarized from the NYC Health + Hospitals Human Subject Research Protections Program Policies and Procedures, 180-9, available in SharePoint, <https://share.nychhc.org/central/ResearchAdmin/ORC/Pages/index.aspx> and on the NYC Health + Hospitals Intranet for Procedures, <http://sites.nychhc.org/Operations/CSS/OP/Default.aspx>. More information about performing human subjects research at NYC Health + Hospitals can also be found at <http://research.nychhc.org/>.

PROCEDURE:

New Projects/Protocol

Require **both** Institutional Review Board (IRB) and NYC Health + Hospitals approvals. During the development phase of a new protocol, the PI shall consult with the following:

- Clinical Director/Administrator of the department in which the research will be conducted;
- Facility Research Coordinator (FRC); FRRC Chair and/or FRRC;

- NYC Health + Hospitals Research Administration office, if applicable (to develop contract/funding agreement/budgets for funded studies);
- NYC Health + Hospitals/Kings County Department of Finance (budget development for funded and unfunded studies);
- SUNY Downstate Medical Center (Research Foundation), if necessary.

IRB Application

IRB approval must be granted prior to receiving NYC Health + Hospitals approval. The IRB review and approval is a mandatory process for all research projects. The PI must submit application and all research-related documents including Informed Consent Forms (ICFs) to a NYC Health + Hospitals approved Institutional Review Board.

STAR Application Form

STAR is the electronic system used by NYC Health + Hospitals for research project approval and is located online at <http://star.nychhc.org/>. The STAR application must be completed and include supporting documentation such as IRB approval letter, approved study materials, research contract, etc., in order to be reviewed STAR.

Facility Research Coordinator Review

In addition to verifying PI and staff credentials, the FRC serves as the point person for PIs to help them navigate and facilitate research at the hospital. The FRC is also the gatekeeper for STAR and conducts initial reviews of projects to ensure a complete application prior to forwarding for Facility Research Review Committee review. The FRC will ensure the following documents, as applicable, are uploaded to support each STAR application:

- IRB approved protocol;
- Current Informed Consent Forms or waivers thereof;
- Current HIPAA Authorizations or waivers thereof;
- Research Agreement, Award Letter and/or Budget.

The FRC will request, via STAR, specific departmental reviews of a protocol dependent upon the appropriate impacted departments, as needed.

Facility Research Review Committee

The Facility Research Review Committee reviews research applications via STAR, electronically indicating their approval of a study within the system. The FRRC consists of representatives from the following departments:

- FRRC Chair
- FRC
- Finance
- Pharmacy
- Diagnostic Services (Clinical Laboratory/Pathology and Radiology)
- Impacted Clinic/Department

NYC Health + Hospitals/Kings County Executive Approval

The FRC shall submit said protocol to the Medical Board President, the Executive Director and Medical Director of the hospital for Executive Approval in STAR. All approvals are evidenced within the system.

NYC Health + Hospitals Authorization

The FRC shall submit said protocol via STAR to the Research Administration office for NYC Health +

Hospitals review and approval. The system generates an automatic approval letter to the PI (copied to the FRC) once the application is approved. If authorization is denied or if clarification is required, email communication will be sent to the PI for such.

Renewal of Ongoing Projects in STAR

NYC Health + Hospitals Authorization lasts for one year and must be renewed prior to study expiration. The following information should be submitted in STAR to initiate FRC, continuing review of a study:

- IRB continuation letter and current ICFs
- Copy of Annual Progress Report as submitted to IRB (NO PHI SHOULD BE INCLUDED IN STAR)

Compliance with these requirements entitles the FRC to grant automatic local renewal for another 365 day period.

NOTE: Substantial changes in protocol require a new STAR application.