CONDUCTING HUMAN SUBJECTS RESEARCH AT HARLEM HOSPITAL

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Central Office
January 13, 2016
OVERARCHING POLICIES

- U.S. Department of Health and Human Services
- Operating Procedure No.: 180-9: HHC Human Subject Research Protections Program Policies and Procedures
- Harlem Hospital Facility Research Policies
KEY PLAYERS

- Researchers

- Facility Research Administrators
  - Facility Research Coordinator
  - Facility Research Review Committee Chair
  - Facility Research Review Committee (includes Finance, Pharmacy and any other specialty ad-hoc reviewers)
  - Medical Director and/or Medical Board President
  - CEO

- Research Administration Office at Central Office
NYC HEALTH + HOSPITALS APPROVAL

All human subjects research projects must be granted NYC Health + Hospitals approval.

Key Components of the NYC Health + Hospitals approval includes:

- Institutional Review Board (“IRB”) approval
- Facility and Central Office approval through System to Track and Approve Research (“STAR”)
WHAT IS HUMAN SUBJECTS RESEARCH?

As defined by the U.S. Department of Health and Human Services:

*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.
WHO CAN CONDUCT RESEARCH?

ANYONE!

Provided that the researcher:
- Has the proper credentials and training to conduct the proposed research.
- Is allowed to conduct research at Harlem Hospital (“HH”).
- Has been approved by their supervisor/Director of Service.
- Has been cleared by the IRB.
THE ROLE OF PRINCIPAL INVESTIGATOR

The Principal Investigator ("PI") is the individual responsible for protecting the rights and welfare of human subjects and for carrying out sound ethical research consistent with protocols approved by the IRB and NYC Health + Hospitals and the overall conduct of the project.

Students, residents and fellows cannot serve as PIs.

* Please note that NYC Health + Hospitals uses an internal term, the site PI. Federal regulations do not acknowledge this term, so IRBs are not familiar with this role.

A site PI is elected when HH collaborates with another institution (including other NYC Health + Hospitals entities) and an official PI was already identified. The site PI is responsible for all aspects of the study at HH.
PROCESS BREAKDOWN

• Pre-Implementation
  • Feasibility assessment
  • IRB review and approval
  • Facility and Central Office approval

• Implementation

• Post implementation
PRE-IMPLEMENTATION
FEASIBILITY ASSESSMENT

Questions you should answer during this phase:

- Why is this project important to HH?
- Do I need to apply for funding?
- Who will be on my research team?
- Are we collaborating with another institution?
- Is this study operationally possible?
- Can we meet the target enrollment?
- Do I need the facility to waive any costs if there is no funding?
- Do I need a research contract or MOU in place?

Please contact your Facility Research Coordinator for a consultation if necessary.
PRE-IMPLEMENTATION
IRB APPROVAL

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<thead>
<tr>
<th>Facility</th>
<th>IRB</th>
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<tbody>
<tr>
<td>Central Office</td>
<td>BRANY</td>
</tr>
<tr>
<td>Bellevue, Gouverneur, Woodhull</td>
<td>NYUSOM</td>
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<tr>
<td>Coney Island</td>
<td>Maimonides</td>
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<tr>
<td>Elmhurst and Queens</td>
<td>Mount Sinai</td>
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<tr>
<td>Harlem</td>
<td>BRANY</td>
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<tr>
<td>Kings County</td>
<td>SUNY Downstate</td>
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<tr>
<td>Jacobi and NCB</td>
<td>Albert Einstein</td>
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<td>Lincoln</td>
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<tr>
<td>Metropolitan</td>
<td>NY Medical College</td>
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- All facilities can use BRANY as an alternative to their associated IRB
- All facilities can use the Central IRB for National Cancer Institute funded studies

- NYC Health + Hospitals does not have an internal IRB. BRANY functions as our central IRB for multi-site projects.
- All research personnel must pass CITI human subjects protection training to participate in research projects.
- IRB determinations: exempt, expedited or full board
PRE-IMPLEMENTATION
FACILITY AND CENTRAL OFFICE APPROVAL

To ensure that researchers comply with NYC Health + Hospitals regulations, studies are entered into STAR for facility and Central Office review.

- A complete application includes: an IRB determination, all IRB-approved documents, budget and contract (when applicable).

- STAR application will be reviewed by Facility Research Administrators including the Medical Board President and the CEO.

- After facility approval, a Central Office reviewer from Research Administration will review and issue NYC Health + Hospitals approval.

- Study implementation can commence upon receipt of this approval.

- NYC Health + Hospitals renewal will align with your IRB renewal date. NYC Health + Hospitals is valid only when IRB approval is current.
The PI and research team must:

- Comply with all IRB and sponsor guidelines, including the reporting of unanticipated and adverse events.

- Maintain and keep study records and source documents in the manner approved by the sponsor, IRB and NYC Health + Hospitals. PHI must be protected.

- If the project is funded, work with Finance and the sponsor to ensure study costs are in order.
After IRB approval:

- The PI should submit a STAR application. If a site PI is identified, the application must be under the site PI’s name.

- A typical complete application includes: an IRB approval, all IRB-approved documents, budget and contracts (when applicable)

- STAR application will be reviewed by Facility Research Administrators, including the Medical Board President and the CEO.

- After facility approval, Research Administration at Central Office will grant NYC Health + Hospitals approval via STAR. **Study implementation can commence upon receipt of this approval.**
POST-IMPLEMENTATION

- Submit closure and final progress reports to the IRB.
- Close the study in STAR.
- Contact Research Administration if they negotiated a contract for your study.
- If publishing or presenting study findings, please consult Operating Procedure No.:180-9 for citation guidelines.
- Send a copy of the published manuscript or presentation to your FRC.
- Maintain research records and source documents for a minimum of seven years or for the length of time required by the sponsor (whichever is longer). Please consult Operating Procedure No.:180-9 for more information.
1. Do I need IRB approval for project evaluation, quality improvement or case studies?

2. Can my facility IRB or departmental IRB review this instead of BRANY?

3. Can multi-site projects receive a blanket NYC Health + Hospitals approval via STAR?

4. I think my study meets the criteria for IRB exemption. Can I make this determination myself?

5. Q & A
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