Conducting Research at Bellevue Hospital Center

Presented by:
Bellevue Research Administration Department
Presentation Outline

- Bellevue Research Administration Department
- Bellevue Research Approval Process
  - Submission
  - Review & Approval
- Bellevue Research Post-Approval Process
  - Invoicing
  - Amendments
  - Continuations
  - Closures
- Credentialing/HR Clearance Process
Bellevue Research Administration Department

Who We Are
- Patricia Gaeta, Director
- Anand Veeraraj, Coordinating Manager/Facility Research Coordinator
- Patrinia Wilson, Coordinating Manager/Facility Research Coordinator

What We Do
- Develop policies, procedures, and processes related to research
  - Research Administration Department Webpage on BHC Intranet
- Collaborate with the NYU OSR
  - IRB and CTSI Scientific Review Committee Meetings
  - CTAC Meetings
  - IRB, OCT, and SPA Administrative Meetings
  - CTSI and ACTU Administrative Meetings
- Assist investigators with budget preparation and protocol submission into ReASOn
- Review and approve all research pertaining to human subjects conducted within the facility
Bellevue Research Approval Process

Approval -> Submission

Review

Approval
New Protocol Submission

IRB and OCT Submission

IRB: Proceed with IRB review
OCT: Proceed with PRA

IRB: Final review decision
OCT: Final PRA approval

Notify PI

BHC Involved?

Yes

IRB and OCT: Communicate with BHC FRC

- Forward New Protocol Submission Application email, including attachments, to FRC
- Forward BHC-specific budget and billing grid to FRC

BHC FRC: Follow-up with PI/study team

- Email New Protocol Submission Letter to PI
  - Accessing ReASON
  - Complete 641 Application without attachments

Notify BHC FRC

- Copied on PI email notification
- FRC retrieves IRB-approved documents from IRB shared drive and attaches in ReASON

No

IRB: Proceed with IRB review
OCT: Proceed with PRA

Yes

BHC Involved?
Review & Approval

Bellevue Research Review Committee (BRRC)

Facility Research Coordinator Review

HHC CO Research Administration Review

Committee Review

Executive Review
FRC Review

Preliminary Review of:
- 641 Application
  - General Information
  - Personnel Summary
    - % effort on study
    - Consistent with study team on IRB application
    - Credentials/HR clearance of study team
- Space
  - Signature of BHC Service Chief on IRB application
- BHC-Specific Budget and Billing Grid
  - Assure BHC can accommodate study
  - Assure all BHC research-related fees have been budgeted
    - Investigational Pharmacy
    - Chart Pull
    - Ancillaries/Visits (Medicare Payment Rate)
  - Do not complete the Patient Care Costs on 641
- Obtain PO#
  - Blanket PO in ePro
Committee Review

- Not an IRB
- Administrative Committee
- Committee Members
  - Medical, Pharmacy, P&T, Pathology, Radiology, Clinical Services, Ambulatory Care Services, Emergency Services, Finance
- Practical Review
  - Workload
  - Financial
Executive Review

- Executive Members
  - Medical Board President
  - Executive Director

- Medical and Administrative Review
  - Medical/Ethical
  - Mission/Vision
HHC CO Research Administration Review

- Final review and approval
- Study may begin **only** upon receipt of an HHC Central Office Approval Letter
  - Emailed to PI and BHC FRC
  - Forwarded by BHC FRC to OCT, CTSI, RC
Invoicing

- Quarterly Billing
- Finance Database
  - Report of 088 Non-Billable Clinic Code
    - Visits and ancillaries
    - Compare to budget and billing grid
    - Reconciled with PI/study team
- Investigational Pharmacy
  - Report from Research Pharmacist
    - Pharmacy services
    - Compare to budget and billing grid
    - Reconciled with PI/study team
- Chart Pulls
  - Chart Pull Request Form
  - Bellevue Medical Records Department processes request
- Prepare and Submit Invoices
  - Blanket PO
  - NYU Accounts Payable
Amendments/Updates

IRB Submission

<table>
<thead>
<tr>
<th>BHC Involved?</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Yes</td>
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- Copied on PI email notification
- FRC reviews IRB Amendment Approval Letter and emails PI to attach amendment in ReASoN (FRC unable to attach amendment)

Notify PI

Notify BHC FRC

IRB: Communicate with BHC FRC

- Forward IRB Amendment Application email, including attachments, to FRC

BHC FRC: Follow-up with PI/study team

- Save IRB Amendment Application email, including attachments, to study folder
Amendments

- ReASOn
  - My Approved Protocols
  - View/Copy/Amend an Active Protocol
  - Click to Amend
  - Amend an Active Protocol
    - Notes
    - Attach Amendment
    - Submit
- Personnel Change (PI)
  - Cannot edit 641 Application in ReASOn
Renewals/Continuations

IRB Submission

BHC Involved?

Yes

IRB: Proceed with IRB review

IRB: Communicate with BHC FRC

No

IRB: Proceed with IRB review

IRB: Final review decision

IRB: Final review decision

Notify PI

Notify BHC FRC

- Copied on PI email notification
- Email BHC Continuation Letter to PI

- Forward IRB Continuation Application email, including attachments, to FRC

BHC FRC: Follow-up with PI/study team

- Save IRB Continuation Application email, including attachments, to study folder
Renewals/Continuations

- HHC approval period = one year
- Renew 60 days prior to HHC expiration date
- ReASOn
  - My Approved Protocols
  - Renew an Active Protocol
  - Click to Renew
  - Renewal History
    - Pick a Renewal Type
      - Local Renewal
      - Proceed to Renewal
        - IRB Continuation Application
        - IRB Continuation Approval Letter
      - Renew Protocol

- BHC FRC
  - Review submission
  - Approve for one year
Final Study Closures

IRB Submission

BHC Involved?

Yes

No

IRB: Proceed with IRB review

IRB: Proceed with IRB review

IRB: Final review decision

IRB: Final review decision

Notify PI

Notify BHC FRC

• Copied on PI email notification
• Closes study in ReASON

• Forward IRB Final Study Closure Application email, including attachments, to FRC

BHC FRC: Follow-up with PI/study team

• Save IRB Final Study Closure Application email, including attachments, to study folder

IRB: Communicate with BHC FRC

• Save IRB Final Study Closure Application email, including attachments, to study folder

Notify BHC FRC
Exempt Studies

- Continuation
  - Initial IRB Exempt Approval Letter
  - Annual Progress Report

- Closure
  - Email to Bellevue FRC
Credentialing/HR Clearance of Study Team

**Current Requirements:**
- One Bellevue-Credentialed Physician or Bellevue-Hired Individual

**Future Requirements:**
- Physicians
  - BHC-Credentialed via MSO
- Non-Physicians
  - HR Clearance
Questions & Answers
Research Administration Department

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