BELLEVUE RESEARCH ADMINISTRATION

Dear Investigators/Research Coordinators/Administrators:

APPLICATION FOR NEW STUDIES

The Bellevue Research Department will contact you when we are notified by NYU/BRANY IRBs/OCT/CTSI that you intend to undertake the study at Bellevue. Prior to initiating your study at Bellevue, you must obtain approval from the Bellevue Research Review Committee (BRRC) and the HHC Central Office Research Administration via the Research Approval System Online (ReASOn):

http://reason.nychhc.org/Home.htm

Principal Investigators without an active ReASOn account, please register first at http://reason.nychhc.org/Home.htm as follows:

- Select the tab entitled, “PI and Reviewers Only”
- Click on “PI’s Click Here” next to “First Time User”
- On the “ReASOn PI Confirmation Form,” select “I am Exclusively a PI – Continue Registration”
- Complete the “ReASOn PI Registration Form” and click “Submit”
- Upon receipt of a confirmation email and temporary password, go back to the URL above to sign in and change your password
- Sign in to ReASOn account with your email address and new password
- Complete a New Protocol Application (Form 641).
- If you have a Research Coordinator, you may wish to delegate her/him as a contact for the study on the system who will then have access to your study on ReASOn and may submit the application on behalf of the Investigator.

Upon receipt of the IRB approval, please attach the following documents after completing Form 641 in REASON.

1. IRB approval letter
2. Attach all documents listed on the IRB approval letter, as titled & dated. These may include Protocol, Protocol Summary, Drug/Device Brochures, Flyers/Ads, Informed Consents, Assents and any other documents listed on the IRB approval letter. If you need additional space to attach documents, insert these documents in folders, list the documents and attach the folders in empty slots.
3. OCT Billing Grid or Exempt letter (where applicable)
4. Bellevue site Budget (if applicable) with all Bellevue costs listed; these costs must also be listed on Form 641 in REASON. [Please see attached Fee Schedules].
5. Grant Award/agreement/contract [with % of funded, unfunded efforts for all researchers]
6. Purchase Order # (obtained from NYU Dept Administrators) for billable services
7. CTSI approval (if applicable)
8. Upload Form - Appendix 24 – signed by Bellevue Director/Chief of Service

Once all required documents have been attached and reviewed, the FRC (Andy) will forward your study to the BRRC and HHC Central Office Research Administration for final review and approval. Please note that the approval process may take approximately 25 to 30 days. Your study may begin only upon receipt of an HHC Central Office Approval Letter, which will be sent to you via your ReASOn email address.

Appendix 24
By signing this form, we attest that we will comply with all HHC/BHC Research Policies/Procedures. We further assure that we would make all necessary provisions for safe/efficient conduct of the study at Bellevue, as noted below:

1. The concerned Clinic Administrators & Nurses (in-charge) have been informed about the study. They have also been provided with copies of the study documents [Protocol, Informed Consent, Instruments etc].
2. All supplies - drugs/devices/instruments/documents required for the study will be procured/stored/dispensed/administered according to the protocol and the Standard Operating Procedures outlined in the HHC/BHC Research Procedures/Guidelines.
3. All researchers on the study team [Investigators, Research Coordinators, Interns and Volunteers] will undergo Bellevue HIPAA training and cleared through the Bellevue Research Administration.
4. The Investigators, where appropriate, will enter/complete Research Patients’ information/procedures under “088” code in QuadraMed [Open and Close the Visits], “Initial Research Patient Note” and “Follow-up Research Patient Note” [see BHC Research procedures, p. 16-18].
5. The study will be conducted only with the approvals from the Bellevue Research Review Committee and the HHC Central Office Research Administration.

For any questions please contact:
Andy Veeraraj, Research Director, Bellevue Hospital Center
Room H-186, Phone: 212-562-4176; Mobile: 646-676-9691
Anand.veeraraj@bellevue.nychhc.org
The Bellevue Research Department is responsible primarily for reviewing and approving all research pertaining to human subjects conducted within the facility. The review and approval process is conducted by the Bellevue Research Review Committee (BRRC), which consists of representatives from Medicine, Pharmacy, Pathology, Radiology, Finance, the Medical Board, and Executive Administration.

The BRRC is not an IRB. It is a Committee that serves to protect the rights and wellbeing of BHC patients who voluntarily consent to participate in research studies and to assure individuals involved in research-related activities at BHC are in compliance with facility and corporate policies and procedures, as well as federal, state and city regulations.

Each member of the BRRC reviews the protocol, focusing on his or her respective area of expertise and approves it as appropriate on ReASON. Once approved by the entire BRRC, the protocol is sent to the HHC Research Review Committee for final review and approval.

It is important to contact the Bellevue Research Administration Department prior to submitting a protocol into ReASON for review by the BRRC to:

- **Assure that BHC can accommodate your study**
- **Ensure that the Study Personnel**
  - obtain Bellevue HIPPA credentials/clearance and BHC ID, and
  - Researchers on Affiliation Contract (on grant funded studies) capture/report their time/efforts spent on the study accurately and reimburse the compensation
- **Assure all BHC research-related fees have been budgeted**
  - Investigational Pharmacy Fees (see attached fee schedule) – page 6&7
  - Pathology and Radiology Fees (based on Medicare rates)
  - Medical Records – Chart Pull fees - page 8

**APPLICATION FOR CONTINUATION**

It is the responsibility of the PIs and the Research Coordinators to ensure that the studies are renewed on REASON before the date of expiration. The Bellevue Research Office will notify the Investigators about the due date.

Please logon to the REASON: [http://reason.nychhc.org](http://reason.nychhc.org), proceed to renew the study as LOCAL RENEWAL and attach the following documents.

1. [First template] Human Subject Enrollment Report [form attached]
2. [Second template] IRB Approval for Continuation, updated Informed Consents, CTSI approval (if applicable). Make a folder and upload.

Note:

1. Please keep in mind that the REASON system will accept Continuation submissions only within 60 days prior to the date of expiration.

2. **EXEMPT Studies: These must be renewed on REASON, [although the IRB will not review/approve Continuation of Exempt studies].**
   - (a) In the first template, attach a progress report for last year, (a brief paragraph) and Study Subject Enrollment Report
   - (b) in the second slot, the initial IRB approval letter.

3. If you have completed the study, please submit IRB Notice of Closure ASAP
4. If there are substantial changes in the protocol or grant/funding status, please contact Bellevue Research Staff.

5. Please settle pending invoices/bills for Research-Related Costs. Approval for Continuation is contingent upon payment of all dues.

AMENDMENTS/MODIFICATIONS/UPDATES/REPORTABLE EVENTS

1. Please upload IRB approved amendments/updates on REASON.

2. If the amendment is for change of Study Personnel, [only if they are assigned to conduct/coordinate research at Bellevue], they must be added as delegates for the study on REASON by the PI.

3. All researchers working at Bellevue are required to obtain Bellevue HIPAA training/certification and Hospital ID:
   a. If they intend to access Electronic Medical Records, and/or
   b. Enroll patients at Bellevue.

4. If any study personnel is removed from the study, please inform Bellevue MIS (contact: Araceli Martinez, Ph: 212-562-4836) to withdraw his/her access to Bellevue Secure Computer Systems and surrender Hospital IDs.

STUDY CLOSURE/DISCONTINUATION/WITHDRAWAL AT BELLEVUE

Notice of closure/discontinuation/withdrawal of studies at Bellevue and Bellevue/CTSI must be uploaded on REASON and forwarded to the BHC Research Director, accompanied by the following supporting documents. [Also upload them on REASON].

1. IRB approval for closure/discontinuation/withdrawal. Please upload the documents on REASON and email the Notice of Closure to the BHC Research Director.

2. For EXEMPT studies: Please note, IRB will not review/renew/close Exempt Studies. Please notify the Research Director with supporting documents.

3. Human Subject Enrollment Report for Bellevue (attached)
4. Findings & abstracts of published reports (if any).
5. Assurance of Finance/Billing clearance/payments (if any).

Any questions, please contact us. Thank you.

Andy Veeraraj, Research Director
Bellevue Research Administration
462 First Ave, H Bldg, Room H-186
New York, NY 10016
Tel: 212-562-4176; fax 212-562-4326
Anand.veeraraj@bellevue.nychhc.org

Bellevue Hospital Center
**HUMAN SUBJECT ENROLLMENT FORM**

Please complete/email or upload on REASON upon renewal/completion of your study.

PI Name: ___________________________     Department: ___________________________

Protocol Title:
___________________________________________________________________________

IRB #: ___________________________    Number of Subjects Approved by IRB: ________________

HHC/BHC Approval Period: _______________ - _______________

# of subjects recruited during approved period: _______ [only Bellevue patients]

Cumulative Total # of subjects recruited: _______ (Life of the project)

Highlight appropriate Tests/Procedures performed:

  - Interview/Questionnaire/Chart Review/Computer Run/Radiology/Specimens/Drug Trial/Device
  - Testing/Observational/Registry/Other(s): Please specify: ________________________________

Any findings/ publications from the study?  If yes, forward an abstract.

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<thead>
<tr>
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<th>MR #</th>
<th>DOB</th>
<th>Gender</th>
<th>Race</th>
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Accessing/obtaining Bellevue Secure Computer Systems (BSCS),
REASON system, Bellevue Hospital IDs (for Researchers),
HIPAA Training, Bellevue Email Account, Health Clearance etc
1. NYU Researchers must first be cleared/authorized by the IRB; the approval letter must be uploaded on REASON.

2. The Researchers complete/sign BSCS/EMR Access/Hospital ID Request Form signed by the Principal Investigator & complete the HIPAA sign-in sheet; forward the forms to the Bellevue Research Office [Andy Veeraraj: 212-562-4176; Room H-186].

3. Attend HIPAA training on scheduled date/time/place and obtain HIPAA Certificate.
   To register for the training, please fill-in the typeable Word document attached. [Do not print the spreadsheet, fill it out by hand and send it as a PDF]. If you wish to register individuals for more than one training, please send separate emails for each training (as opposed to sending one email with two separate spreadsheets).

4. Upload the HIPAA Certificate, the IRB (PSC) approvals and signed EMR access form (attached) on the REASON system.

5. The Research Department will forward completed/signed BSCS form to the EMR/IT Dept, request access to the EMR systems, and cc all concerned.

6. Researchers then complete EMR application(s) [PACS, Unity, QuadraMed forms]. Research Director will request Araceli Martinez to grant access to QuadraMed [212-562-4836] for the duration of the study. [Note: The NYU Study personnel will be granted access to BSCSs for the approved study period or as specified by the PI. It is the responsibility of the PI/RCs to inform the Bellevue Research Department and the EMR/IT about any changes of authorized study personnel/duration of the study].

7. All Researchers must show proof of health clearance granted/endorsed by their sponsoring IRBs/Schools.

8. Researchers complete Hospital ID request form, signed/endorsed by the Research Director. [Once cleared, obtain Hospital ID at the Hospital Police ID Office [Room AG-67, Ph: 212-562-3870]. IDs will be granted for one year, with the option to be renewed annually. IDs must be surrendered to the Research Office upon expiry or when the researcher leaves/complete the study project].

9. Researchers who need Bellevue email accounts should contact the IT Department [Room # H5W9 - Enterprise Service Desk, 212-562-3400 / 877-934-8442, EnterpriseServiceDesk@nychhc.org].

   Andy (Anand) Veeraraj, Research Director
   H Building, First Floor, Room H-186
   Ph: 212-562-4176; Anand.veeraraj@bellevue.nychhc.org
HOSPITAL ID, EMAIL REQUEST FORM

NYU/BRANY Researcher for whom Bellevue privileges and access to hospital research resources are requested:

Name: ________________________________      Job Title: ________________________________

Phone #: ______________________________      Email: ________________________________

STUDY INFORMATION (If applicable): [Copy and complete separate forms for additional study staff and/or protocols]

Principal Investigator/or Bellevue Co-PI: _______________________________________

Phone #: _______      Department: ____________________      Email: ______________________________

IRB #: _______;    Study Title: ______________________________________________________________

Period for which access is requested:  From_______________________ To ______________________________

BHC Secure Computer Systems to which access is requested: (Check all that apply)

EMR: QUADRAMED: ____   Radiology Systems: ____  Pathology Systems: ____  PACS:____  UNITY:____     Other: _______

Do you have IRB authorization: Yes________     No ____________ (If yes, upload the PSC amendment on REASON)

Do you have Health Clearance (Flu Shot etc) granted/endorsed by the sponsoring IRB/School/Hospital? Yes______
No_______

Do you have/need a Bellevue ID?    Yes_____    No______    (If yes, please contact the Bellevue Research Director for signature)

Did you complete the CITI Tutorial?  Yes______   No_________ (not required for most researchers)

Did you obtain Bellevue HIPAA training/certification?  Yes ______   No______  (If yes, upload the certificate on REASON)

Do you have/need a Bellevue email account?  Yes ______  No _______

If yes, enter Bellevue email: ___________________________

AUTHORIZATION SIGNATURES:

_______________________________________________ __________________
Research Staff’s Signature                    Date

_______________________________________ ______________
Principal Investigator’s Signature   Date

Anand Veeraraj, BHC Research Director                     Date                     .
## HIPAA Privacy and Security

**Stand-Up Training**

**Sign–In Sheet**

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<tr>
<th>Print Name (First, Last)</th>
<th>Department</th>
<th>Department Contact Person</th>
<th>Signature</th>
<th>Birthday</th>
<th>Job Grouping A, C, V, T, E</th>
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Investigational Pharmacy

Fee Schedule – Industry Sponsored

[Effective May 1, 2012]

<table>
<thead>
<tr>
<th>Service</th>
<th>Description</th>
<th>Fee/Total</th>
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<tbody>
<tr>
<td>Initiation Fee</td>
<td>• Order and/or receive study medications</td>
<td>$1,250</td>
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<tr>
<td></td>
<td>• Create and maintain accountability Records</td>
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<td></td>
<td>• Develop dispensing guidelines</td>
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<td></td>
<td>• Meet with Principal Investigator and/or Research Coordinator</td>
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<tr>
<td>Low-Intensity Dispensing/</td>
<td>• No Compounding</td>
<td>$65/Patient/dose*</td>
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<tr>
<td>Administrative Fee</td>
<td>• Simple dispensing of one or two non-sterile medications</td>
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<td></td>
<td>• Fee to double if more than two medications are dispensed</td>
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<tr>
<td>Moderate-Intensity</td>
<td>• Simple preparation of sterile products</td>
<td>$130/Patient/dose*</td>
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<tr>
<td>Dispensing/行政管理费</td>
<td>• Fee to double if more than two medications are dispensed</td>
<td></td>
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<tr>
<td>High-Intensity</td>
<td>• Preparation of bio-hazardous sterile products or pharmacist-performed compounding</td>
<td>$195/Patient/dose*</td>
</tr>
<tr>
<td>Dispensing/行政管理费</td>
<td>• Fee to double if more than two medications are dispensed</td>
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<tr>
<td></td>
<td>• Controlled Substances</td>
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<tr>
<td>Annual Maintenance Fee</td>
<td>• Process orders</td>
<td>$100/Patient</td>
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<td>• Maintain dispensing records</td>
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<td>• Monitor visits</td>
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<td>• Maintain records of returned drugs</td>
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<td></td>
<td>• Provide administrative support</td>
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<tr>
<td>Closure Fee</td>
<td>• Reconcile inventories</td>
<td>$500 (Per Protocol)</td>
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<td>• Return drugs</td>
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<td>• Close out protocol</td>
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<tr>
<td>Destruction Fee</td>
<td>• Destruction of drugs</td>
<td>Minimum of $50 + $1.00 additional for more than 50 items additional</td>
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<td>• (expired, returns)</td>
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<td>• If more than 50 items/vial/bottle</td>
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NOTE: A One-time Principle Investigator Self-Storage Fee of $250/ per protocol will be charged to those PI’s who select to store part of their study drug off-site after an initial inspection of the storage site by the investigational pharmacist that the site will meet State, and Federal and Study requirements for drug storage.

- Charge is for each dispensing of a prescription
### Investigational Pharmacy

**Fee Schedule – Non-Industry Sponsored**

[Effective May 1, 2012]

<table>
<thead>
<tr>
<th>Protocol #</th>
<th>PI:</th>
<th>Date:</th>
<th>Est Number of Patient:</th>
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<tbody>
<tr>
<td><strong>Service</strong></td>
<td><strong>Description</strong></td>
<td><strong>Fee</strong></td>
<td><strong>Total</strong></td>
</tr>
</tbody>
</table>
| **Initiation Fee** | • Order and/or receive study medications  
• Create and maintain accountability Records  
• Develop dispensing guidelines  
• Meet with Principal Investigator and/or Research Coordinator | $1,250 | |
| **Low-Intensity Dispensing/ Administrative Fee** | • No Compounding  
• Simple dispensing of one or two non-sterile medications  
• Fee to double if more than two medications are dispensed | $50/ Patient/dose* | |
| **Moderate-Intensity Dispensing/ Administrative Fee** | • Simple preparation of sterile products  
• Fee to double if more than two medications are dispensed | $100/ Patient/dose* | |
| **High-Intensity Dispensing/ Administrative Fee** | • Preparation of bio-hazardous sterile products or pharmacist-performed compounding  
• Fee to double if more than two medications are dispensed  
• Controlled Substances | $150/ Patient/dose* | |
| **Annual Maintenance Fee** | • Process orders  
• Maintain dispensing records  
• Monitor visits  
• Maintain records of returned drugs  
• Provide administrative support | $100/ Patient | |
| **Closure Fee** | • Reconcile inventories  
• Return drugs  
• Close out protocol | $500 (Per Protocol) | |
| **Destruction Fee** | • Destruction of drugs  
• (expired, returns)  
• If more than 50 items/vial/bottle | Minimum of $50 + $1.00 additional for more than 50 items additional | |

**Total**

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NOTE: A One-time Principle Investigator Self –Storage Fee of $ 250/ per protocol will be charged to those PI’s who elect to store part of their study drug off-site after an initial inspection of the storage site by the investigational pharmacist that the site will meet State, and Federal and Study requirements for drug storage.

*Charge is for each dispensing of a prescription*
# HIM/MEDICAL RECORDS DEPARTMENT

## FEE SCHEDULE

**Effective Date: January 26, 2012**

<table>
<thead>
<tr>
<th>SERVICE</th>
<th>DESCRIPTION</th>
<th>FEE</th>
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| Chart Pull | • Patient look-up in computer  
|          | • Chart retrieval                | $15/chart |
|          | • Chart sign-out and sign-in     |       |
|          | • Chart re-file                  |       |

Some helpful contact information on Bellevue Research Department Associates
Investigational Pharmacy:
Lance Goodman, 212-562-3605; lance.goodman@bellevue.nychhc.org
Lily Yuan, 212-562-3605; lily.yuan@bellevue.nychhc.org

HIPAA Compliance/Certification/Training Schedule:
Chad Borden, 212.562.6614; Fax: 212.562.2769; Chad.Borden@bellevue.nychhc.org
Christopher.Fussell@beelevue.nychhc.org; 212-562-4752

Pathology:
Patience Mancho, 212-562-3411; patience.mancho@bellevue.nychhc.org
Neil Peckman (backup), 212-562-7859; neil.peckman@bellevue.nychhc.org

Radiology: Vernonica Bugenis, 212-562-3325; veronica.bugenis@bellevue.nychhc.org
Louis Colon (backup), 212-562-2170; Louis.colon@bellevue.nychhc.org

Medical Records:
Jacqueline Marshall, Director
Ph: 212-562-7992; Fax: 212-562-4126; Jacqueline.marshall@bellevue.nychhc.org

Electronic Medical Records/QuadraMed:
Yudelka.pena@bellevue.nychhc.org, 212-562-4836
[EMR access: H-5W43; Unity access: H-5W47]

Human Resource Department: To obtain Hospital ID: Phone: 212-562-6283
Shamelle Watkins, 212-562-6432 Shamelle.Watkins@bellevue.nychhc.org

Purchase Order #:
Vito Amitrano, Asst Director, Purchasing, 212-562-2888; Vito.amitrano@bellevue.nychhc.org

CTSI/Bellevue: Yau-Mei Rosa Hsieh; ph: 212-263-7492; fax: 212-263-8501; Rosa.Hsieh@nyumc.org

NYU IRB: Elan Czeisler, 646.754.4624, IRB-info@nyumc.org
Mohit Sakhrani, 646-754-4642, irb-expedited@nyumc.org

Bellevue Patients Accounts/Research Billing/CPT Codes/Costs
Orrin White, 212-562-3203, orrin.white@bellevue.nychhc.org
Silvia Chetronie, 212-562-2390 silvia.chetronie@bellevue.nychhc.org

NYU Office of Clinical Trials:
Patricia Corby, DDS, MS, Patricia.Corby@nyumc.org
Sunita Latchman, 646-754-4590, sunita.latchman@nyumc.org

NYU Accounts Payable/Invoice/Check Payments:
Angela Rivas, Financial Coordinator, NYU Cancer Institute; 215 Lexington Ave 15th Fl, New York 10016
Tel: 212 263-3765 / Fax: 212 263-0715 email: Angela.Rivas@nyumc.org

HHC Central Office, Research Administration & help with IT needs:
Christina Pili, 646-458-2743, Christina.Pili@nychhc.org
HIPAA Alert: The “Need-To-Know” Rule

HHC has established policies and procedures to safeguard protected health information (‘‘PHI’’) by limiting access to only those workforce members who require it, and only to specific PHI that they need to carry out their assigned job functions.

If you have access to PHI, you may only use and disclose PHI to fulfill a function of your job. You cannot use your access privileges to obtain information “out of curiosity” for yourself or anyone else, or to obtain information as a favor for a friend or family member. This includes entering into the medical record of a patient whose treatment you are not involved in.

Even in cases where your access to PHI is appropriate, it is your responsibility to ensure that any further disclosure of PHI by you is made only to those who also have a need to know and is restricted to only the minimum necessary.

If you suspect a privacy or security breach you should report it to your supervisor and the Facility Privacy Officer, Christopher Roberson at (212) 562-4316.
FIGHT THE FLU
GET VACCINATED

• Facility personnel can get free flu vaccinations in these locations:

Vaccinations For Staff

• 12th Floor Employee Cafeteria “H” Building
  Monday - Friday, 6:00 AM - 10:00 PM.

• All nursing stations, Floors 6-17, 24 hours a day, 7 days a week.

For those with egg allergies, there is a vaccine available that contains No Eggs.

• Patient and community flu vaccinations are available at these times and locations:

Vaccinations For Patients Without Appointments

• Bellevue “D” Building, Ground Floor Rotunda.
  Monday - Friday, 9:00 AM - 5:00 PM.

HHC personnel must get vaccinated against the flu or wear a surgical or procedure mask for the duration of the flu season.
“088” Research Clinic Code & Research Patient Note in QuadraMed

For every patient enrolled in research studies at Bellevue, please use “088” Clinic Code. All patients’ visits must be **opened** and **closed** under this Clinic Code. This would help our Billing Staff/Coders to track research patients/procedures and prepare/forward encounter tickets/bills/invoices to the respective study PIs/Sponsors/Administrators.

Please be informed that two new research notes entitled, "Initial Research Patient Note" and "Follow-up Research Patient Note" (see first attachment) have been created in the Bellevue electronic medical record system, **QuadraMed**, and located under the "Research" tab (see second attachment).

They currently are available to **Physicians, Nurses, Psychologists, and Social Workers** for all visit types (outpatient, inpatient, and emergency); however, they may be made available to other members of the research team as appropriate upon request.

**It is required** that you complete the **Initial Research Patient Note** upon enrolling a Bellevue patient in research involving a **drug, device or greater-than-minimal-risk procedure, or as clinically indicated**. (Note that a Bellevue patient is a patient with a Bellevue medical record number, independent of where he receives his medical care.) The completion of this note will **alert (in red under the "Items for Review" tab)** other clinicians involved in the patient's care that this is a research patient (see third attachment).

Upon completion of the Initial Research Patient Note, the **Follow-up Research Patient Note** is to be completed **as clinically indicated** upon follow-up research visits.

We appreciate your cooperation and ask that you inform other investigators within your departments of this new requirement. We would also welcome your feedback regarding the content of the notes so that they can be improved to better meet your documentation needs.

Please let me know if you have questions or are unable to view or locate the research notes or “088” Clinic Code. This will allow us to follow up with IT to grant you proper access.

Thank you.
Items for Review Tab

Research Patient Alert (Inpatient View):

Research Patient Alert (Outpatient view):
Research Tab

Research Notes under Research Tab

Initial and Follow-up Research Patient Notes will reside in Chart Review under Field #4 Research Patient

Field #4 Research Patient

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2-18-2015