BELLEVUE HOSPITAL CENTER
ADMINISTRATIVE POLICY AND PROCEDURE

MANUAL CODE: R-21

SUBJECT: REVIEW, APPROVAL, AND COST RECOVERY FOR RESEARCH ACTIVITIES

DATE EFFECTIVE: 2/2/01

DATE REVISED: 8/5/05, 5/2/12

DATE REVIEWED:

SUPERCEDES: NONE

I. PURPOSE

The purpose of this policy is to assure that those involved with human subject research activities at Bellevue Hospital Center (BHC) are knowledgeable of applicable federal, state and city regulations, New York City Health and Hospitals Corporation’s (HHC) research-related policies, BHC-specific research policies, the implementation of these policies, and the responsibilities to meet the requirements of obtaining approval to conduct research at BHC. This Policy and Procedure establishes the mechanism for administrative review and approval of all research activity conducted at BHC, both affiliate-sponsored and non-affiliate sponsored, and includes a mechanism for the recovery of related research expenses.

II. SCOPE

This policy is intended to ensure that adequate review and approval has been given to each protocol. It is intended to inform all those doing research at BHC, including, but not limited to, faculty staff of the Affiliate, NYU SoM, its affiliates [the Department of Veteran’s Affairs New York Harbor Healthcare (VA Hospital) the Hospital for Joint Diseases Orthopedic Institute (HJD), NYU College of Dentistry and Nursing, Nathan Kline Institute, BRANY], and BHC, as well as any employee or agent of the Affiliate or BHC, that the approval process includes a multi-level review and approval by the IRB, BRRC, and HHC RRC, Faculty staff, employees, or agents may not activate human subject research protocols until they have received written notification of all required approvals and have obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. Also, it is intended to affirm the requirement that all persons conducting research at BHC comply with all facility and HHC policies and procedures for every research protocol.

III. DEFINITIONS

Agent refers to an individual that acts or has the authority to act on behalf of the institution.
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Assent [as defined by 45 CFR 46 §46.402 (b) and 21 CFR 50 §50.3 (n)] means a child’s affirmation agreement to participate in research. Mere failure to object should not, absent affirmation agreement, be construed as assent.

Bellevue patients are patients with a BHC medical record number, independent of where they receive their medical care.

Bellevue Research Review Committee (BRRC) is responsible for reviewing and approving all research pertaining to human subjects conducted within the facility. It is not an IRB. It is a clinical and administrative committee of the Medical Board with representatives from Medicine, Pharmacy, Pharmacy & Therapeutics Committee, Pathology, Radiology, Ambulatory Care, Clinical Services, Finance, the Medical Board, and Executive Administration (see Attachment 1).

Biomedical Research Alliance of New York (BRANY) refers to a joint venture with New York University School of Medicine (NYU SoM) and four other leading academic medical centers to expand industry-sponsored clinical trials. NYU SoM faculty whose protocols are reviewed by the BRANY IRB and who intend to carry out the study wholly or in part at BHC are required to follow the BHC policy and procedures for obtaining BHC and HHC approvals of the study.

Children [as defined by 45 CFR 46 §46.402 (a) and 21 CFR 50 §50.3 (o)] are persons who have not attained the legal age of consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Clinical investigation [as defined by 21 CFR 50 §50.3 (c) and 21 CFR 56 §56.102 (c)] means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Covered Entity [as defined by the DHHS NIH Publication, “Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule”] refers to a health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form in connection with a transaction for which HHS has adopted a standard.

DHHS [as defined by 45 CFR 46 §46.303 (b)] means the Department of Health and Human Services.

Emergency use [as defined by 21 CFR 56 §56.102 (d)] means the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.
Guardian [as defined by 45 CFR 46 §46.402 (e) and 21 CFR 50 §50.3 (s)] means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

Health & Hospitals Association Research Review Committee (HHC RRC) is responsible for reviewing and approving all research pertaining to human subjects conducted within the corporation. The Committee is comprised of an Executive Director, Chair, and Finance reviewer.

Health Information [as defined by the DHHS NIH Publication, “Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule”] is any information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Human subject [as defined by 45 CFR 46 §46.102 (f)] means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

Human subject [as defined by 21 CFR 50 §50.3 (g) and 21 CFR 56 §56.102 (e)] means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject by be either a healthy individual or a patient.

Individually Identifiable Health Information [as defined by the DHHS NIH Publication, “Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule”] is information that is a subset of health information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Institutional Review Board (IRB) [as defined by 21 CFR 56 §56.102 (g)] means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.

Interaction [as defined by 45 CFR 46, Subpart A, §46.102] includes communication or interpersonal contact between investigator and subject.
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**Intervention** [as defined by 45 CFR 46, Subpart A, §46.102 (f) (2)] includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject of the subject's environment that are performed for research purposes.

**Investigator** [as defined by 21 CFR 50 §50.3 (d) and 21 CFR 56 §56.102 (h)] means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. For the purpose of this Policy, investigator refers to the principal investigator and/or study team members.

**IRB** [as defined by 45 CFR 46 §46.102 (g)] means an institutional review board established in accordance with and for the purposes expressed in this policy.

**IRB approval** [as defined by 45 CFR 46 §46.102 (h) and 21 CFR 56 §56.102 (m)] means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional or Federal requirements.

**Minimal risk** [as defined by 45 CFR 46 §46.102 (i) and 21 CFR 50 §50.3 (k) and 21 CFR 56 §56.102 (i)] means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**NYU-HHC Clinical and Translational Science Institute’s Clinical Research Center (CRC)** provides resources for investigators to conduct research protocols and study patients as outpatients or inpatients at all of the CTSI sites. The CRC has trained research nurses with technical expertise, including monitoring, critical assessment and teaching of patients. It also has Research Coordinators who can support studies with tasks such as preparation and submission of regulatory documents, screening and recruitment, acquisition of consent, and more. The resources of the CRC are available to the faculty, staff, and students of the NYU Langone Medical Center, BHC and other HHC collaborating sites. All research projects require approval by the IRB, the CTSI Scientific Review Committee (SRC), the CTSI Executive Committee (EC), the BRRC, and HHC RRC.

**Office of Clinical Trials (OCT)** [as defined by the NYU SoM IRB P&P for Human Subjects’ Research Protection] provides administrative services related to the testing, in the clinical research setting, of new pharmaceutical and medical devices. These include industry-sponsored and investigator-initiated studies. OCT helps prepare and develop budgets, negotiate contracts, and engage in business development. The OCT provides financial oversight and support in the administration of the NYU Medical Center's research billing compliance program.

**Parent** [as defined by 45 CFR 46 §46.402 (d) and 21 CFR 50 §50.3 (p)] means a child’s biological or adoptive parent.
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Permission as defined by 45 CFR 46 §46.402 (c) and 21 CFR 50 §50.3 (r)] means the agreement of parent(s) or guardian to the participation of their child or ward in research.

Prisoner as defined by 45 CFR 46 §46.303 (c)] means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Private information as defined by 45 CFR 46 §46.102 (f) (2)] includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Protected Health Information (PHI) as defined by the DHHS NIH Publication, “Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule”] is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium.

Protocol Review and Monitoring Committee (PRMC) as defined by the NYU SoM IRB P&P for Human Subjects’ Research Protection] provides the mechanism for assessing the scientific merit of new oncology trials and the authority to close trials that are not meeting accrual. All new clinical protocols, after being approved by Disease Management Groups and assigned priority scores, are submitted to the PRMC. The PRMC coordinates the submissions for the Biostatistical Group as well as coordinating the Peer Review of protocols for approvals before submission to the IRB.

Research as defined by DHHS regulation 45 CFR 46 §46.102 (d)] 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.

Research Application System Online (ReASON) refers to HHC’s current online research approval system.

Research-related costs are costs to BHC attributable to a research activity that would not have been incurred in routine clinical care in the absence of the relevant research protocol.
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Secretary [as defined by 45 CFR 46 §46.303 (a)] means the Secretary of Health and Human Services and any other officer or employee or the Department of Health and Human Services to whom authority has been delegated.

Test article [as defined by 21 CFR 56, Subpart A, §56.102 (l)] included any drug, biological product or medical device for human use, human food additive, color additive, electronic product, food, or infant formula.

Ward [as defined by 21 CFR 50 §50.3 (q)] means a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable federal, state, and local law.

IV. POLICY

BHC encourages clinical investigation and research as an essential part of fulfilling its mission of providing the highest quality of care to the patients and communities it serves. Investigators are encouraged to undertake research to improve patient care and to increase the responsiveness of BHC’s services to the needs of its population. BHC also endorses research that seeks new biomedical knowledge leading to the control of disease and enhanced well-being. Any research involving BHC patients, services, resources, or staff may not begin without the written approval of the designated IRB, BRRC and IIHC RRC. BHC shall maintain a research review process that protects the rights and interests of the patients, facility, and HHC in the research project. Such a review process shall recognize the Affiliate review process, including its Assurance Agreement with the Federal Government in compliance with Code of Federal Regulations 45 CFR 46 and other regulations regarding the protection of the rights and welfare of human subjects. BHC’s approval of research projects shall not be withheld or delayed without just cause.

Investigators who wish to conduct research at BHC are obligated to abide by all applicable federal and state regulations, as well as BHC and HHC policies and procedures. Investigators who do not comply with all noted regulations, policies, and procedures are subject to suspension or loss of research privileges at BHC and to the immediate termination of any protocol(s) in question.

Federal/State Regulations

All research shall be conducted in accordance with federal and state regulations, including but not limited to, the Department of Health and Human Services (DHHS) Code of Federal Regulations (CFR) 45 CFR 46 (also known as “The Common Rule”) entitled, “Protection of Human Subjects,” the Food and Drug Administration (FDA) regulations 21 CFR 50 entitled, “Protection of Human Subjects” and 21 CFR 56 entitled, “Institutional Review Boards,” the New York State Public Health Law Article 24-A entitled, “Protection of Human Subjects,” and with any and all other such federal or state regulations that specifically address human subject research.
Ethical Guidelines

While reviewing research projects, the BRRC is guided by ethical principles established by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, “Ethical Principles and Guidelines for the Protection of Human Subjects of Research” (often referred to as “The Belmont Report”). The three basic Principles are Respect for Persons (Voluntary Participation and Informed Consent), Beneficence (The Risk-Benefit Ratio), and Justice (The Fair Selection of Research Subjects).

Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

[DHHS NIH Publication, “Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule”]

The Department of Health and Human Services (HHS) issued the Privacy Rule in December 2000 to carry out HIPAA’s mandate that HHS establish federal standards for safeguarding the privacy of individually identifiable health information. HHS amended the Privacy Rule on August 14, 2002. Most covered entities were required to comply with the Privacy Rule by April 14, 2003.

The HIPAA Privacy Rule regulates the way certain covered entities under the Rule handle the individually identifiable health information known as protected health information (PHI). The Privacy Rule establishes the conditions under which covered entities can use or disclose PHI for many purposes, including for research.

The Privacy Rule does not apply to research; it applies to covered entities. BHC is a covered entity and requires researchers who are working with PHI to comply with the Rule. All BHC research subjects have a right to expect that their privacy shall be protected and communications and records pertaining to their care shall be treated as confidential.

The Rule allows:

(a) Covered entities to use and disclose PHI for research if authorized to do so by the subject in accordance with the Privacy Rule;

(b) In certain circumstances, entities to use and disclose PHI without authorization for certain types of research activities. For example, PHI can be used or disclosed for research if a covered entity obtains documentation that an IRB has waived the requirement for authorization or allowed an alteration;

(c) A covered entity to enter into a data use agreement for sharing a limited data set; and

(d) Separate provisions for how PHI can be used or disclosed for activities preparatory to research and for research on decedents’ information.

There are circumstances in which health information maintained by a covered entity is not protected by the Privacy Rule. PHI excludes health information that is de-identified according to

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specific standards. Health information that is de-identified can be used and disclosed by a covered entity, including a researcher who is a covered entity, without authorization or any other permission specified in the Privacy Rule.

In addition to establishing conditions for the use and disclosure of PHI, the Privacy Rule establishes certain rights of individuals with respect to their health information. The Rule:

(a) Requires covered entities to provide individuals with written notice of the entity’s privacy practices and the individual’s privacy rights;

(b) Permits individuals to gain access to, request amendment of, request restrictions on, and request confidential communication of certain records related to their health care;

(c) Permits individuals the right to request and receive a written account from a covered entity of when and why their PHI has been disclosed without their authorization, except under limited circumstances; and

(d) Permits individuals the right to complain to the covered entity and to the Secretary of Health and Human Services if they believe a violation of the Privacy Rule has occurred.

Commencement and Termination of Research

Investigators may not commence their projects until they have received written approval from HHC, except as provided in the instance of an emergency approval. Subject participation in a research protocol at BHC may not extend beyond the HHC or IRB approval period, whichever is shorter. Subjects must be removed from participation in protocols that are no longer authorized in a manner that provides for the safety and well-being of the patient.

Emergency Approval of Research

Emergency approval of an IRB approved research project may be granted on a patient-specific basis in the following circumstance:

(1) The patient’s condition must be serious;
(2) It must be treated without delay; and
(3) No other acceptable form of therapy is available.

An emergency approval for a thirty (30) day period may be granted to the investigator by the Executive Director (or Delegate), Chairperson of the BRRC, and Medical Board President for that patient only. The circumstances of the emergency approval must be reported as soon as possible to the Chairperson of the HHC RRC who shall review it within 72 hours of receipt. This approval does not relieve the investigator of the responsibility of submitting HHC form 641. If such documentation is not received within seven (7) days of the emergency approval, the emergency approval may be withdrawn.
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Investigational Pharmacy

In accordance with the BHC Pharmacy Department’s Policy and Procedures Manual Index #78.21, before any investigational drug study protocol may be instituted at BHC, the investigator must obtain written approval from the BRRRC, which includes approval from the Chair of the Pharmacy & Therapeutics Committee, and the HHC RRC.

The investigator must furnish the BHC Pharmacy with:

(a) The final version of the approved protocol, consent form, copies of any letters of approvals that are not already on file in the Pharmacy, any amendments/modifications made to the protocol, and the completed pharmacy screening form;

(b) All medications and/or supplies that are to be distributed to inpatients or outpatients of BHC;

(c) A copy of the coding of any blinded study or provision of a telephone number or equivalent means for learning the nature of the medication being administered on a 24-hour basis, in order to permit the proper care of the patient in the event of an emergency; and

(d) The investigator must notify Pharmacy upon any changes with the investigational study including, but not limited to, drug recall, discontinuation of study, and any amendments or modifications.

Emergency Approval for an Investigational Drug or Device

Emergency approval of an investigational drug or device shall be granted and conducted in accordance with the BHC Pharmacy Department’s Policy and Procedures Manual Index #78.21, which states:

(a) All of the following must be completed prior to the emergency administration of any investigational drug:

1. Consult with the Chairperson of the Committee on Pharmacy & Therapeutic regarding the emergent need for the agent, obtain approval, and complete the required Committee forms;
2. Contact the IRB to obtain a faxed copy of the emergency approval form. Complete all forms and obtain approval from the IRB;
3. Contact the BRRC to arrange HHC approvals;
4. Contact the BHC Investigational Drug Service, BHC ext. 2940, to arrange procurement, distribution, and administration of the investigational drug; and
5. After obtaining the necessary approvals and obtaining appropriate informed consent, the drug may be administered or device used.

(2) Administer the emergency investigational agent according to the proposed protocol.
Informed Consent (45 CFR 46 and 21 CFR 50)

General Requirements (§46.116 and §50.20)

No investigator may involve a human being as a subject in research covered unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The investigator shall maintain all information given to subjects, along with the consent form, in the medical record or research file (The Joint Commission 2012 Rights and Responsibilities Standard RI.01.03.05). The research file shall be accessible upon request to BHC Administration and retained by the investigator for a minimum of five (5) years after the completion of the research.

The informed consent form must be stamped by the IRB to certify compliance with all federal regulations and to indicate:
   (1) It is the final, IRB-authorized version of the consent form; and
   (2) The duration of the IRB approval period.

(a) Basic Elements of Informed Consent. In seeking informed consent, the following information shall be provided to each subject:
   (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
   (2) A description of any reasonably foreseeable risks or discomforts to the subject;
   (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
   (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
   (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
   (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
   (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
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(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional Elements of Informed Consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
(3) Any additional costs to the subject that may result from participation in the research;
(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
(6) The approximate number of subjects involved in the study.

(c) Waiver or Alteration of Informed Consent. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
   (i) Public benefit or service programs;
   (ii) Procedures for obtaining benefits or services under those programs;
   (iii) Possible changes in or alternatives to those programs or procedures; or
   (iv) Possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practically be carried out without the waiver or alteration.

(d) Waiver or Alteration of Informed Consent. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) The research could not practically be carried out without the waiver or alteration; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
(e) The informed consent requirements are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

Documentation of Informed Consent (§ 46.117 and §50.27)

(a) Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) The consent form may be either of the following:
   (1) A written consent document that embodies the elements of informed consent. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
   (2) A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used:
      (i) There shall be a witness to the oral presentation;
      (ii) The IRB shall approve a written summary of what is to be said to and signed by the subject or the representative;
      (iii) Only the short form itself is to be signed by the subject or the representative;
      (iv) The witness shall sign both the short form and a copy of the summary;
      (v) The person actually obtaining consent shall sign a copy of the summary; and
      (vi) A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
   (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
   (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
Vulnerable Populations

Research Involving Pregnant Women and Human Fetuses (45 CFR 46, Subpart B, §46.204)

Pregnant women or fetuses may be involved in research at BHC if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the provisions for informed consent;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the provisions for informed consent, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children who are pregnant, assent and permission are obtained in accord with the provisions for permission and assent;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.
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Research Involving Neonates (45 CFR 46, Subpart B, §46.205)

(a) Neonates of uncertain viability and nonviable neonates may be involved in research at BHC if all of the following conditions are met:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;
2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate;
3. Individuals engaged in the research will have no part in determining the viability of a neonate; and
4. The requirements of Neonates of Uncertain Viability or Nonviability Neonates have been met as applicable.

(b) Neonates of Uncertain Viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research at BHC unless the following additional conditions have been met:

1. The IRB determines that:
   - The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective; or
   - The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
2. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

(c) Nonviable Neonates. After delivery, a nonviable neonate may not be involved in research at BHC unless all of the following additional conditions are met:

1. Vital functions of the neonate will not be artificially maintained;
2. The research will not terminate the heartbeat or respiration of the neonate;
3. There will be no added risk to the neonate resulting from the research;
4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
5. The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part (Protection of Human Research Subjects), except that the waiver and alteration provisions of §46.116 (c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.
(d) Viable Neonates. A neonate, after delivery, that has been determined to be viable may be included in research at BHC only to the extent permitted by and in accord with the requirements of the IRB Review Process and Research Involving Children.

Research Involving Prisoners (45 CFR 46, Subpart C)

Research may involve prisoners as subjects at BHC if one of the following conditions has been met (§46.306):

(a) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(b) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(c) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or

(d) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

Research Involving Children (45 CFR 46, Subpart D and 21 CFR 50, Subpart D)

Children may be involved as subjects in research at BHC if:

(a) For research not involving greater than minimal risk (§46.404 and §50.51), adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408 and §50.55.

(b) For research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (§46.405 and §50.52):
   (1) The risk is justified by the anticipated benefit to the subjects;
   (2) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
   (3) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408 and §50.55.

(c) For research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition (§46.406 and §50.53):
   (1) The risk represents a minor increase over minimal risk;
BELLEVUE HOSPITAL CENTER
ADMINISTRATIVE POLICY AND PROCEDURE

(2) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
(3) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
(4) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408 and §50.55.

(d) For research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (§46.407 and §50.54):

(1) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
(2) The Secretary of Health and Human Services for federally-funded research in this category or the Commissioner of Food and Drugs for FDA-regulated research in this category determines either:

(i) That the research in fact satisfies the conditions of the previous categories, as applicable, or
(ii) That the following conditions are met:

(a) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(b) The research will be conducted in accordance with sound ethical principles; and

(c) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408 and §50.55.

(e) Adequate provisions are made for soliciting the assent of the children when the children are capable of providing assent.

(f) Adequate provisions are made for soliciting the permission of each child’s parents or guardian. Where parental permission is to be obtained the IRB may find that the permission of one parent is sufficient for research to be conducted.

Wards (45 CFR 46, Subpart D, §46.409)

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research at BHC if it has been determined that the research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual
acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child’s participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

**Completion of Research Notes in Medical Record**

Investigators are required to complete the “Initial Research Patient Note” (see Attachment 2) in the BHC electronic medical record for BHC patients who are subjects of research involving a drug, device or procedure (therapeutic trial) or as clinically indicated. (Note that BHC patients are patients with a BHC medical record number, independent of where they receive their 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.

Upon completion of the “Initial Research Patient Note,” the “Follow-up Research Patient Note” (see Attachment 3) is to be completed as clinically indicated upon follow-up research visits.

**Admission or Extension of Hospitalization for Research Purposes**

Except for admission to specified and approved research services, patients may be admitted to inpatient or outpatient units of BHC solely for research purposes only if the protocol has been specifically approved for such admission or extension of stay. Unless waived by the Chief Financial Officer (CFO) (or Delegate), any such admission or extension of hospitalization for research purposes must be fully reimbursed to BHC. Assurance of such reimbursement must be provided, in writing, in advance of admission or extension, except in the instance of emergency procedures.

**Research-Related Costs**

All research-related fees, including, but not limited to, Investigational Pharmacy fees, ancillary fees, and chart-pull fees, shall be obtained through the BHC Research Administration Department and budgeted by the investigator. The CFO (or Delegate), as a member of the BRRC, must approve the BHC-specific budget and billing grid prior to commencement of the study at BHC. The investigator shall not commit BHC resources in any research project without the written approval of CFO (or Delegate).

Payment by the Affiliate for costs incurred for research activities encompassed by the NYU-HHC CTSI located at BHC shall continue to be the subject of separate agreement between the Parties involved. In the event that any research activities not encompassed by the CTSI are consolidated in a separate center similar to the CTSI, the Parties will negotiate a separate agreement, comparable to the governing CTSI activities, for payment to BHC for associated costs.
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Quality Assurance

The BHC Research Administration Department will conduct quality assurance (QA) activities to assure investigators are in compliance with our policies as they relate to the protection of human subjects. Such QA activities include, but are not limited to, a review of the research file and/or BHC medical record to monitor documentation of informed consent and research note(s) as required in this policy (see Attachment 4).

Audits

Audits of any aspect of the research process may be conducted by officials of federal, state and city regulatory agencies and authorized institutional officials of BHC or HHC. Investigators are expected to fully cooperate with such audits.

Routine Monitoring of Research Files by the Sponsor

Authorized representatives of a sponsoring agency (the Sponsor) shall be granted access to the research files as necessary for appropriate monitoring. Access to other PHI, including the BHC medical record, is prohibited.

Publications

Research reports and articles, whether published or not, must acknowledge cooperation from BHC and HHC. A copy of such report or article should be forwarded to BHC’s Executive Director prior to publication.

V. PROCEDURES

New Protocol Submission Process

An investigator (or designee) must submit a new protocol to the IRB, OCT, BRRC, and HHC RRC for review and approval prior to initiating their study at BHC as follows: (see Attachment 5)

(a) The investigator (or designee) emails their New Protocol Submission Application to the IRB.

(b) The IRB checks to see if BHC is selected as a site.
   (a) If it is not, then they will proceed with the IRB review and approval process.
   (b) If BHC is selected as a site, then they will proceed with the IRB review and approval process, but also will forward the email, along with the attachments, to the BHC Facility Research Coordinator (FRC).

(c) The FRC will email to the investigator the BHC New Protocol Submission Letter (see Attachment 6), which instructs them to complete the 641 Application in ReASON at this time, as opposed to waiting for IRB approval. It asks that they complete the 641; however, not to attach any documents.
BELLEVUE HOSPITAL CENTER
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(d) Once the IRB approves the study, they will email to the investigator an approval letter, on which the BHC FRC will be copied.

(e) This will be the FRC’s queue to retrieve the IRB-approved documents from the IRB server and attach them, along with other required documents to the 641 in ReASON. Required documents include:
   (1) IRB Approval Letter and all IRB-approved documents listed on the approval letter, including, but not limited to:
      (i) Protocol
      (ii) Informed Consent Form
      (iii) CTSI SRC Approval Letter (if applicable)
      (iv) PRMC Approval Letter (if applicable)
   (2) IRB Application signed by BHC Director of Service
   (3) BHC-Specific Budget
   (4) NYU OCT Billing Grid

(f) The same occurs with the OCT. If BHC is identified as a site, they will forward the BHC-specific budget and billing grid to the FRC to attach in ReASON.

New Protocol Approval Process

The new protocol review and approval process involves a number of separate reviews:

(a) BRRC review
   (1) FRC review
   (2) Committee review
   (3) Executive review

(b) HHC RRC review

FRC Review

The FRC will conduct a preliminary review of the 641 Form, the New Protocol Submission Application and attachments, and the BHC-specific budget and billing grid while the study is still under review at the IRB.

The FRC will:

(a) Assure the Personnel Summary section of the 641 Form is accurately completed,

(b) Confirm the Credentials/Human Resources clearance of study team,

(c) Assure the BHC Director of Service signed the IRB application,

(d) Assure BHC can accommodate study,
(e) Assure all BHC research-related fees, including, but not limited to, Investigational Pharmacy fees (see Attachment 7), ancillary and visit fees, and chart-pull fees (see Attachment 8), have been budgeted, and

(f) Obtain a purchase order (PO) number.

Once the FRC review is complete, they forward the study to the Committee Level for review and approval.

Committee Review

The Committee is not an IRB. It is an administrative committee of BHC physicians, pharmacists, and administrators who review protocols to assure:

1. The research is medically sound;
2. BHC can accommodate the workload; and
3. BHC’s research fees have been budgeted.

This review can take up to seven calendar days. Once the Committee approves the study, the FRC moves it along to the Executive Level for review.

Executive Level

The Executive review is conducted by the Medical Board President and the Executive Director and usually takes only a day or two. They conduct more of a medical/ethical review, assuring the proposed research is in line with BHC’s mission and vision.

Once the Executive Level approves the study, the FRC moves it along to the HHC RRC for final review and approval.

HHC RRC

The HHC RRC conducts a final review of the study. Upon approval, a HHC Central Office Approval Letter is emailed to the investigator’s ReASOn email address and the BHC FRC. The FRC then forwards the approval email to the OCT, as well as the CTSI and the Research Coordinator, if applicable.

A study may begin at BHC only upon receipt of a HHC Central Office Approval Letter.

Amendment Submission and Approval Process

BHC reviews study-related amendments to ensure all applicable guidelines have been followed.

Amendments follow the same path as a New Protocol Submission (see Attachment 9).

(a) When the investigator (or designee) submits their amendment application to the IRB, the IRB will look to see if BHC is site.

1. If it is not, then they will proceed with the IRB review and approval process.
BELLEVUE HOSPITAL CENTER
ADMINISTRATIVE POLICY AND PROCEDURE

(2) If BHC is selected as a site, then they will proceed with the IRB review and approval process, but also will forward the email, along with the attachments, to the BHC FRC.

(b) The FRC will save the IRB Amendment Application email, including attachments, to the electronic study folder on our shared drive.

(c) Once the IRB approves the study, they will email to the investigator an approval letter, on which the BHC FRC will be copied.

(d) The FRC will review the IRB Amendment Approval Letter and email the investigator instructing them to attach the amendment in ReASON as follows:
   (1) Log on to ReASON and go to My Approved Protocol;
   (2) Under My Approved Protocols, select View/Copy/Amend an Active Protocol;
   (3) Then click on Click to Amend;
   (4) Select Amend an Active Protocol;
   (5) Write a description of the amendment in the Notes section; and
   (6) Attach the Amendment and click on Submit

Note that ReASON does not allow the FRC to attach documents once the study is approved by HHC. Nor does ReASON allow the investigator or the FRC to edit the investigator information on the 641 Application. Therefore, when submitting an amendment for a change to the principal investigator, the FRC will make a note of this change to assure that the correct investigator receives ongoing study-related emails.

Renewal/Continuation Submission and Approval Process

BHC reviews Renewals/Continuations to ensure all applicable guidelines have been followed.

Renewals/Continuations follow the same path as that of Amendments and New Protocols (see Attachment 10).

(a) When an investigator (or designee) submits their continuation application to the IRB, the IRB will look to see if BHC is site.
   (1) If it is not, then they will proceed with the IRB review and approval process.
   (2) If BHC is selected as a site, then they will proceed with the IRB review and approval process, but also will forward the email, along with the attachments, to the BHC FRC.

(b) The FRC will save the IRB Continuation Application email, including attachments, to the electronic study folder on our shared drive.

(c) Once the IRB approves the study, they will email to the investigator an approval letter, on which the BHC FRC will be copied.

(d) The FRC will email to the investigator the BHC Continuation Letter, which instructs them to submit their protocol into ReASON for review and approval for continuation at BHC. Note that an investigator (or designee) can renew their protocol in ReASON no sooner than 60 days prior to...
the HHC expiration date. IRB approval for continuation must be obtained before the protocol is renewed with BHC. An investigator (or designee) would renew their protocol by:

1. Logging on to ReASON and selecting My Approved Protocols;
2. Then click on Renew an Active Protocol and Click to Renew;
3. Under Renewal History, click on Pick a Renewal Type and select Local Renewal; do not select Central Office Renewal;
4. Proceed to Renewal and attach both the IRB Continuation Application and IRB Continuation Approval Letter; and
5. Then click Renew Protocol.

(e) The FRC will review the submission and approve it for one year. They then will email via ReASON a Local Office Renewal Approval Letter to the investigator.

Final Study Closure Submission and Approval Process

The Final Study Closures process follows the same path as the other processes listed above (see Attachment 11).

(a) When an investigator (or designee) submits their Final Study Closure Application to the IRB, if BHC is a site, then they will forward it to the BHC FRC.

(b) The FRC will save the IRB Final Study Closure Application email and attachments to electronic study folder.

(c) Once the IRB approves the application, they will email the investigator the Final Study Closure Approval Letter and copy the BHC FRC.

(d) The FRC will then close the study in ReASON.

Exempt Studies

Once the IRB approves an exempt study, they do not require the investigator to submit a continuation or closure application.

However, BHC requires that the investigator submit their exempt study for continuation in ReASON at least sixty (60) days prior to the HHC expiration date. In order to do this, the investigator (or designee) must log on to ReASON and follow the steps stated above on how to renew/continue a study, being sure to select Local Renewal. Instead of attaching an IRB Continuation Application and IRB Continuation Approval Letter, attach the initial IRB Exempt Approval Letter and an annual progress report. The BHC FRC will review the renewal request and approve it for one year.

BHC also requires that an investigator closes an exempt study in ReASON by sending an email to the BHC FRC stating that the study is now closed. The FRC will go into ReASON and formally close the study.
Invoicing for BHC Research-Related Fees

On a quarterly basis, the BHC Research Administration Department, referencing the BHC-specific budget and billing grid, will invoice the investigator for BHC research-related fees. The invoice includes the PO number, description and dollar amount of the service, and information instructing the investigator to make the check payable to BHC and mail it to:
Bellevue Hospital Center
462 First Avenue
Finance/Controller’s Office, H1S11
New York, NY 10016

The Finance/Controller’s Office, upon receipt of the check, will notify the BHC Research Administration Department, who, in turn, will submit to the Controller a deposit memo indicating the related research services, study number, and name of investigator, as well as instructions for deposit.

Investigator Responsibilities

Investigators who conduct research at BHC must:

(a) Obtain approval from the BRRC and HHC RRC via ReASON prior to initiating their study at BHC;

(b) Obtain CTSI and/or PRMC approval as appropriate;
(c) Assure that research activity, including subject recruitment, will not commence until the date of HHC approval;

(d) Budget all BHC fees for research, including, but not limited to, Investigational Pharmacy fees, ancillary fees, and chart-pull fees;

(e) Provide a BHC-specific budget and billing grid, if applicable, that delineates all BHC research activities and costs from those that are standard of care;

(f) Present all investigational drugs to the BHC Pharmacy for appropriate handling and dispensing prior to being administered at BHC;

(g) Maintain all information given to subjects, along with the consent form, in the medical record or research file;

(h) Make the research file accessible upon request to BHC Administration;

(i) Retain the research file for a minimum of five (5) years after the completion of the research;

(j) Complete the “Initial Research Patient Note” in the BHC electronic medical record for BHC patients who are subjects of research involving a drug, device, or procedure (therapeutic trial) or
as clinically indicated. 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;

(k) Upon completion of the “Initial Research Patient Note,” complete the “Follow-up Research Patient Note” as clinically indicated upon follow-up research visits;

(l) Assure that all research, including recruitment and treatment, will conclude on the date of termination indicated by the IRB or HHC approval, whichever is shorter;

(m) Submit a Human Subject Enrollment Log upon request to the BHC Research Administration Department for quality assurance (QA) purposes;

(n) Report all protocol-related, unanticipated, adverse events to the IRB and BRRC; and

(o) Submit for study continuation via ReASOn up to sixty (60) days prior to, but no later than, the HHC expiration date of initial approval.
BELLEVUE HOSPITAL CENTER
ADMINISTRATIVE POLICY AND PROCEDURE

POLICY R-21: REVIEW, APPROVAL, AND COST RECOVERY FOR RESEARCH ACTIVITIES

Prepared by:

Patricia A. Gaeta
Director
Research Administration Department

Approved by:

Machelle Allen, MD
Interim Medical Director

Lynda D. Curtis
Senior Network Vice President/
Executive Director
<table>
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<td>Anand Veeraraj (FRC)</td>
<td>Preliminary</td>
<td>Administrative</td>
<td>Completeness and Accuracy of Application</td>
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<td>Completeness and Accuracy of Application; Finance</td>
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<td>Medical</td>
<td>Medical and Ethical</td>
<td><a href="mailto:Benard.dreyer@nyumc.org">Benard.dreyer@nyumc.org</a></td>
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<tr>
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<td>Mission and Vision</td>
<td><a href="mailto:Patricia.gaeta@bellevue.nychhc.org">Patricia.gaeta@bellevue.nychhc.org</a></td>
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BELLEVUE HOSPITAL CENTER
ADMINISTRATIVE POLICY AND PROCEDURE

Attachment 2: Initial Research Patient Note

![Initial Research Patient Note Form]

1) Protocol Name:

2) Drug(s) or Device(s):

3) Contraindications:

4) Start Date:

5) End Date:

6) Contact Person:

7) Contact Number:

8) Note:

Manual Code: R21
Attachment 3: Follow-Up Research Patient Note

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1) Drug Name:  
2) Dose:  
3) Route:  
4) Admin Date/Time:  
5) Note:  
6) Written By: Rosario Medina, RN
Date:

To: Principal Investigator

From: Research Administration Department

Subject: Research Chart Review for Quality Assurance Purposes

In an effort to satisfy our quality assurance requirements, the Bellevue Research Administration Department is requesting that you complete the attached Human Subject Enrollment Form and return it to us within ten business days. Upon receipt, we will utilize this information to conduct a review of the research files and/or Bellevue medical records to assure compliance with our policies as they relate to the protection of human subjects.

Please provide us with the medical record numbers and dates of birth for Bellevue subjects during the current Bellevue/HHC approval period.

Let us know if you have questions or require additional information. We appreciate your cooperation and look forward to continuing to work together to provide research opportunities to the Bellevue patients. Thank you.
HUMAN SUBJECT ENROLLMENT FORM

Please submit to the Bellevue Research Administration Department within ten business days of receipt.

Pl Name: __________________ Department: __________________ Phone Number: __________________

Protocol Title: ____________________________________________________________

IRB #: __________________ HHC/BHC Approval Period: __________ - __________

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BELLEVUE HOSPITAL CENTER
ADMINISTRATIVE POLICY AND PROCEDURE

Attachment 5: New Protocol Submission Process

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: Proceed with IRB review
OCT: Proceed with PRA

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

Manual Code: R21
The Bellevue Hospital Center Research Administration Department is in receipt of your New Protocol Submission to the IRB for the above-referenced study, which indicates Bellevue as a site.

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).

Please note that our protocol submission process has changed.

In an effort to decrease protocol review and approval time, we are asking that you sign in to ReASON, http://reason.nychhc.org/Home.htm, using your ReASON email address and password, and complete and submit a New Protocol Application (Form 641) at this time (as opposed to waiting to receive IRB approval). Complete the 641 Form, but do not attach any documents.*

*ReASON requires you to attach your Protocol and Consent before the 641 Form can be submitted to the FRC. In order to bypass the system, in the “Attach Docs” section of the 641 Form, check the “Research Protocol” and “Consent or Consent Waiver Application” boxes and indicate the Submission Method as “By Fax.” This will allow you to submit the Application (Form 641) without actually attaching any documents.

The study will remain at the Facility Research Coordinator (FRC) Level in ReASON until IRB approval is obtained. During this time, we will conduct a preliminary review of the 641 Form, as well as the Bellevue-specific budget and billing grid forwarded to us from the Office of Clinical Trials. This will allow us to contact you with questions or concerns while your study is still under review at the IRB.
BELLEVUE HOSPITAL CENTER
ADMINISTRATIVE POLICY AND PROCEDURE

Attachment 6, Continued: BHC New Protocol Submission Letter

Upon receipt of the IRB approval email, the FRC will attach the IRB Approval Letter and other required documents as needed to the 641 Form. Once all required documents have been attached, the FRC will forward your study to the BRRC and HHC Central Office Research Administration for final review and approval.

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.

For Principal Investigators without an active ReASON account, you first will have to register 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
- Complete the New Protocol Application (Form 641) as stated above.

If you have questions or require additional information, please contact us as follows:

- Patricia Gaeta, Director
  212-562-7059 or patricia.gaeta@bellevue.nychhc.org

- Andy Veeraraj, FRC
  212-562-4176 or anand.veeraraj@bellevue.nychhc.org

- Patrinia Wilson, FRC
  212-562-7075 or patrinia.wilson@bellevue.nychhc.org

- Departmental Email Address: BellevueResearch@Bellevue.nychhc.org

Thank you and we look forward to working with you.
**Fee Schedule – Industry Sponsored**

**Effective May 1, 2012**

<table>
<thead>
<tr>
<th>Protocol #:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Service</th>
<th>Description</th>
<th>Fee</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation Fee</td>
<td>Order and/or receive study medications</td>
<td>$1,250</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Create and maintain accountability Records</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Develop dispensing guidelines</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Meet with Principal Investigator and/or Research Coordinator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low-Intensity Dispensing/ Administrative Fee</td>
<td>No Compounding</td>
<td>$65/ Patient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Simple dispensing of one or two non-sterile medications</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fee to double if more than two medications are dispensed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate-Intensity Dispensing/ Administrative Fee</td>
<td>Simple preparation of sterile products</td>
<td>$130/ Patient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fee to double if more than two medications are dispensed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High-Intensity Dispensing/ Administrative Fee</td>
<td>Preparation of bio-hazardous sterile products or pharmacist-performed compounding</td>
<td>$195/ Patient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fee to double if more than two medications are dispensed</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Controlled Substances</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual Maintenance Fee</td>
<td>Process orders</td>
<td>$100/ Patient</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maintain dispensing records</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monitor visits</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maintain records of returned drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Provide administrative support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Closure Fee</td>
<td>Reconcile inventories</td>
<td>$500</td>
<td></td>
</tr>
</tbody>
</table>

Manual Code: R21
BELLEVUE HOSPITAL CENTER  
ADMINISTRATIVE POLICY AND PROCEDURE  

<table>
<thead>
<tr>
<th>Service</th>
<th>Description</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation Fee</td>
<td>Order and/or receive study medications</td>
<td>$1,250</td>
</tr>
<tr>
<td></td>
<td>Create and maintain accountability Records</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Develop dispensing guidelines</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Meet with Principal Investigator and/or Research Coordinator</td>
<td></td>
</tr>
<tr>
<td>Low-Intensity Dispensing/</td>
<td>No Compounding</td>
<td>$50/ Patient</td>
</tr>
<tr>
<td>Administrative Fee</td>
<td>Simple dispensing of one or two non-sterile medications</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fee to double if more than two medications are dispensed</td>
<td></td>
</tr>
<tr>
<td>Moderate- Intensity Dispensing/</td>
<td>Simple preparation of sterile products</td>
<td>$100/ Patient</td>
</tr>
<tr>
<td>Administrative Fee</td>
<td>Fee to double if more than two medications are dispensed</td>
<td></td>
</tr>
<tr>
<td>High- Intensity Dispensing/</td>
<td>Preparation of bio-hazardous sterile products or pharmacist-performed</td>
<td>$150/ Patient</td>
</tr>
<tr>
<td>Administrative Fee</td>
<td>compounding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fee to double if more than two medications are dispensed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Controlled Substances</td>
<td></td>
</tr>
<tr>
<td>Annual Maintenance Fee</td>
<td>Process orders</td>
<td>$100/ Patient</td>
</tr>
<tr>
<td></td>
<td>Maintain dispensing records</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monitor visits</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maintain records of returned drugs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Provide administrative support</td>
<td></td>
</tr>
<tr>
<td>Closure Fee</td>
<td>Reconcile inventories</td>
<td>$500 (Per Protocol)</td>
</tr>
<tr>
<td></td>
<td>Return drugs</td>
<td></td>
</tr>
</tbody>
</table>

Total:  

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.

Fee Schedule – Non-Industry Sponsored  

Effective May 1, 2012  

Protocol #:  
PI:  
Date:  
Estimated Number of Patients:

Manual Code: R21
<table>
<thead>
<tr>
<th>Destruction Fee</th>
<th>Close out protocol</th>
<th>Minimum of $50 + $1.00 additional for more than 50 items additional</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Destruction of drugs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(expired, returns)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If more than 50 items/vial/bottle</td>
<td></td>
</tr>
</tbody>
</table>

**Total**

**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.
HIM/MEDICAL RECORDS DEPARTMENT

FEE SCHEDULE

Effective Date: January 26, 2012

<table>
<thead>
<tr>
<th>SERVICE</th>
<th>DESCRIPTION</th>
<th>FEE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chart Pull</td>
<td>• Patient look-up in computer&lt;br&gt;• Chart retrieval&lt;br&gt;• Chart sign-out and sign-in&lt;br&gt;• Chart re-file</td>
<td>$15/chart</td>
</tr>
</tbody>
</table>
BELLEVUE HOSPITAL CENTER
ADMINISTRATIVE POLICY AND PROCEDURE

Attachment 9: Amendment Submission and Approval Process

Amendments/Updates

IRB Submission

BHC Involved?

Yes

No

IRB: Proceed with IRB review

IRB: Final review decision

IRB: Communicate with BHC FRC

BHC FRC: Follow-up with PI/study team

Notify PI

Notify BHC FRC

- Copied on PI email notification
- FRC reviews IRB Amendment Approval Letter and emails PI to attach amendment in ReASON (FRC unable to attach amendment)

- Forward IRB Amendment Application email, including attachments, to FRC
- Save IRB Amendment Application email, including attachments, to study folder
Renewals/Continuations

IRB Submission

BHC Involved?

Yes

No

IRB: Proceed with IRB review

IRB: Final review decision

Notify PI

Notify BHC FRC

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

IRB: Proceed with IRB review

IRB: Final review decision

BHC FRC: Follow-up with PI/study team

• Save IRB Continuation Application email, including attachments, to study folder

IRB: Communicate with BHC FRC

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

Manual Code: R21
Final Study Closures

IRB Submission

IRB: Proceed with IRB review

IRB: Final review decision

Notify PI

BHC Involved?

Yes

No

IRB: Proceed with IRB review

IRB: Final review decision

Notify BHC FRC

BHC FRC: Follow-up with PI/study team

- Copied on PI email notification
- Closes study in ReASON

IRB: Communicate with BHC FRC

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

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