Human Research Seminar Series:

What You Need to Know About Submitting Human Research Applications

Thursday, October 7, 2010

Presented by:
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Manager
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Science at the heart of medicine

Einstein Institutional Review Board (IRB)

Human Research Seminar Series
What You Need To Know About Submitting an Application for Human Research

Presented by:
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Overview

• Historical Background
• Oversight Responsibilities/Mechanism
• Basic Requirements (e.g. Education)
• Categories of Review
• How to Apply/Submit
• Additional Approvals
The Belmont Report

- In 1974 Congress passed the National Research Act which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- This Commission wrote the ethical principles and guidelines known as the **Belmont Report**, which was published in the Federal Register in 1979.
- The federal regulations for the protection of human subjects are based on these principles and guidelines.

The Belmont Report: Basic Ethical Principles

- The Belmont Report contains the ethical principles upon which the federal regulations for protection of human subjects are based:
  - Respect for Persons
  - Beneficence
  - Justice
- The full report is available online at:  
  [http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm)
The Belmont Report: Respect for Persons

- Incorporates two ethical convictions:
  > Individuals should be treated as autonomous agents, and
  > Persons with diminished autonomy (e.g. prisoners, children, some mentally disabled, individuals with dementia or other cognitive disorders) are entitled to increased protections.
- This principle is captured in the informed consent process.

The Belmont Report: Beneficence

- Two general rules have been formulated as complementary expressions of beneficent actions in this sense:
  > Do not harm and
  > Maximize possible benefits and minimize possible harms.
- The obligations of beneficence affect both individuals and society.
- The principle of beneficence is captured in the assessment of risks and benefits.
The Belmont Report: Justice

- The selection of subjects should be from all classes of the population.
- Justice demands that research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent benefits of the research.
- The principle of justice is captured in the selection of research subjects.
- A scientific justification is required when excluding men, women, pregnant women, minors, and non-English speaking participants.

What is Research?

- The following definition of research is found in the Federal Regulations 45 CFR 46.102(e):
  Research means a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- The October 21, 2003 report from Chronicle of Higher Education states:
  The OHRP issued the decision in a letter to representatives of the American Historical Association and the Oral History Association that oral-history interviews generally are not designed to contribute to generalizable knowledge and, therefore, do not require IRB review.
What is a Human Subject?

- Einstein IRB review is required when the research involves human subjects. The regulations define a **human subject** as a living individual about whom an investigator obtains:
  - either data through intervention or interaction with the individual, or
  - through identifiable private information.
- This includes research using surveys, data analysis, school based research, human specimens, etc.
- Note: Institutional policy extends the definition to include decedent research.

What is a Human Specimen?

- Definition of human specimen:
  - A human specimen consists of any sample of hair, skin, cells, blood, tissue, organ, bodily fluid, excreted or secreted material or derivative substance obtained from a patient or volunteer, that may or may not contain living or desquamated cells.
What is an Institutional Review Board?

• An Institutional Review Board (IRB) is a body of members appointed by institutional officials to review human research and ensure that:
  > The rights and welfare of subjects involved in the research are adequately protected.
  > That any risks entailed by the research are outweighed by the potential benefits.

What is the IRB’s Authority?

• With regard to human subjects research, the IRB has the authority to:
  > Approve.
  > Require modifications.
  > Disapprove research activities, including proposed changes in previously approved research.
  > Stop previously approved research.
Einstein IRB Mandate

- The primary mandate of the Einstein IRB is to ensure:
  > That the rights and dignity of participants are protected.
  > That any risk entailed by the research is outweighed by the potential benefit.
  > That participants, researchers, the institution, and the reputation of science are protected from harm.

- The Einstein IRB must consider:
  > The risks to subjects.
  > The anticipated benefits to the subjects and others.
  > The importance of the knowledge that may reasonably result.
  > The informed consent process/document.

Einstein IRB Responsibilities (How We Accomplish Our Mandate)

- The Einstein IRB is responsible for the initial review, approval and on-going monitoring of all human research until its completion. This includes:
  > Initial research protocol/proposal
  > Amendments (changes to a protocol)
  > Adverse Events
  > Progress Reports: Re-review is required not more than one year from initial and continuing review. (Applies to non-Exempt research only.)
What’s This I Hear About a Merger of the Einstein and Montefiore IRBs?

• Until recently, Einstein and Montefiore each had their own IRB.
  > Einstein’s IRB was known as the Committee on Clinical Investigations.
  > Montefiore’s IRB was called the MMC IRB.
• Late last year Einstein and Montefiore signed an affiliation agreement to merge their research infrastructures.
• Going forward both will be known as the Einstein IRB
  > The CCI will be known as the East Campus IRB.
  > The MMC IRB will be known as the West Campus IRB.

What Does the Merger Mean to Me?

• At the moment, not much has changed.
• The most noticeable changes will occur after new IRB software is implemented – expected sometime in 2011.
  > Electronic signatures
  > Two IRBs available for review
  > Mac (and PC) compatibility
• Until then, the submission rules remain as follows:
  > IRB (East vs. West) is determined per the rules on the following slides.
  > East Campus IRB Submissions: Through PATS
  > West Campus IRB Submissions: MS-Word forms
Which IRB Should Review?

The East Campus IRB when:
- The PI is a YU employee.
- External support is through Einstein.
- The PI is a New York Medical Association (NYMA) or HHC employee
- The research is conducted at the North Bronx Healthcare Network (JMC/NCB).

The West Einstein IRB when:
- The PI is a Montefiore employee.
- External support is through Montefiore.
  > Exception: New NIH grants go through Einstein and review is conducted by the East Campus IRB.

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1. “Other” includes unfunded research, Non-Governmental Awards, and non-NIH Federal Agency Grants.
2. NEW: MMC PIs applying for new NIH grants apply through Einstein.
3. MMC PIs applying for Private Industry and non-NIH grants continue to do so through MMC, for now. This may change in the near future.
4. Research to be reviewed by East Campus IRB.
5. Research to be reviewed by West Campus IRB.
IRB Review Exceptions

• Exceptions require approval by:
  > The Einstein Executive Dean, Dr. Ed Burns (ed.burns@einstein.yu.edu)
  and
  > The Montefiore Director of Research and Sponsored Programs, Dr. Vic Hatcher (vhatcher@montefiore.org)

Single IRB Review

• Generally review by only one IRB is required even if both YU/Einstein and Montefiore personnel and/or facilities are used.
  > **Exception:** If the West Campus IRB is the designated review committee, and NBHN (JMC/NCHB) resources (personnel and/or facilities) are utilized, review by the East Campus IRB is also required.
    • The researcher submits all materials to the West Campus IRB, which forwards relevant materials to the East Campus IRB.
    • **Exception:** When review is performed by both committees, the PI is required to send Adverse Event Reports to both IRBs simultaneously.
The North Bronx Healthcare Network

- The North Bronx Healthcare Network (NBHN) is comprised of the Jacobi Medical Center (JMC) and the North Central Bronx Hospital (NCBH).
- Research utilizing NBHN resources (personnel and/or facilities) requires multiple reviews:
  > IRB review is conducted by the East Campus IRB.
  > Administrative review is conducted by NBHN Research Protocol Working Group (RPWG) and the Health and Hospitals Corporation (HHC).
    - No research may begin at NBHN without written HHC approval.
    - Contact: Howie Nadel, Director of Research, howard.nadel@nbhn.net

How Do You Obtain RPWG/HHC Approval?

- The East Campus IRB Administrative Office assists researchers in the process.
- The PI must submit a completed HHC 641 to the Einstein IRB office in duplicate. Both the PI’s and Chair/Chief’s signatures are required. The form is found at: http://www.einstein.yu.edu/uploadedfiles/CCI/forms/other/hhc-641.pdf
- YU/Einstein researchers are required to complete the NBHN Research Form for review by Barbara Levy prior to beginning discussions with the NBHN Research Office or NBHN collaborating departments. The form is found at: http://www.einstein.yu.edu/uploadedFiles/CCI/NBHN_Research_Form.doc
Who May Be Principal Investigator?

- Individuals having a faculty appointment to:
  - Einstein at the level of Instructor or higher
  - Einstein at the level of Principal Associate or higher
  - Other Yeshiva University schools
- Exceptions require approval by the Executive Dean, Dr. Ed Burns.

Required Education

- The Principal Investigator and Key Personnel are required to complete the web-based tutorial, Collaborative Institutional Training Initiative (CITI) Human Research Course.
  - After 5 years, researchers must complete the CITI refresher course.
  - The CITI requirement applies to all researchers affiliated with YU/Einstein, Montefiore, and NBHN (JMC/NCB).
  - Registration information for both courses is available at: http://www.einstein.yu.edu/cci/page.aspx?id=9746
  - Key Personnel is defined by the Einstein IRB as any person who meaningfully contributes in a substantive way to the scientific development or execution of the project, or the informed consent process.
Additional Education (Optional)

- Administrative seminars are held annually at Einstein. (It is anticipated that these may be offered at the West Campus in the Spring.) Topics include:
  - Grant Submission & Private Industry Sponsored Research: Guidelines and Requirements
  - Post-Approval Requirements: Progress Reports, Amendments, and Adverse Event Reporting
  - Adverse Event Reporting: Interactive Session
  - Informed Consent Process & HIPAA Authorization Requirements
  - Essential Documentation: What it is and How to be Prepared for a Site Review Visit
- The schedule and handouts can be found at: http://www.einstein.yu.edu/cci/page.aspx?ID=9712

Categories of Review and Submission Dates

<table>
<thead>
<tr>
<th>Category of Review</th>
<th>Einstein IRB Form</th>
<th>Submission Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempt</td>
<td>East: PATS Exempt Form West: MS-Word Form</td>
<td>Any time</td>
</tr>
<tr>
<td>Expedited</td>
<td>East: PATS Research Application West: MS-Word Research Application</td>
<td>Any time</td>
</tr>
<tr>
<td>Full</td>
<td></td>
<td>By required deadline*</td>
</tr>
</tbody>
</table>

*Deadline dates are found online:
West Campus IRB: http://www.montefiore.org/prof/research/IRB/irbforms/
Exempt Research

• Certain federally defined categories of research are Exempt from federal regulations. The Exempt Policy is found at: http://www.einstein.yu.edu/cci/page.aspx?ID=9780

• Review Procedure:
  > Exempt research requires verification by the Einstein IRB.
  > Researcher must submit to the Einstein IRB: Exempt Application and detailed protocol. A complete grant application is required, when applicable.
  > Einstein IRB will send the PI a written exemption verification letter and a grant approval letter, when applicable.
  > Per institutional policy, research utilizing Fetal Tissue is not eligible for Exemption. See the Fetal Tissue Research Policy http://www.einstein.yu.edu/cci/page.aspx?ID=9752

Exempt Research: Category 1

• Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
Exempt Research: Category 2

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  > information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and
  > any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- This exemption does not apply to research with children, except for:
  > Educational tests and
  > Observations of public behavior when the researchers do not participate in the activities being observed.

Exempt Research: Category 4

- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
  > In contrast to “Research Not Involving Human Subjects” and “Research in Which the Institution is ‘Not Engaged,’” this category allows the researcher to view identifiable private information during the de-identification process.
Research Not Involving Human Subjects

• Research that involves the study of data or specimens is not considered human subject research, as defined under 45CFR46.102(f), if:
  > the data or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals, and
  > the researchers cannot readily ascertain the identity of the individuals.
• This determination must be made by the Einstein IRB.

Research in Which the Institution is “Not Engaged”

• Consultants or collaborators obtain de-identified or coded private information or human biological specimens from an institution engaged in human subjects research that retains a link to individually identifying information.
• If the data/specimens are coded, an agreement prohibiting the release of the key to the code to the consultants or collaborators is required.
• This determination must be made by the Einstein IRB.
### Expedited Review

- Research must involve no more than **minimal risk** and involve only procedures listed in one or more of the federally defined categories.
  - The Expedited Policy, including the list of categories, is found at: [http://www.einstein.yu.edu/cci/page.aspx?ID=9782](http://www.einstein.yu.edu/cci/page.aspx?ID=9782)
  - **Minimal risk** 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.

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### Expedited Review

- Protocol application and subsequent transactions are reviewed by Einstein IRB Chairman (or designee) and reported to the rest of the committee at the next meeting.
- The reviewer may ask for additional information, request revisions to the protocol or the informed consent document, or request that the study be reviewed by the Full Committee.
- The final determination regarding the appropriateness of Expedited Review rests with the Einstein IRB.
Expedited Review: Category 2

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   > from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   > from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Expedited Review: Category 3

3. Prospective collection of biological specimens for research purposes by noninvasive means.
   > Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
Expedited Review: Category 4

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.

- Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Expedited Review: Categories 5-6

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes
Expedited Review: Category 7

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

> Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects.

Deception

• There are two categories of deception in research:
  > Intentionally misleading subjects, or
  > Withholding information about the nature of the research

• Deception
  > Interferes with the participant’s ability to give informed consent
  > Is permitted under federal regulations when it is justified (e.g. a study in which full disclosure would bias the study results)
  > Requires full committee review
Full Committee Review

- Research that doesn’t qualify for Exempt or Expedited review requires Full Committee review, including:
  > Research presenting more than minimal risk to participants
  > Research involving deception
  > Research involving certain populations requiring special protection:
    - Patients in significant pain and women in labor. See http://www.einstein.yu.edu/cci/page.aspx?ID=9942
    - Patients who have an altered mental status (e.g. patients under the influence of sedatives or narcotics, etc.).
    - Patients who may not be capable of giving consent (e.g. mental retardation, dementia, acute psychiatric disorders).

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Full Committee Review

- Protocols must be received by the Einstein IRB Administrative Office by the deadline. The schedule is found at: http://www.einstein.yu.edu/cci/page.aspx?ID=9670
- 35 single-sided copies of the PATS Research Application, detailed protocol and required documents are required.
  > Required protocol elements are found at: http://www.einstein.yu.edu/cci/page.aspx?ID=9774
- The Principal Investigator or designated Key Personnel is requested to attend the Einstein IRB meeting.
Full Committee Review

- All IRB members are provided copies of all full review protocols for review and discussion at the meeting.
- A Primary and Secondary Reviewer are assigned to conduct an in-depth review.
  > The reviewers frequently consult with the PI to resolve issues before the IRB meeting.
- At the meeting, the protocol is presented by the reviewers, followed by discussion by the committee, including additional questions to the PI.
- The PI and any IRB members with a conflict of interest leave the room.
- There is further discussion by committee members.
- The committee votes to approve, defer, or disapprove the protocol.

East Campus IRB Numbers

- All protocols are assigned a unique identifying number.
- This number consists of two parts:
  > The first part indicates the year the protocol application was started (in PATS),
  > The second part is a sequential number assigned as protocols are started (e.g. 001, 002, 003).
- Use the IRB number and PI name when contacting the East Campus IRB with inquiries.
Protocol Application & Tracking System (PATS)

- Online system for the electronic submission and tracking of protocols from any PC-compatible computer worldwide.
- Error checking and consent form development/dating are electronically maintained by the system, and are available to researchers at any time.
- The system requires Internet Explorer version 6.0 (or higher). Software requirements are not capable with Macintosh machines.
  > NOTE: Text cannot be pasted from MS-Word into the PATS ICD editor – copying through Notepad is required.
- Training is required. The schedule and additional information are found at: [http://www.einstein.yu.edu/cc/page.aspx?ID=9650](http://www.einstein.yu.edu/cc/page.aspx?ID=9650)

PATS Application Types

- **Chart Review/Database Study Application**: Study Examples: Medical Records review, Hospital Databases, Public Database, Data Analysis, etc.
- **Behavioral/Observational Study Application**: Study Examples: School based research, or research using Focus Groups or questionnaires, etc.
- **Specimen Study Application**: No direct research intervention by PI. Study Examples: research on leftover specimens, identifiable previously collected specimens, prospective specimens, etc.
- **Clinical Research Study Application**: Direct research intervention by PI. Study Examples: blood drawing, MRIs, radioisotopes, drugs, or devices, etc.
## Required Protocol Elements

Each new research application must be accompanied by a detailed protocol which contains the following elements:

- Background/Significance
- Methods/Design
- Consent Process
- Data Management/Analysis
- Aims/Objectives
- Recruitment Process
- Steps Ensuring Confidentiality
- References


## Informed Consent Process

- Informed consent is a **process**, a dialogue, that takes place between the prospective subject and the investigator, before, during and sometimes after the study.
- Freely given informed consent must be obtained from every volunteer before any research procedures have begun.
- The consent process contains three components:
  - Information
  - Comprehension
  - Voluntariness
Informed Consent Process: Information

- Research volunteers are to be given sufficient information. These items include:
  - Purpose
  - Procedures
  - Risks
  - Benefits
  - Alternatives
- The Einstein IRB requires that consent documents conform to our templates available as follows:
  - East Campus: in PATS.
  - West Campus: on the MMC Intranet
    http://intranet/websitefiles/mmcintranet25168/body.cfm?id=2995

Informed Consent Process: Comprehension

- The manner and context in which information is conveyed is as important as the information.
- Information should be:
  - Organized.
  - In simple lay terms and at an 6th-8th grade level.
  - Provided slowly and clearly, permitting time for questions and answers.
Informed Consent Process: Voluntariness

- An agreement to participate in research constitutes a valid consent only if voluntarily given.
- Consent must be free of coercion and undue influence.
- Volunteers must be told that they are free to decline participation and to withdraw from the study at any time after it has begun.

Informed Consent: Research with Minors

- Under NY State law and federal regulations:
  - Parental permission is required to enroll minors (individuals under the age of 18) in research.
    - Exceptions are permitted, as stated in the Enrollment of Minor’s Policy, “Where notification of the parents may be potentially harmful to the adolescent, the Einstein IRB, in consultation with legal counsel, may waive parental consent.”
  - Assent of minors ages 7 to 17, capable of understanding, is also required.
Informed Consent: Research with Minors (cont’d)

• A simplified assent form is used for children aged 7-12.
• A combined Parental Permission and Young Adult Assent, similar to an adult’s consent form, is used for children aged 13 - 17. Both the minor and the parent sign the document.
• The Enrollment of Minor’s Policy is found at http://www.einstein.yu.edu/cci/page.aspx?id=9952

Informed Consent: Waiver/Alteration

• A waiver of informed consent is permitted under the regulations in certain circumstances, but requires Einstein IRB approval.
• The Informed Consent Waiver form are included in the Einstein IRB Research Applications and contains the waiver criteria defined under federal regulations and Einstein IRB policy.
• Under certain circumstances, e.g., school based research, the investigator may consider an alternate consent mechanism.
  > Example: Parents are informed of the study (by mail) and given an opportunity to inform the researcher that they do not want their child to participate (to “opt out”). No response constitutes authorization.
  > Written assent from the minor usually is required.
  > Not permitted by HHC, in NYC public schools, and may not be permitted in NJ schools.
Informed Consent: Waiver/Alteration Criteria

- All of the following criteria must be met in order to qualify for either a waiver or alteration of informed consent:
  - The research involves no more than minimal risk to the subjects;
  - The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - The research could not practicably be carried out without the waiver or alteration; and
  - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Informed Consent: Oral Consent

- A waiver of signed documentation (oral consent) is permitted under the regulations in certain circumstances, but requires Einstein IRB approval.
- The **Waiver of Signed Documentation** form is included in the Einstein IRB Research Applications and contains the waiver criteria defined under federal regulations and Einstein IRB policy.
- When oral consent is obtained, the research record should contain documentation of the consent process, including the date and time.
Informed Consent: Oral Consent Criteria

• Either of the following criteria must be met in order to qualify for a waiver of signed documentation:
  > 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; or
  > 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.

Is Consent Required for the Collection of Specimens?

• Prospective collection of specimens generally requires informed consent.
• Previously obtained specimens generally qualify for a consent waiver. Re-consent may be required for genetic research studies, especially for research posing possible risk to an individual through breach of confidentiality, or harm to a particular population, e.g., American Indian, Jewish, Hispanic, etc.
• The Einstein IRB makes the final determination when reviewing the protocol.
Consent Requirements: Genetic Research

- New York CLS 79-2(b) specifies the consent language required for:
  > protocols that include genetic testing and analysis and
  > consent to use specimens for future genetic research.
- Template consent language is available online at:
  > Genetic Research in the Current Study: [http://www.einstein.yu.edu/cci/Appendix_A.htm](http://www.einstein.yu.edu/cci/Appendix_A.htm)
  > Future Use of Specimens: [http://www.einstein.yu.edu/cci/Appendices_B-C.htm](http://www.einstein.yu.edu/cci/Appendices_B-C.htm)

Confidentiality: HIPAA

- The Health Insurance Portability & Accountability Act (HIPAA) provides another layer of protection for protected health information (PHI).
- HIPAA Authorization is required from each research participant unless the study qualifies for a HIPAA Waiver or Exemption.
Conflict of Interest

- The Einstein IRB Conflict of Interest Policy is online at: http://www.einstein.yu.edu/cci/page.aspx?ID=9922
- Institutional policy requires that the PI and each of the Key Personnel on the protocol at either YU/Einstein, Montefiore, JMC or NCB, complete, sign and submit a Financial Conflict of Interest Form.
- COI Forms must be submitted when individuals join a study (either with a new Research Application or Amendment) and with each Progress Report.

FDA Approved Drugs Used for Clinical Care

- For clinical care, use of an FDA approved drug, off-label, does not require IRB approval.
- Hospital and department protocol apply.
Investigational New Drug (IND) Application

- Non-FDA approved drugs require an Investigational New Drug (IND) application to be filed with the FDA.
- FDA approved drugs used off-label require either an Investigational New Drug (IND) application to be filed with the FDA or an IND Exemption.
- For sponsor written protocols, the IND application is filed by the sponsor who provides the PI with the IND number. This number must be submitted to the Einstein IRB on the application.
- For PI written protocols, the PI is responsible for filing the IND Application with the FDA. A copy of the FDA IND application (and all subsequent FDA correspondence) must be submitted to the Einstein IRB. Information is available at: http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm

Drug Storage

- Drugs are generally required to be stored in the Pharmacy.
- A waiver to store the drug outside of the Pharmacy requires approval by the Einstein IRB and the Pharmacy Department.
  > The CRC Director’s signature is also required if the drug will be stored in the CRC.
- The Drug Storage Waiver form is included in the Einstein IRB Research Applications.
Device Studies

- Use of an investigational device generally requires full review. The Einstein IRB Research Applications contain the required Device Form.
- When applicable, an Investigational Device Exemption (IDE) application must be filed with the FDA.
  > For sponsored research involving devices, the sponsor files the IDE and provides the PI with the IDE number.

Administrative Approvals

- PI's Department Chair is responsible for the first level of review of research proposals.
- Key Personnel Department Chairs are required to sign.
- Only the Chair (or the Chair’s designee) may sign. The Chair is required to inform the Einstein IRB of a designee in writing.
- A study will not be reviewed by the Einstein IRB without the required administrative approvals. Guidance is found at: http://www.einstein.yu.edu/cci/page.aspx?ID=9778
Other Institutional Approvals

• Cancer Center Protocol Review & Monitoring Committee (PRMC) – Research involving cancer patients as the study population.
  > For information about the PRMC process and requirements, contact Lisa Escobar at 718-904-2730 or lescobar@montefiore.org.
• Magnetic Resonance Research Center – Research utilizing the MRRC facility.
  > MRRC approval is required for any research involving the MRRC facility, prior to initiation the MRRC component of the study. Please note that MRRC review may lead to modifications of the research protocol.

Other Institutional Approvals (Cont’d)

• Radiation Safety Committee (RSC) – Research utilizing radioisotopes or radiation (when the tests or procedures are beyond standard clinical care).
  > The Einstein IRB staff forwards the protocol to the RSC for approval.
• Clinical Research Center PRC (CRC PRC) – Research utilizing the CRC.
  > Review by the Einstein IRB and the PRC may be concurrent. However, approval by both committees is required in order for the protocol to be approved. Refer to the CRC Website at http://www.einstein.yu.edu/ictr or contact Margaret Armin at 718-430-3606.
Einstein IRB Approval Requirements

• Written Einstein IRB approval will be issued to the PI when the following requirements are met:
  > All protocol/consent revisions are approved by Einstein IRB.
  > Applicable Institutional Committee approvals are received.
  > For private industry sponsored research, a contract, including indemnification, is fully executed by all parties.

Collaborating IRB Approval

• Collaborating institution’s written IRB approval is required prior to initiating a collaboration with that site.
• Examples include the exchange of specimens or data, or when the local PI is administratively responsible for a multi-center study.
• Einstein IRB review and approval can go forward with the proviso that research may not begin at the collaborating site until the collaborating institution’s IRB approval is received by the Einstein IRB.
Protocol Approval Letter

- The approval letter references:
  - Title of Protocol
  - Approval period
  - Consent documents/mechanism
  - HIPAA
  - Stipulations: Such as, other required collaborating institutional IRB approvals, translations of consent, HHC approval, etc.

Protocol Approval/Expiration Dates

- Federal regulations require that ongoing research be re-reviewed by the Einstein IRB for a time period not to exceed one year. Studies not recertified in the required time period will be suspended and may require resubmission of the application materials to continue the research.
  - Note: The approval period for Full Committee protocols begins from the date of the meeting at which the protocol is reviewed, not the date of final approval.
- The Einstein IRB determines the re-review period at the time of the initial review, based on the degree of risk to subjects.
Informed Consent Documents Approval/Expiration Dates

- Informed Consent Documents (ICDs) are “stamped” on the first and last pages showing:
  - Approval Date (From)
  - Expiration Date (To)
- The most recently approved ICDs must be used when enrolling research participants.
  - For East Campus IRB protocols, current stamped consents are available in PATS.

ICD Stamp Samples

**APPROVED**

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**VALID (Manual)**

**Institutional Review Board**

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**INVALID (PATS - not yet approved)**

**APPROVED**

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**VALID (PATS)**

**Institutional Review Board**

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<td>12/17/2007</td>
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**INVALID (PATS - expired)**
ClinicalTrials.gov Registration Requirement

- Recent FDA regulations now require that the following trials be registered:
  > Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and
  > Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance.
- NIH encourages registration of ALL trials whether required under the law or not.
- Furthermore, in June 2007 ICMJE accepted WHO’s definition of clinical trials:
  > Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.
- Those who are uncertain whether their trial meets either definition should err on the side of registration. For guidance, see our website:
  http://www.einstein.yu.edu/cci/page.aspx?id=9652

Einstein IRB Contact Information

- East Campus IRB (CCI)
  > Einstein IRB
  Belfer Building, Room 1002
  1300 Morris Park Avenue
  Bronx, NY 10461
- Phone: 718-430-2237
- Fax: 718-430-8817
- Website: http://www.einstein.yu.edu/cci
  > Including: Policies and Procedures, Submission Guidelines, and Educational Materials

- West Campus IRB (MMC IRB)
  > 3308 Rochambeau Ave
  Bronx, NY 10467
  Tel: 718-798-0406
- Phone: 718-798-0406
- Fax: 718-798-5687
- Website: http://www.montefiore.org/prof/research/IRB/
COMMITTEE ON CLINICAL INVESTIGATIONS

EXEMPT CATEGORIES

Exempt Categories
Common Rule 45 CFR 46.101(b)

Review Procedure:

Verification of the exemption status of a research proposal is achieved through a review by the CCI Chairperson or by one or more experienced reviewers from among members of the CCI in accordance with the requirements set forth in 45 CFR 46.110. A completed Exemption form and protocol will be reviewed in accordance with CCI Guidelines. Written verification of exemption status will be issued to the Principal Investigator.

Research activities that are considered Exempt, are those in which the only involvement of human subjects will be in one or more of the following:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   i. research on regular and special education instructional strategies, or
   ii. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   i. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   ii. any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

   NOTE: Survey or interview procedures involving minors (0-17) are not exempt, as well as observations of public behavior except when the investigator(s) do not participate in the activities being observed.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under item #2 above, if:
   i. The human subjects are elected or public officials or candidates for public office; or
   ii. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Existing Data or Specimens:* Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
   *Left-over specimens must be completely de-identified or identified with a code that is not derived from individual personal information (e.g. name, medical record #, date of birth, etc.). Kindly explain in the protocol how specimens will be obtained and anonymity ensured.
NOTE: Ongoing Collection of Data or Specimens: The ongoing collection of data or specimens does not meet the definition of human subject research, as defined by 45 CFR 46.102(f), provided:

i. the data/specimens are not collected specifically for the currently proposed research project, and
ii. the data/specimens received by the investigator do not contain a code derived from individual personal information (e.g. name, medical record #, date of birth, etc.).

NOTE: Data/Specimen Analysis: The analysis of coded data/specimens by a local researcher in a multi-site study is not subject to the requirements of 45 CFR 46, provided:

i. the local PI's sole research activity in the proposed project is to analyze data/specimens, and
ii. the local PI and the holder of the key enter into an agreement prohibiting the release of the key to the local researcher(s) under any circumstances.

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are 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 service under those programs.

6. Taste and food quality evaluation and consumer acceptance studies,

i. if wholesome foods without additives are consumed, or
ii. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Revised: 12/27/00
Revised: 8/30/04
Revised: 1/5/05
Revised: 3/10/05
Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Start

Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? [45 CFR 46.102(d)]

YES

Activity is research. Does the research involve obtaining information about living* individuals? [45 CFR 46.102(f)]

*NOTE: Institutional policy extends this definition to include decedent research.

YES

Does the research involve intervention or interaction with the individuals? [45 CFR 46.102(f)(1-2)]

NO

Is the research not research involving human subjects, and 45 CFR part 46 does not apply. NOTE: CCI/IRB review is still required.

NO

Will the only involvement of human subjects be in research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens? (Existing means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)

YES

Research is exempt under 45 CFR 46.101(b)(4) from all 45 CFR part 46 requirements. NOTE: CCI/IRB review is still required.

NO

Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

YES

Is the institution engaged in the research? [45 CFR 46.103(a)]

YES

45 CFR 46 does not apply to the local research activities. NOTE: CCI/IRB review is still required.

NO

Is the institution engaged in the research?

BUT

NO

45 CFR 46 applies. NOTE: Full or Expedited review by the CCI/IRB is required.

Other Federal, State and local laws and/or regulations, and institutional policies may apply to the activity. [45 CFR 46.101(f)]

NO

Will the information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

NO

Are these sources publicly available?

YES

Research is exempt under 45 CFR 46.101(b)(4) from all 45 CFR part 46 requirements. NOTE: CCI/IRB review is still required.

NO

Is the information individually identifiable (i.e., the identity of the subjects is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)]

YES

Is the information private? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.) [45 CFR 46.102(f)(2)]

NO

NO

45 CFR 46 does not apply to the local research activities.

BUT

45 CFR 46 applies. NOTE: Full or Expedited review by the CCI/IRB is required.
COMMITTEE ON CLINICAL INVESTIGATIONS

MINIMAL-RISK PROCEDURES - EXPEDITED CATEGORIES

REVIEW PROCEDURE:

An Expedited Review procedure consists of a review by the CCI Chairperson or by one or more experienced reviewers from among members of the CCI in accordance with the requirements set forth in 45 CFR 46.110. Each study reviewed under the Expedited Regulations will be sent to a reviewer for an in-depth review of the protocol and consent forms, as applicable. If any reviewer has questions about the study design or merits of the study, it will be brought before the Full Committee for review. A study reviewed under the Expedited Review Procedure may not be disapproved. A research activity may be disapproved only after review in accordance with the non-expedited procedure (review by the Full Committee.)

CLASSES OF THE POPULATION REQUIRING SPECIAL PROTECTION

Research involving the following populations require FULL REVIEW:

MINORS - (Only category 1. See below.)

PATIENTS IN SIGNIFICANT PAIN

PATIENTS WHO HAVE AN ALTERED MENTAL STATUS
(e.g. Patients who are under the influence of sedatives or narcotics, etc.)

PATIENTS WHO MAY NOT BE CAPABLE OF GIVING INFORMED CONSENT
(e.g. mental retardation, dementia, acute psychiatric disorders)

WOMEN IN LABOR

COMMON RULE 45 CFR 46.110

Applicability

(A) Research activities that

(1) present no more than minimal risk to human subjects, and

(2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses
would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protection will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review. Categories eight (8) and nine (9) pertain to continuing studies only.

**COMMON RULE 45 CFR 46.110 Expedited Categories**

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b. Research on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

   Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).

   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Note: The Following applies to Continuing review of research only.

8. Continuing review of research previously approved by the convened IRB as follows:
   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b. where no subjects have been enrolled and no additional risks have been identified; or
   c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Expguide
Dated: November, 1998
October 4, 2000
December 13, 2000
Revised June 12, 2002
COMMITTEE ON CLINICAL INVESTIGATIONS

CCI MEETING DATES AND SUBMISSION DEADLINES

Below is the list of meeting dates. The meetings are generally held on Wednesdays, at 3:00 P.M. in the Board of Overseers Room, Ground Floor, Forchheimer Building. The September and December 2010 & June and October 2011 meetings will deviate (as noted below) due to scheduling conflicts.

The CCI requests that Investigators attend the meeting at which their protocol is being reviewed.

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West Campus IRB (MMC IRB) Meeting Dates and Deadlines

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Protocol Submission Checklist


☐ Write the protocol. See the following two links for guidance:
  - Protocol Element Checklist - To be used as a checklist guide in the review of your protocol, prior to submission to the Committee on Clinical Investigations. This document will assist the investigator in ensuring that all of the research protocol design criteria are met. http://www.einstein.yu.edu/cci/page.aspx?ID=9776

☐ Attend a PATS Training. See the schedule, registration, and more information at http://www.einstein.yu.edu/cci/page.aspx?ID=9650

☐ Determine review type. See the following links for guidance:

☐ Complete Application
  - Chart Review/Database Study Application: Study Examples: Medical Records review, Hospital Databases, Public Database, Data Analysis, etc.
  - Behavioral/Observational Study Application: Study Examples: School based research, or research using Focus Groups or questionnaires, etc.
  - Specimen Study Application: No direct research intervention by PI. Study Examples: research on leftover specimens, identifiable previously collected specimens, prospective specimens, etc.
  - Clinical Research Study Application: Direct research intervention by PI. Study Examples: blood drawing, MRI’s, radioisotopes, drugs, or devices, etc.

☐ Prepare recruitment tools/methods. These may include consent/assent forms, waivers of consent of written documentation of consent, Dear Parent/Participant letters, advertisements, etc.


☐ CCI Process
  - Audit
  - Review
    - Internet security verification
  - Approval

☐ Receive approval letter – research may begin.

☐ Ongoing Monitoring:
  - Amendments – Any changes to your protocol must be submitted to the CCI for review and approval.
  - Progress Reports – Annual updates regarding the status of the protocol are required for Full and Expedited Review protocols.
  - Research Records – The regulations require that research records must be maintained by the Investigator and stored for specific amounts of time.