Human Research Seminar Series

What Requires IRB Review?

Thursday, March 14, 2013

Presented by:
David Wallach, CIP
Director
TABLE OF CONTENTS

What Requires IRB Review? .................................................................................................................. 1

Minimal Risk Research

Exempt Categories ................................................................................................................................... 23

Expedited Categories ............................................................................................................................... 26

2013 Meeting Dates and Submission Deadlines ....................................................................................... 29

Full Review Protocol Submission Checklists .......................................................................................... 31
Einstein Institutional Review Board (IRB)

Human Research Seminar Series
What Requires IRB Review?

Presented by:
David Wallach, CIP, Director
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.
- FDA definition 312.3(b) and 812.3(h)
  > Clinical investigation means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.
  > Investigation means a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.

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.
- However, the prospective study of an approved drug (e.g. for an off-label use) does require IRB review and approval.
What is a Human Subject?

- Einstein IRB review is required when the research involves human subjects, which the regulations (45 CFR 46) define as a living individual about whom an investigator obtains:
  - data through intervention or interaction with the individual, or
  - identifiable private information.
- Note: Institutional policy extends the definition to include decedent research.
- FDA regulations specify that Subject means a human who participates in an investigation,
  - either as a recipient of the investigational new drug or as a control. A subject may be a healthy human or a patient with a disease. (21 CFR 312.3(b))
  - either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease. (21 CFR 812.3(p))

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.
- Einstein IRB Guidelines for the Collection and/or Study of Human Specimens are at:
  - http://einstein.yu.edu/docs/administration/institutional-review-board/policies/specimens.pdf
Is Consent Required for the Study of Human 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.

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
• This authority is granted by the FDA and the Office for Human Research Protections (OHRP) under the Code of Federal Regulations:
  > 45 CFR 46
  > 21 CFR 50 and 56

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 a few years ago, 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.
- In 2009, Einstein and Montefiore signed an affiliation agreement to merge their research infrastructures.
- Now both IRBs are known as the Einstein IRB
  > The CCI is now Einstein’s East Campus IRB.
  > The MMC IRB is now Einstein’s West Campus IRB.
What Does the Merger Mean to Me?

• Federal and foundation grants are processed through Einstein only.
• The most noticeable changes have started with the rolling out of our new software, iRIS. The system features:
  > Electronic signatures, paperless submission
  > Two IRBs available for review
  > Support for various browsers and computers (Mac and PC)
• iRIS is currently used for on Exempt and Expedited studies. For Full Review studies, the submission rules remain as follows:
  > Selection of IRB (East vs. West) is determined per the rules on the following slide.
  > East Campus IRB Submissions: Through PATS
  > West Campus IRB Submissions: MS-Word forms

Which IRB Should Review (Full Review)?

<table>
<thead>
<tr>
<th>PI Payroll</th>
<th>East Campus IRB</th>
<th>West Campus IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yeshiva University</td>
<td>All</td>
<td>---</td>
</tr>
<tr>
<td>Montefiore</td>
<td>Foundation/Federally Funded</td>
<td>Private Industry Funded or Unfunded</td>
</tr>
<tr>
<td>NYMA</td>
<td>All</td>
<td>---</td>
</tr>
</tbody>
</table>

• Exceptions require approval by:
  > The Einstein Executive Dean, Dr. Burns
  (ed.burns@einstein.yu.edu)
Who May Be Principal Investigator?

• Employees of YU/Einstein/Montefiore/NBHN 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.
• See Principal Investigator Requirements policy at: http://www.einstein.yu.edu/docs/administration/institutional-review-board/policies/pi-requirements.pdf

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>iRIS</td>
<td>Anytime</td>
</tr>
<tr>
<td>Expedited</td>
<td>iRIS</td>
<td>Anytime</td>
</tr>
<tr>
<td>Full</td>
<td>East: PATS Research Application</td>
<td>By required deadline*</td>
</tr>
<tr>
<td></td>
<td>West: MS-Word Research Application</td>
<td></td>
</tr>
</tbody>
</table>

*Deadlines and meeting dates are found online: http://einstein.yu.edu/administration/institutional-review-board/meeting-dates-deadlines.aspx
iRIS is Here!

How Can I Learn More About iRIS?

- General iRIS info including training opportunities: http://www.einstein.yu.edu/administration/institutional-review-board/education/iris.aspx
- iRIS FAQ: http://www.einstein.yu.edu/administration/institutional-review-board/irb.aspx?id=38577
- iRIS Handbooks: Available for download from the “Help” link within iRIS.
- iRIS: http://iris.einstein.yu.edu
Exempt Research

- Certain federally defined categories of research are Exempt from federal regulations. The Exempt Policy is found at: http://einstein.yu.edu/docs/administration/institutional-review-board/policies/exempt.pdf
- 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.
  > Per institutional policy, research utilizing Fetal Tissue is not eligible for Exemption. See the Fetal Tissue Research Policy http://einstein.yu.edu/docs/administration/institutional-review-board/policies/fetal-tissue.pdf

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.
  > **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.
  > The Expedited Policy, including the list of categories and exceptions, is found at: http://einstein.yu.edu/docs/administration/institutional-review-board/policies/expedited.pdf

Expedited Review

• Protocol application and subsequent transactions are reviewed by Einstein IRB Chairman (or designee) and reported to the rest of the IRB 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 Board.
• 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, non-pregnant 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 gum base 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, electoretinography, 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 5-7

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).

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.
Exceptions from Expedited Review: Classes of the Population Requiring Special Protection

- Research involving the following populations require Full board review:
  - 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

Exceptions from Expedited Review: Classes of Studies Requiring Full Board Review

- Studies in which the primary risk is the result of a randomization process that inhibits the therapeutic choices of subject and treating physician, even if the alternatives interventions each might be considered 'standard-of-care'.
Exceptions from Expedited Review: 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 board review

Full Board Review

- Applies to all research that doesn’t qualify for Exempt or Expedited review.
- Protocols must be received by the Einstein IRB Administrative Office by the deadline.
- 6 copies of the Application, detailed protocol and required documents are required. Submission Checklist is available at:
  - West: http://einstein.yu.edu/docs/administration/institutional-review-board/forms/full-checklist-w.doc
  - East: http://einstein.yu.edu/docs/administration/institutional-review-board/forms/full-checklist-e.doc
- The Principal Investigator or designated Key Personnel is requested to attend the Einstein IRB meeting.
How Does Full Board Review Work?

- The protocol is assigned to two members of the IRB for detailed review.
- The reviewers frequently consult with the PI to resolve issues before the IRB meeting.
- The IRB requests that the PI or designee attend the IRB meeting.
- The protocol is presented by the reviewers, followed by discussion by the IRB, including any questions for the PI.
- The PI and any IRB members who have a conflict of interest leave the room.
- There is further discussion by IRB members.
- The IRB votes to approve (full or provisional), defer, or disapprove the protocol.
- The outcome and any changes required to gain approval are communicated to the researcher following the meeting.

PATS Application Types

- **Exempt Application**: See the definition of Exempt Research.
- **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**: Direct research intervention by PI. Study Examples: Research on leftover specimens, identifiable previously collected (e.g., banked, prospective specimens, etc.
- **Clinical Research Study Application**: Direct research intervention by PI. Study Examples: blood drawing, MRIs, radioisotopes, drugs, or devices, etc.
Application Types

- **Exempt Application**: See the definition of Exempt Research.
- **Expedited Application (Chart Reviews only)**
- **Expedited Application** (see below for additional Addenda & Checklists)
- **Full Review Application** (see below for additional Addenda & Checklists)
  > Biohazard/Gene Transfer COI Disclosure
  > Drug/Device Drug Storage Waiver
  > Expedited Review Human Specimens
  > IND Exemption Request Investigational Device
  > Ionizing Radiation/Isotopes Ionizing Radiation Exposure Form
  > Nursing OCT New Study Activation
  > Patient Information Confidentiality Agreement
  > Placebo

Protocol Approval Letter

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

- Federal regulations limit IRB approval to a time period of one year or less. 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 Board 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.
  > Similarly, current stamped consents are available in iRIS for studies processed in iRIS.
Is IRB Review Required? (Is it Research?)

- Clinical Care
  - Typically data not collected/analyzed beyond patient care.

- Quality Assurance
  - Quality assurance (QA) measures compliance against certain necessary standards.

- Quality Improvement
  - Quality improvement is a proactive approach to improve processes and systems.

---

QA vs. QI

<table>
<thead>
<tr>
<th>Motivation</th>
<th>Quality Assurance</th>
<th>Quality Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meas</td>
<td>Measurement</td>
<td>Prevention</td>
</tr>
<tr>
<td>Attitude</td>
<td>Inspection</td>
<td>Prevention</td>
</tr>
<tr>
<td>Focus</td>
<td>Outliers: “Bad apples”</td>
<td>Processes Systems</td>
</tr>
<tr>
<td>Scope</td>
<td>Medical provider</td>
<td>Patient care</td>
</tr>
<tr>
<td>Responsibility</td>
<td>Few</td>
<td>All</td>
</tr>
</tbody>
</table>


Science at the heart of medicine
# Einstein IRB Contact Information

<table>
<thead>
<tr>
<th>East Campus IRB</th>
<th>West Campus IRB</th>
</tr>
</thead>
</table>
| • Belfer Building, Room 1002  
  1300 Morris Park Avenue  
  Bronx, NY 10461  
  Phone: 718-430-2237  
  Fax: 718-430-8817 | • 3308 Rochambeau Ave  
  Bronx, NY 10467  
  Phone: 718-798-0406  
  Fax: 718-798-5687 |

Website: [http://www.einstein.yu.edu/irb](http://www.einstein.yu.edu/irb)
Includes: Policies and Procedures, Submission Guidelines, Forms, and Educational Materials
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:

iii. the local PI’s sole research activity in the proposed project is to analyze data/specimens, and

iv. 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
Research Eligible for Expedited Review

Review Procedure:
The Expedited Review procedure consists of a review by the IRB Chairperson or by one or more experienced reviewers from among members of the IRB 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:

- 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

Classes of Studies Requiring Full Board Review
- Studies in which the primary risk is the result of a randomization process that inhibits the therapeutic choices of subject and treating physician, even if the alternatives interventions each might be considered ‘standard-of-care’.

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, electoretinography, 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.
Institutional Review Board

Meeting Dates and Submission Deadlines

The Einstein IRB requests that Investigators attend the meeting at which their protocol is being reviewed. The Einstein IRB holds two meetings per month:

- The East Campus IRB generally meets on the second Wednesday of the month, at 3:00 P.M. in the Dean's Conference Room (Belfer Building, Room 303).
- The West Campus IRB generally meets on the fourth Friday of the month, at 12:00 in the Neurology Conference Room (blue zone). Starting in 2013, West Campus IRB meetings will be held in Tishman 4.

Please note that these deadlines only apply to new applications and amendments undergoing full review. All other transactions are reviewed on an ongoing basis upon receipt.

**East Campus IRB**

<table>
<thead>
<tr>
<th>SUBMISSION DEADLINES</th>
<th>MEETING DATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/13/2012</td>
<td>1/9/2013 (Location: Price 351)</td>
</tr>
<tr>
<td>1/17/2013</td>
<td>2/13/2013 (Location: Price 351)</td>
</tr>
<tr>
<td>2/14/2013</td>
<td>3/13/2013</td>
</tr>
<tr>
<td>3/14/2013</td>
<td>4/10/2013</td>
</tr>
<tr>
<td>5/17/2013</td>
<td>6/12/2013</td>
</tr>
<tr>
<td>6/13/2013</td>
<td>7/10/2013</td>
</tr>
<tr>
<td>7/18/2013</td>
<td>8/14/2013</td>
</tr>
<tr>
<td>8/15/2013</td>
<td>9/11/2013</td>
</tr>
<tr>
<td>9/12/2013</td>
<td>10/9/2013</td>
</tr>
<tr>
<td>10/17/2013</td>
<td>11/13/2013</td>
</tr>
<tr>
<td>11/14/2013</td>
<td>12/11/2013</td>
</tr>
</tbody>
</table>

**West Campus IRB**
Contact the West Campus IRB office by the Protocol Number Request Deadline to request an IRB number for your submission. Include the following information:

- PI Name
- Protocol Title
- Sponsor (if any)

<table>
<thead>
<tr>
<th>PROTOCOL NUMBER REQUEST DEADLINES</th>
<th>SUBMISSION DEADLINES</th>
<th>MEETING DATES</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/21/2012</td>
<td>12/31/2012</td>
<td>1/25/2013</td>
</tr>
<tr>
<td>1/18/2013</td>
<td>1/28/2013</td>
<td>2/22/2013</td>
</tr>
<tr>
<td>4/29/2013</td>
<td>5/6/2013</td>
<td>5/31/2013 (5th Friday)</td>
</tr>
<tr>
<td>6/24/2013</td>
<td>7/1/2013</td>
<td>7/26/2013</td>
</tr>
<tr>
<td>8/30/2013</td>
<td>9/9/2013</td>
<td>10/4/2013 (instead of September)</td>
</tr>
<tr>
<td>10/21/2013</td>
<td>10/28/2013</td>
<td>11/22/2013</td>
</tr>
</tbody>
</table>
Checklist for New Full Board Protocol Submissions (East Campus IRB Only)

<table>
<thead>
<tr>
<th>PI Name:</th>
<th>IRB #:</th>
</tr>
</thead>
</table>

**Submission Instructions:**
1. Complete the PI Name and IRB # above.
2. Organize 6 (six) “Application Packets” containing the following documents, in the order specified. (Items in **bold** are always required.) Check off each item included.
3. Complete Application Packets must be received by the IRB by the deadline (for a list of deadlines see: [http://www.einstein.yu.edu/irb/meeting-dates-deadlines.aspx#east](http://www.einstein.yu.edu/irb/meeting-dates-deadlines.aspx#east)).
4. For studies that involve private industry support, the OCT New Study Activation Form* is also required; submit it directly to OCT@montefiore.org.

**Checklist for New Full Board Protocol Submissions**

- **PATS Application printout including:**
  - Original signatures of PI, Chair, etc. (stamped signatures are not permitted)
  - Conflict of Interest Disclosure form (for each key personnel)
- Biohazard/Gene Therapy* (if study involves the use of potentially infectious materials)
- IND Exemption Request* (if FDA approved drug will be used off-label)
- Use of Placebo* (if placebo will be used during the course of the study)
- Ionizing Radiation Exposure Form* (if subjects will be exposed to radiation for research purposes)
- Nursing Form* (for MMC Oncology protocols that involve the nursing staff)
- PRMC Approval (for all cancer studies)
- Informed Consent/Assent Form(s) (printed from PATS)
- Scientific narrative:
  - Complete grant application (if funded) OR
  - Detailed Protocol (must include a version date and/or number)

**The Principal Investigator’s current CV/biosketch**

- FDA 1572 Form (for investigational drugs under an IND)
- Investigator Brochure or Package Insert (for each study drug)
- Patient Information Confidentiality Agreement* (For key personnel who will be reviewing medical records)
- NBHN Research Questionnaire* (for studies involving JMC/NCB conducted by non-PAGNY PIs)
- HHC-641* (for studies involving JMC/NCB)
- Additional Study Document (specify):
- Additional Study Document (specify):
- Additional Study Document (specify):
- Additional Study Document (specify):
- Additional Study Document (specify):

---

*Available at: [http://www.einstein.yu.edu/administration/institutional-review-board/forms.aspx](http://www.einstein.yu.edu/administration/institutional-review-board/forms.aspx)
Checklist for New Full Board Protocol Submissions (West Campus IRB Only)

**Submission Instructions:**
1. Complete the PI Name and IRB # above. (Email irb-west@einstein.yu.edu to request an IRB #. Include the PI name, protocol title, and sponsor if applicable.)
2. Organize 6 (six) “Application Packets” containing the following documents, in the order specified. (Items in **bold** are always required.) Check off each item included.
3. Complete Application Packets must be received by the IRB by the deadline (for a list of deadlines see: http://www.einstein.yu.edu/irb/meeting-dates-deadlines.aspx#west).
4. Email the Microsoft Word (*.DOC or *.DOCX) versions of the consent document(s) to: irb-west@einstein.yu.edu.
5. For studies that involve private industry support, the OCT New Study Activation Form* is also required; submit it directly to OCT@montefiore.org.

**Checklist for New Full Board Protocol Submissions** (this form)

- [ ] **IRB Application Form** with required original signatures (stamped signatures are not permitted)
  - Biohazard/Gene Transfer* (If study involves the use of potentially infectious materials)
  - Human Specimens* (If specimen/genetic research will be conducted)
  - Drug/Device* (If study involves the use of drugs and/or devices)
  - Drug Storage Waiver* (If study drug will not be stored in the pharmacy)
  - IND Exemption Request* (for studies involving the off-label use of approved drugs)
  - Use of Placebo* (If placebo will be used during the course of the study)
  - Ionizing Radiation/Isotopes* (If radioisotopes or other ionizing radiation will be used during the course of the study)
  - Ionizing Radiation Exposure Form* (For studies involving the use of radiation beyond clinical care)
  - Nursing* (For oncology studies that involve the nursing staff)
  - Request for Waiver/Alteration or Exemption from HIPAA Authorization and Informed Consent* (If informed consent and/or HIPAA Authorization will not be obtained)

- [ ] **Informed Consent/Assent Form(s)**
- [ ] HIPAA Authorization Form(s)*
- [ ] Detailed Protocol (must include a version date and/or number)
- [ ] The Principal Investigator’s current CV/biosketch
- [ ] FDA 1572 Form (for investigational drugs)
- [ ] Investigator Brochure or Package Insert (for each study drug)
- [ ] Conflict of Interest Disclosure* for all key personnel
  - Patient Information Confidentiality Agreement* (For key personnel who will be reviewing medical records)
  - PRMC Approval (For all cancer studies)
  - NBHN Research Questionnaire* (for studies involving JMC/NCB conducted by non-PAGNY PIs)
  - HHC-641* (for studies involving JMC/NCB)
- Additional Study Document (specify):
- Additional Study Document (specify):
- Additional Study Document (specify):
- Additional Study Document (specify):

*Available at: [http://www.einstein.yu.edu/administration/institutional-review-board/forms.aspx](http://www.einstein.yu.edu/administration/institutional-review-board/forms.aspx)