

IRB Makeover

Top Ten Recent Changes

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EXCEPTIONAL CARE. WITHOUT EXCEPTION.



Learning objectives

- Describe the significant recent changes in requirements for human subjects research at BMC and BU Medical Campus
- Identify changes that impact attendee's existing and future research
- Explain ways to continue to learn about future changes

Why the IRB makeover?

Preparing for Accreditation

- Not required, but increasingly expected
- Opportunity to direct resources towards greatest impact on subject protection
- Major changes – May to December

Possibly – getting ready for a Final Rule

Clinical Research Times

An Online Resource for Clinical Researchers Provided by the Office of Clinical Research

FEATURE ARTICLE

A Year of Changing Policies

FEATURE ARTICLE

Altered IRB Requirements for certain Low-Risk Research and other changes

FEATURE ARTICLE

Investigator Responsibilities and New Training Requirements

FEATURE ARTICLE

Renewal of Exempt Determinations and Other New Policies

FEATURE ARTICLE

Changes in Obtaining Consent and Protecting Vulnerable Populations

**Boston Medical Center and Boston University Medical Campus
Human Research Protection Program
Policies and Procedures**

Revision History

Revision History

Approved 1/14/2003, 2/2/2010

Revisions approved 10/3/2014

- Section VI. Principal Investigators, Co-investigators and Other Research Personnel (Adverse Event Reporting)

Revisions approved 3/13/2015

- Section VIII. Informed Consent (Use of External Sponsor Drafted Consent Forms)

Revisions approved 4/10/2015

- Section VI. Principal Investigators, Co-investigators and Other Research Personnel (Adverse Event Reporting)

Revisions approved 2/12/2016

- Section VI. Principal Investigators, Co-investigators and Other Research Personnel (Adverse Event Reporting)

Revisions approved 3/28/2016

- All sections. Formatting and typo corrections; updates: FWA-related changes, institutional language changes, legal reference corrections, electronic system details, panel details, recertification procedure, response deadlines, consent form stamping, PI eligibility
- Section II. International Research – content modified
- Section VI. Principal Investigators, Co-investigators and Other Research Personnel (Study Closure – section name changed from Final Report, content modified)
- Section VI. Principal Investigators, Co-investigators and Other Research Personnel (New section: Registration Requirements for Clinical Trials)

Revisions approved 4/25/2016

- All sections. Section and subsection headings have been renumbered, edited, and added
- Sections dated 3/28/16 – no additional changes
- Sections dated 4/25/16 – incorporation of existing policies, and in addition:
 - Section 1.2 – specifying the plan for updating this document
 - Section 6.6.2.5.2 – specifying that when changes are made to eliminate an immediate hazard, this meets the definition of an Unanticipated Problem
 - Section 6.6.5.2 – specifying reporting for changes made to eliminate an immediate hazard
 - Section 10.2.2.1 – specifying the process for designating Expeditors
 - Section 10.2.2.4.2 – specifying criteria for minor modifications
 - Section 10.4.2 – specifying the process for verifying no unapproved changes have occurred
 - Section 11.4 – specifying responsibilities for subject safety when approval is suspended or terminated

Revisions approved 5/27/16

- Sections dated 5/27/16 – incorporation of existing policies, and in addition:
 - Section 1.3.2.4 – specifying a timeline for the HRPP quality improvement process
 - Sections 2.1.2, 8.1.3.4, 9.2.4.5, 9.3.1, 9.3.4, 9.4.1, 9.4.3, 10.2.2.4.1.1, 10.2.2.4.1.2, 10.2.2.4.1.3, 10.2.4.1, 10.2.4.2.2, 10.2.4.3, 10.4.1.1, and 10.4.1.3 – adding equivalent protection standards for minimal risk research not required to follow federal regulations
 - Section 6.6.3.2 – changing the reporting requirement to 7 days for Unanticipated Problems not associated with a fatal or life-threatening incident
 - Sections 7.2.1 and 7.2.2.2 – specifying when a separate protocol is required in the submission
 - Section 8.4.5.1 – changing the required attestation for translations from a second translator to the PI
 - Section 9.2.4.5 – specifying how the availability of the second parent for permission for child research is interpreted

Top Ten

- 1. Suicide safety plan**
2. Reporting for ceded studies
3. PI responsibilities attestation
4. Child assent documentation
5. Required protocol for clinical trials

1. Suicide Safety Plan

If you are likely to receive information indicating suicide risk

Then you must have a suicide safety plan

Suicide Safety Plan Considerations

Level of risk identified

- I have thoughts of killing myself, but would not carry them out
- I would like to kill myself
- I would kill myself if I had the chance

Response

- Provide list of mental health resources
- Encourage subject to contact healthcare provider
- Notify family members
- Escort to Emergency Department
- Call 911

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2. Ceded Review Reporting

If a different IRB is overseeing your study (BMC/BU Medical Campus has ceded review)

Then you have to report to us as well as to the other IRB in two cases:

1. Changes in study staff
2. Unanticipated Problems

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3. PI Responsibilities

All PI's must acknowledge PI responsibilities

AND

If the PI (or Faculty Sponsor) changes on your study

Then the amendment request must include an acknowledgement by the new PI/FS

The PI is required to

1. Understand what research activities are overseen by the HRPP and consult with HRPP staff if in doubt about whether **submission to the IRB is required**; and
2. Personally log into the electronic system using his or her individual username and password as an **electronic signature**; and
3. Provide information to the HRPP that is **complete and accurate** to the best of his or her knowledge; and
4. **Design studies** to protect individuals conducting the study, to adhere to ethical principles and standards appropriate to his or her discipline, to safeguard the rights and welfare of all human subjects, to minimize risks, to have adequate provisions to monitor the data for safety, to draw subjects from a population selected to distribute the risks and benefits fairly, to employ additional safeguards necessary to protect vulnerable populations, to safeguard research data, and to meet all applicable HIPAA requirements; and

The PI is required to

5. Determine that **adequate resources** will be available to carry out the study, including facilities, access to an appropriate population, medical and psychological resources for subjects, and sufficient time from himself or herself and staff to conduct the research; and
6. Ensure that prior to beginning work on the study, the Principal Investigator and all members of the research team meet all applicable Boston Medical Center and Boston University requirements for the disclosure and management of **conflicts of interest**; have all **required training**, qualifications, credentials, and licenses; and are trained on and appropriately delegated responsibility for study procedures; and
7. **Not initiate** any human subjects research activities until an IRB final outcome letter has been received and all required institutional approvals have been obtained; and
8. Be responsible for execution and management of the study, including **oversight** of all study personnel and any sub-awardees/subcontractors under his or her direction; and

The PI is required to

9. **Comply** with all applicable terms, conditions, assurances and certifications referenced in the application, award (grant or contract), and protocol; and with all applicable state, federal, and local laws, rules, regulations, policies, and guidelines, as well as institutional policies (including those pertaining to IRB requirements, patient confidentiality, HIPAA, debarment, finances and record retention) related to this study; and
10. **Follow the IRB-approved research** plan by recruiting subjects in a fair and equitable manner; by adhering to and documenting adherence to the approved inclusion and exclusion criteria; by employing the approved process for obtaining and documenting informed consent; by meeting all applicable HIPAA and other data security requirements; by maintaining the privacy of subjects and protecting the confidentiality of data; by responding appropriately to and documenting the response to subjects, prospective subjects, and family members who request information or have concerns or complaints; and by providing aggregate and/or individual study results to subjects if promised; and

The PI is required to

11. Maintain all required **records** and cooperate with any request for auditing by the HRPP, sponsor, or government agency; and
12. Comply with all requirements for identifying and **reporting** Unanticipated Problems, Adverse Events, deviations, and safety monitors' reports, and any other new or significant information that might impact a subject's safety or willingness to continue in the study; and
13. Ensure that IRB approval is obtained **prior to making any change** to the approved study plan, consent form, or study personnel unless the change is immediately necessary for the safety of subjects; that IRB **approval for continuation** is obtained prior to the study expiration date; and that a Final Report is submitted to close the study at the appropriate time.

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4. Child Assent Documentation

If your study has children as subjects

Then the person obtaining parental consent is the one who documents child assent.

Researcher Signature Choice 1

All children will be capable of assent

I have personally explained the research to the above-named child and to the parents/legal guardians. I have answered all questions. I believe that they understand what is involved in the study and freely agree to participate.

Researcher Signature Choice 2

Some but not all children will be capable of assent

I have personally explained the research to the above-named parents/legal guardians and answered all questions. I believe that they understand what is involved in the study and freely agree for their child to participate. I consider that the above-named child (check one):

- is capable of understanding what is involved in the study and freely agrees to participate.
- is not capable of understanding what is involved in the study.

Researcher Signature Choice 3

No children will be capable of assent

I have personally explained the research to the above-named parents/legal guardians and answered all questions. I believe that they understand what is involved in the study and freely agree for their child to participate.

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5. Required Protocol

If your study is a clinical trial with a medical or surgical intervention

Then you must have a separate protocol document

- Required for submissions on or after Nov. 1st
- You will be able to skip some INSPIR sections
- October's seminar covers the new template

Top Ten

6. Exempt expiration
7. Re-consenting subjects
8. New consent form template
9. GCP training & sponsor-investigator training
10. Equivalent protections

6. Exempt Expirations

If your study received an exempt determination

Then you must renew or close after 3 years

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7. Re-consenting Subjects

If a revised consent form is approved

Then the IRB will tell you whether currently-enrolled subject must be re-consented

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8. New Consent Form Template

If/When you submit a study on or after Nov. 1st

Then you must use the new consent form template

- New required elements
- New signature pages

Workshops starting next week!

Consent Form Template Workshops

Monday	Tuesday	Wednesday	Thursday	Friday
Sept. 19 3:00-4:00 pm		Sept. 21 8:00-9:00 am		Sept. 23 12:30-1:30 pm
Sept. 26 12:30-1:30 pm		Sept. 28 3:00-4:00 pm		Sept. 30 8:00-9:00 am
Oct. 3 3:00-4:00 pm		Oct. 5 8:00-9:00 am		Oct. 7 10:00-11:00 am

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9. GCP Training & Sponsor-Investigator Training

If your study is a clinical trial

Then all study staff must complete Good Clinical Practice (GCP) training

- Biomedical trials submitted on or after Nov. 1st
- Social-behavioral trials TBD

If the PI holds the IND or IDE

Then the PI must complete sponsor training

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10. Equivalent Protections

If your study does not have external funding and is low risk

Then some requirements might change

- 3-year approval period
- Exempt determination
 - Socio-behavioral research
 - Chart reviews

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Thank you!

Other Changes Affecting Investigators (1)

- Translated consent form attestation is by PI
- Women of child-bearing potential don't need protection against coercion
- PI's must agree not to take kickbacks or recruitment bonuses
- Applications must describe privacy protections

Other Changes Affecting Investigators (2)

- Standards are formalized for research involving:
 - Certificates of Confidentiality
 - Decisionally-impaired subjects
 - Homeless individuals
 - Terminally-ill individuals
 - Individuals with psychiatric disorders
 - Pregnant partners of male research subjects

Other Changes Affecting Investigators (3)

- Deadline for reporting Unanticipated Problems is 2 days if fatal or life-threatening event and 7 days otherwise
- All clinical trials meeting the ICMJE definition must be listed on [ClinicalTrials.gov](https://clinicaltrials.gov)
- You must let the IRB know if the FDA is coming for an audit