DIY IRB ABCs
Teaching You to Fish

Fanny Ennever, PhD, CIP
Manager, Regulatory Policy Development
Office of Human Research Affairs
Boston Medical Center and Boston University Medical Campus
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Learning objectives

• Explain how to use the INSPIR application and the IRB website to understand IRB requirements

• Identify some changes in the Human Research Protection Program in 2016 and 2017

• Describe what is expected to change as a result of the implementation of the Final Common Rule in 2018
Why You Need Help

IRB requirements are:

• Complicated
• Study-specific
• Changing
  o Just finished 18 months of local changes
  o Gearing up for changes to Common Rule
How to Provide Help

• IRB users have different:
  o Schedules
  o Areas of expertise
  o Preferences for receiving information
Your knowledge

IRB Policies

Help needed “ABCs”

Your study
IRB Policies

Help needed “ABCs”

Your study

Your knowledge
IRB Policies

Your study

Your knowledge
IRB Requirements

• Authoritative source is one single document
• Posted on the HRPP website
  http://www.bumc.bu.edu/ohra/hrpp-policies/
  1. Bookmarked Adobe document for downloading
  2. Single html webpage with internal links
Policies & Procedures – Webpage Version

URL: www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#7.2.2.20

Ctrl+F: Protocol

Quick link: HRPP Policies

Links: Protocol Requirements

(Revised 6/29/17)
The requirement to provide detailed information about the conduct of the study must be fulfilled by attaching a separate protocol to the submission for studies that meet the definition in Section 13 of a clinical trial and that involve a medical intervention (administration of a drug or biological agent or use of a device) or surgical intervention (use of a surgical procedure) intended to modify a health outcome. This requirement is effective for studies submitted on or after November 1, 2016. For other studies, the Principal Investigator has the choice between attaching a separate protocol or completing the sections that are required for submissions without a separate protocol (Sections 7.2.2.13, 7.2.2.14, and 7.2.2.15).
IRB Requirements

• We strive to make sure other sources are consistent
  • INSPIR application
  • Templates
  • CR TIMES articles
  • CRRO seminars
8.1 Separate Protocol

Is this a new submission with a separate protocol? This protocol must be from the sponsor or cooperative group or be based on the protocol template found on the IRB website, and must include the purpose, inclusion/exclusion criteria, design/procedure, and data safety and monitoring plan. A separate protocol is REQUIRED for all initial submissions of medical or surgical clinical trials. A GRANT APPLICATION IS NOT A PROTOCOL.

- Yes
- No
- Not applicable, this is not a new submission
Protocol Template

Protocol Title

Version number and date

Template version 1.0, 10/3/2016

GENERAL INSTRUCTIONS – delete this box from the submitted Protocol

This template is for investigators at Boston Medical Center and Boston University Medical Campus who are preparing a detailed protocol for a study at their site only. If you are preparing a protocol for a multi-site study, contact the IRB at medirb@bu.edu for assistance. A detailed protocol is required to be attached to the INSPIR submission for initial review of studies that are clinical trials involving medical or surgical interventions and are submitted on or after November 1, 2016. If you have a protocol from an external sponsor or cooperative group, attach that protocol to the INSPIR submission and do not use this template. Investigators may also choose to use this template for studies that are not clinical trials.
October INSPR Changes
October 2016 Issue

Separate Protocol

The Navigation Menu has a new question asking whether a separate protocol is attached. This question concerns new submissions; for amendment submissions, you can indicate the question is not applicable. A separate protocol is REQUIRED for clinical trials of medical or surgical interventions for initial review submissions on or after November 1, 2016. We expect that in most cases, the sponsor will have provided a separate protocol. If not, a template has been posted on the IRB website for the investigator to create the protocol.
CRRO Seminars

http://www.bumc.bu.edu/crro/past-seminars/

## Past Seminars

<table>
<thead>
<tr>
<th>Seminar Date</th>
<th>Clinical Research Seminar and R &amp; R Roundtable Title &amp; Speaker(s)</th>
<th>Slide PDFs, Videos, Podcasts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>John F. Ennever, MD, PhD, CIP</td>
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Starting Point

• We think many users will start with INSPIR
• INSPIR contains a lot of instructions
• When appropriate, we provide links to website or official policies and procedures
## 5.0 Required Training and Conflict of Interest

### 5.1 BMC/BU Medical Campus Institutional Requirements for training

- The PI confirms the following:
  - All individuals listed in Sections 3.1, 3.2, and 3.4 are up to date with human subjects training and with GCP training if required. For more information, click [here](#).
Required Training for Human Researchers

BMC and Boston University Medical Campus require that all researchers involved in human research must receive formal training. Depending on the type of research you conduct, there are several levels of required training.

- **Human Subjects Protection training** – Required for all individuals involved in human subject research studies (exempt and non-exempt) who have contact with subjects or their identifiable data.
- **Good Clinical Practice (GCP) training** – Required for all individuals involved in the conduct of clinical trials.
Help on the Web

• INSPIR instructions webpage has many forms and instructions [http://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/](http://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/)
INSPIR II Instructions for Investigators

How To

General

- How to get access to INSPIR II
- How to log-in to INSPIR II
- How to update your Personal Profile (required for everyone listed on a study)
INSPIR II Instructions for Investigators

How To

General

- How to get access to INSPIR II
- How to log-in to INSPIR II
- How to update your Personal Profile (required for everyone listed on a study)
It is a violation of Institutional policy to log in using someone else’s user name and Kerberos password or to give your user name and Kerberos password to someone else.
Your Turn
Now
Coming in January 2018

Behavioral Research

Consent forms

Expiration

Ceding 2020
Thank you!