

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

9/13/2017



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

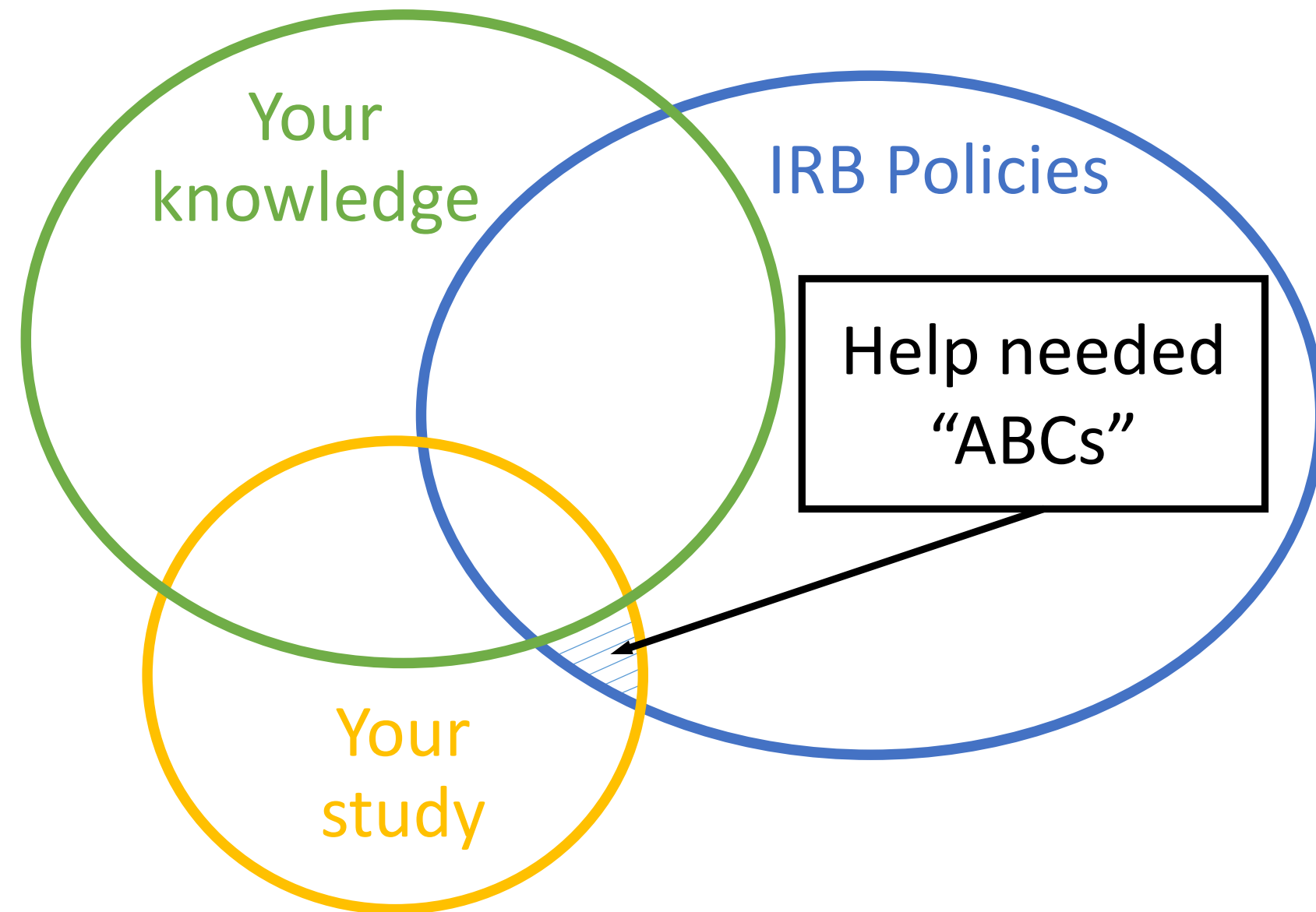
Why You Need Help

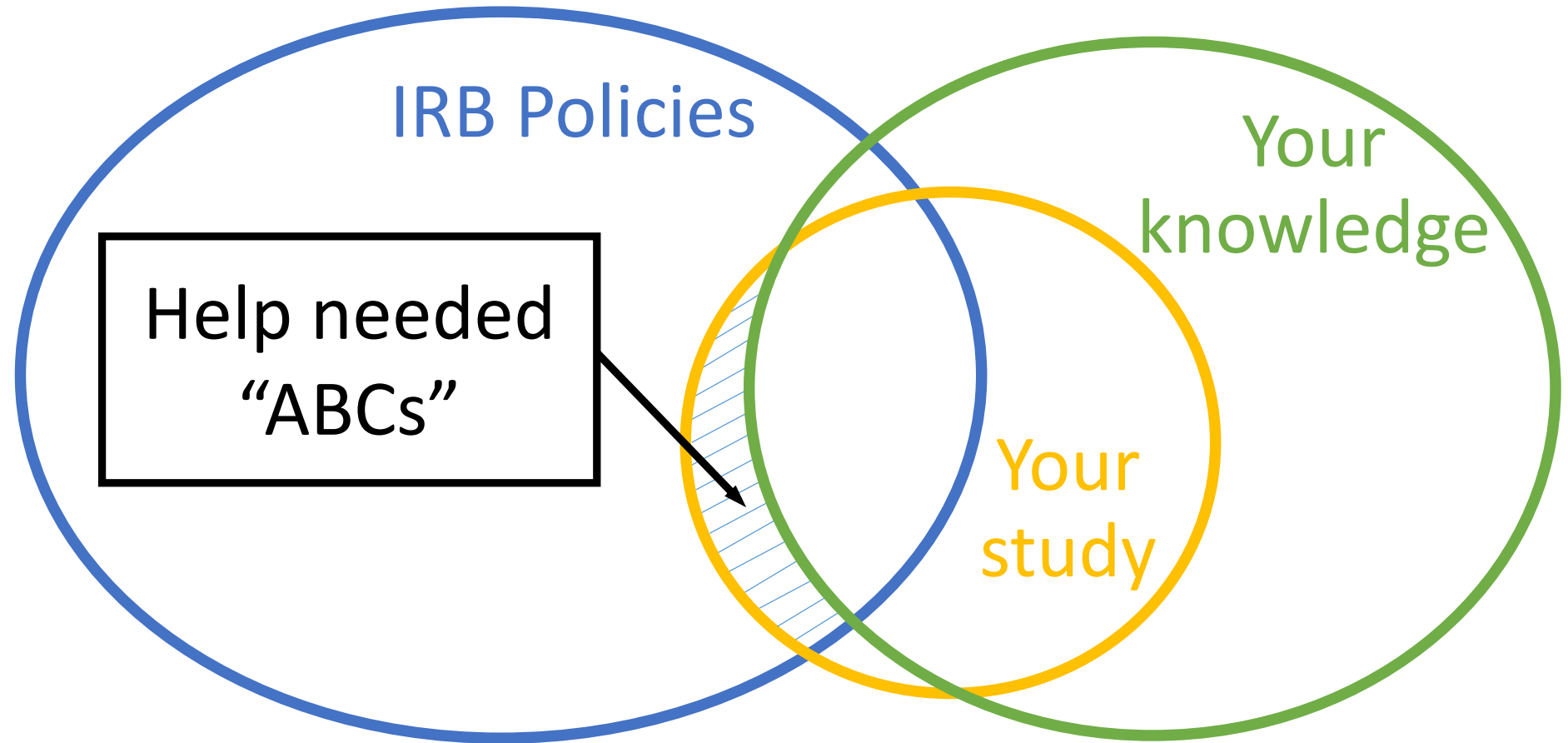
IRB requirements are:

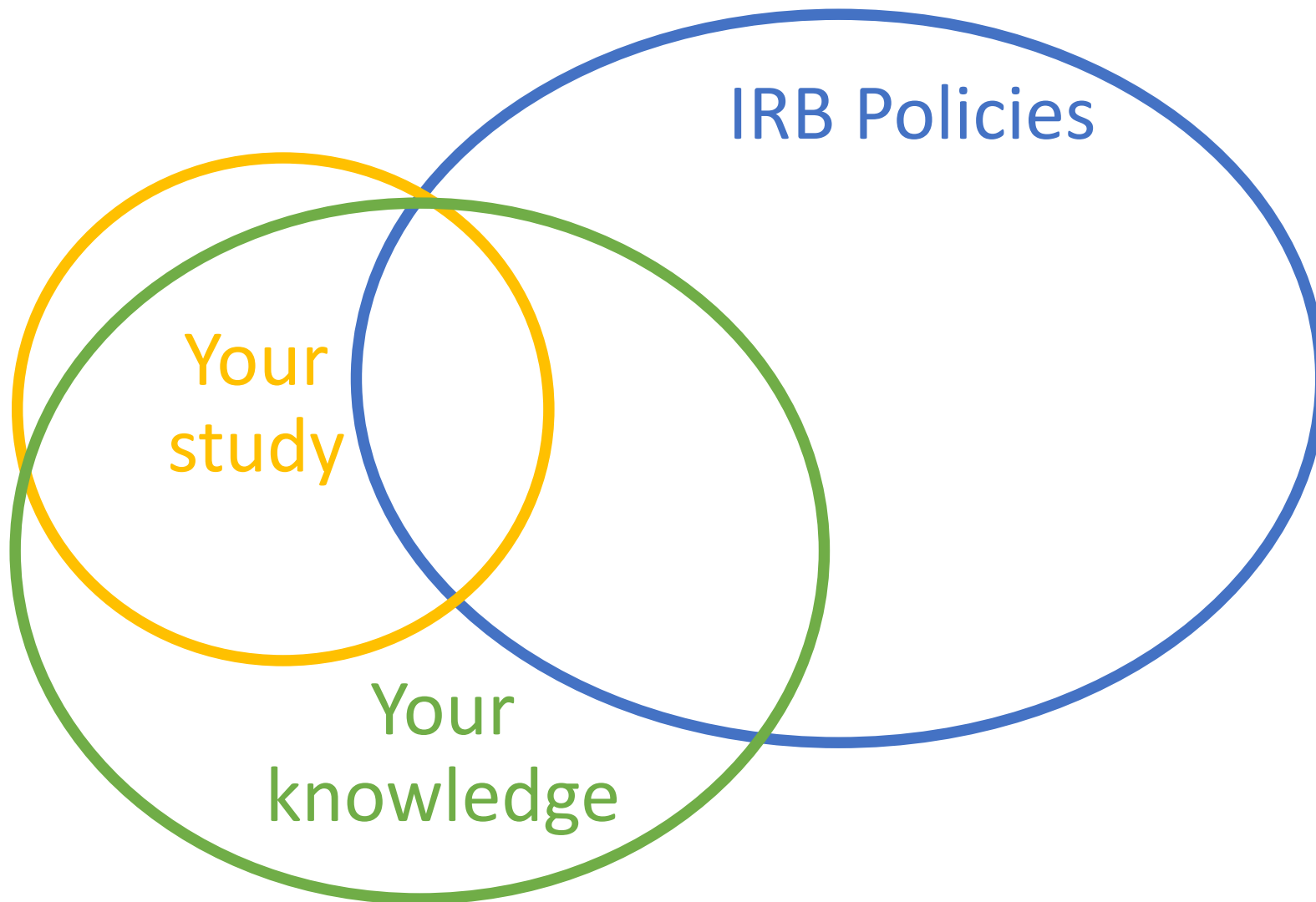
- Complicated
- Study-specific
- Changing
 - Just finished 18 months of local changes
 - Gearing up for changes to Common Rule

How to Provide Help

- IRB users have different:
 - Schedules
 - Areas of expertise
 - Preferences for receiving information







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 – pdf Version

The screenshot displays the Adobe Acrobat Pro DC interface. The title bar shows the file name "Boston-Medical-Center-and-BU-Medical-Campus-HR... Procedures.pdf". The menu bar includes "File", "Edit", "View", "Window", and "Help". The toolbar contains icons for "Home", "Tools", "Document", and various actions like "Save", "Share", "Print", "Email", "Find", "Previous", "Next", "Page 68 / 165", "Comments", and "Sign".

Annotations with red boxes and lines point to specific features:

- Ctrl+F**: Points to the "Find" icon in the toolbar.
- Bookmarks**: Points to the "Bookmarks" panel on the left side of the document.
- 7.2.2 Requirements for Submitted Materials**: Points to a specific bookmark entry in the "Bookmarks" panel.
- Links**: Points to a red box containing the text "7.2.2.13, 7.2.2.14, and 7.2.2.15" within the main text area.

The main text area shows a list of requirements, including "Residents or fe...", "Boston Univers...", "Whether homeless...", and "A description of pla...". Below this, the section "7.2.2.20 Protocol Requirements" is highlighted. The text below this section states: "(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)".

Policies & Procedures – Webpage Version

The screenshot shows a web browser window with the URL www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#7.2.2.20 in the address bar. A search bar in the top right corner contains the text "Protocol". The page header identifies the institution as Boston University Medical Campus and Boston Medical Center, Office of Human Research Affairs. A navigation bar includes links for About Us, HRPP Policies, Clinical Data Warehouse, Required Training, Audits, Funding Opportunities, and ClinicalTrials.gov, along with buttons for OHRA, CRRO, and IRB. The main content area is titled "7.2.2.20 Protocol Requirements" and includes a paragraph about the requirement to provide detailed information about the conduct of the study. A "Quick Links" sidebar on the right lists Required Training, PI Responsibilities, and HRPP Policies. Annotations with red boxes and lines point to the URL, the search bar, the word "protocol" in the text, the HRPP Policies link, and the word "Links" in the bottom left corner.

URL

Ctrl+F

Protocol

36 of 74

Boston University Medical Campus and Boston Medical Center:
Office of Human Research Affairs

About Us HRPP Policies Clinical Data Warehouse Required Training Audits Funding Opportunities ClinicalTrials.gov

OHRA CRRO IRB

7.2.2.20 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 (Section 7.2.2.13, 7.2.2.14, and 7.2.2.15)

Quick Links

Required Training

PI Responsibilities

HRPP Policies

Quick link

Links

IRB Requirements

- We strive to make sure other sources are consistent
 - INSPIR application
 - Templates
 - CR TIMES articles
 - CRRO seminars

INSPIR Application

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

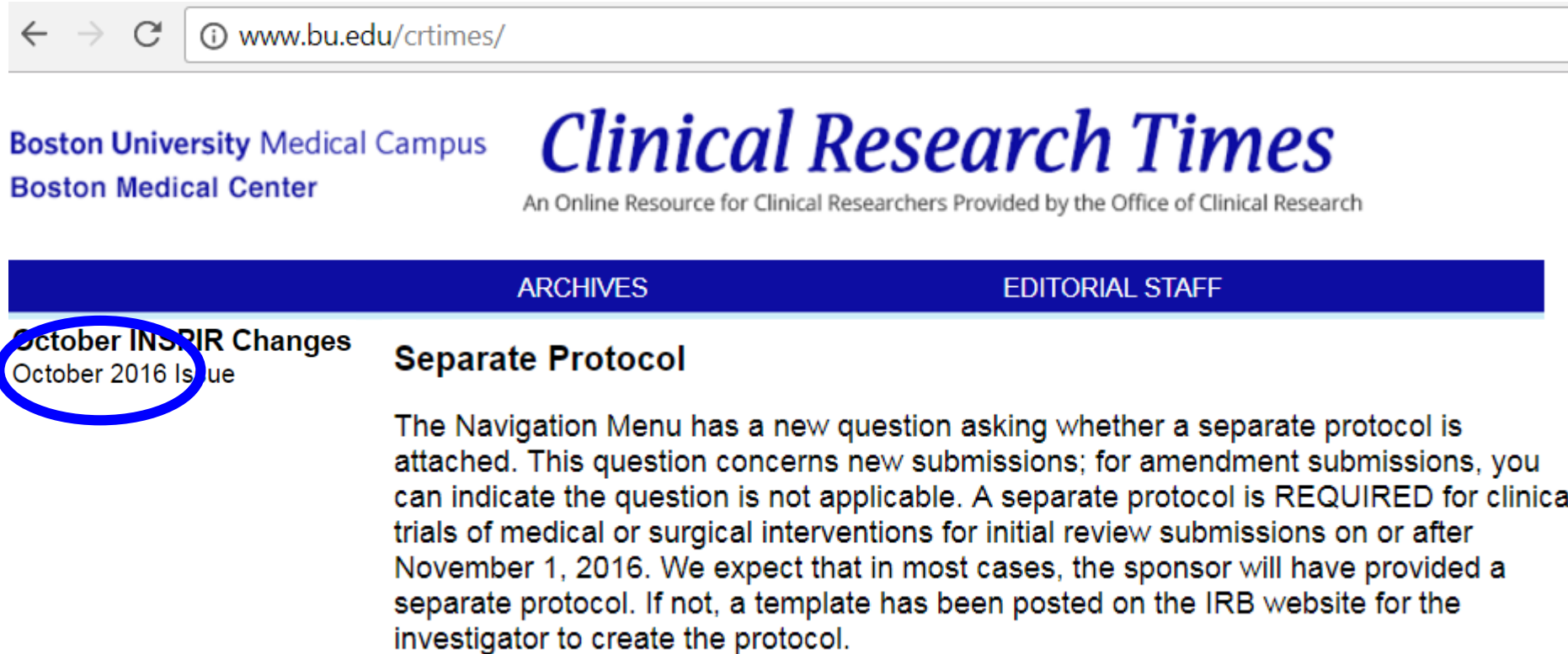
Version number and date

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.

Clinical Research Times



The screenshot shows the Clinical Research Times website. At the top, there is a browser address bar with the URL www.bu.edu/crtimes/. Below the address bar, the text "Boston University Medical Campus" and "Boston Medical Center" is displayed on the left, and the title "Clinical Research Times" is displayed in a large, stylized font on the right. Under the title, it says "An Online Resource for Clinical Researchers Provided by the Office of Clinical Research". A dark blue navigation bar contains the links "ARCHIVES" and "EDITORIAL STAFF". Below the navigation bar, there are two main sections. The left section is titled "October INSPIR Changes" with "October 2016 Issue" below it; the word "INSPIR" is circled in blue. The right section is titled "Separate Protocol" and contains a paragraph of text.

← → ↻ ⓘ www.bu.edu/crtimes/

Boston University Medical Campus
Boston Medical Center

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

ARCHIVES EDITORIAL STAFF

October INSPIR 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/crr/past-seminars/>

Past Seminars

Seminar Date	Clinical Research Seminar and R & R Roundtable Title & Speaker(s)	Slide PDFs, Videos, Podcasts
10/26/2016	INSPIRING Changes to the IRB Process: New Templates and More John F. Ennever, MD, PhD, CIP	Slides  Video Podcast

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

INSPIR Application

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](#).

Boston University Medical Campus and **Boston Medical Center:**
Office of Human Research Affairs

[About Us](#) [HRPP Policies](#) [Clinical Data Warehouse](#) **[Required Training](#)** [Audits](#) [Funding Opportunities](#) [ClinicalTrials.gov](#)

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/>

Boston University Medical Campus and **Boston Medical Center:**
Institutional Review Board

[About Us](#) [INSPIR II](#) [Submission Requirements](#) [Maintaining IRB Approval](#) [CR Times Newsletter](#) [IRB Information](#)

OHRA

CRRO

IRB



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)

Boston University Medical Campus and **Boston Medical Center:**
Institutional Review Board

[About Us](#) [INSPIR II](#) [Submission Requirements](#) [Maintaining IRB Approval](#) [CR Times Newsletter](#) [IRB Information](#)

OHRA

CRRO

IRB



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)

The image is a screenshot of a web browser displaying the INSPIR II login page. The browser's address bar shows the URL <https://inspir.bu.edu>. A blue callout box on the right contains the same URL and the text: "Clicking on the URL will bring you to this INSPIR II log-in page". A large blue arrow points from the address bar to the "Log In" text on the page. The page itself features the Boston University and Boston Medical Center logos, the title "INSPIR II Integrated Network for Subject Protection In Research", and a login form with fields for "User ID:" and "Password:", followed by a "Log In" button. A red callout bubble on the left contains the text: "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". At the bottom of the page, there is a "System/Browser Requirements" link and four circular icons labeled "INSPIR II Home", "INSPIR II Manual", "IRB Review Times", and "User Satisfaction".

<https://inspir.bu.edu>

Clicking on the URL will bring you to this INSPIR II log-in page

Log In

BOSTON UNIVERSITY **BOSTON MEDICAL CENTER**
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

INSPIR II
Integrated Network for Subject Protection In Research

User ID:

Password:

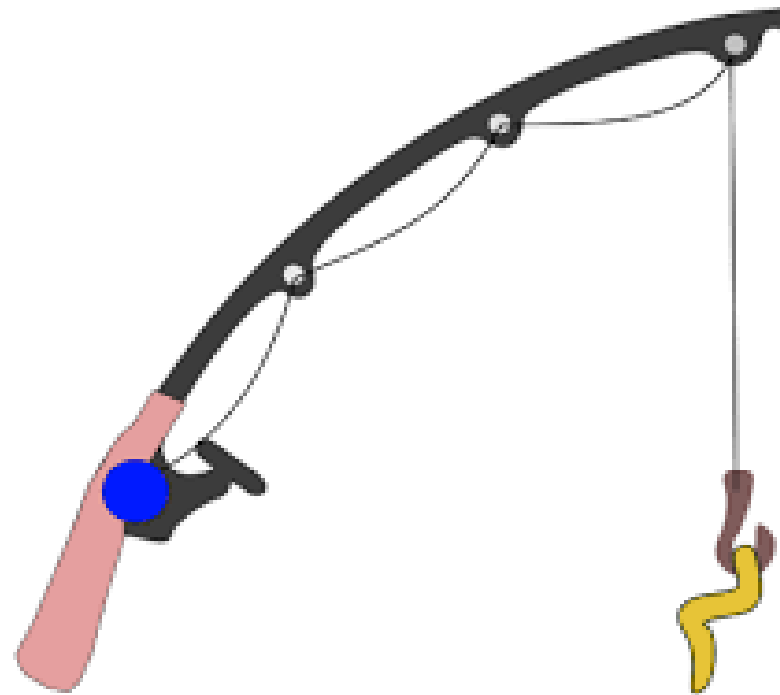
Log In

System/Browser Requirements

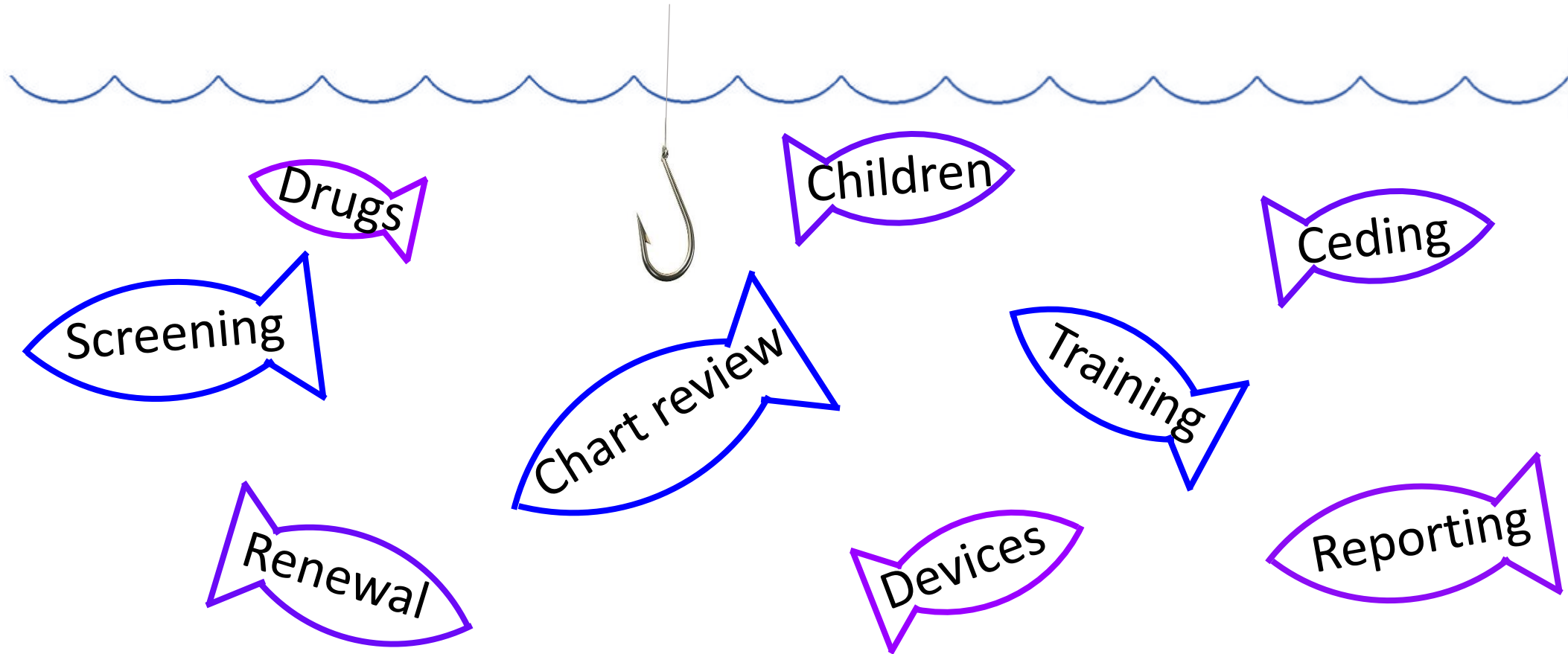
INSPIR II Home INSPIR II Manual IRB Review Times User Satisfaction

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

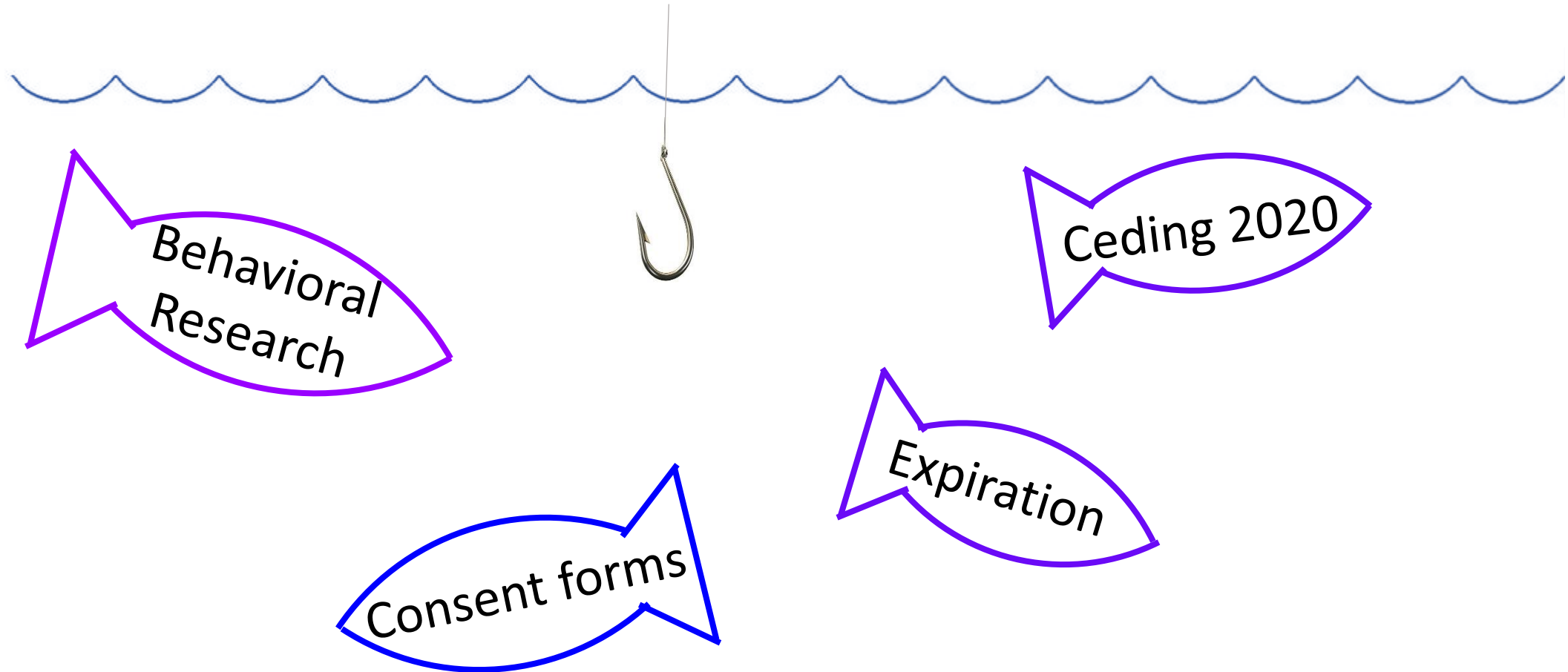
Your Turn



Now



Coming in January 2018



Thank you!