DIY IRB ABCs
Teaching You to Fish

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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

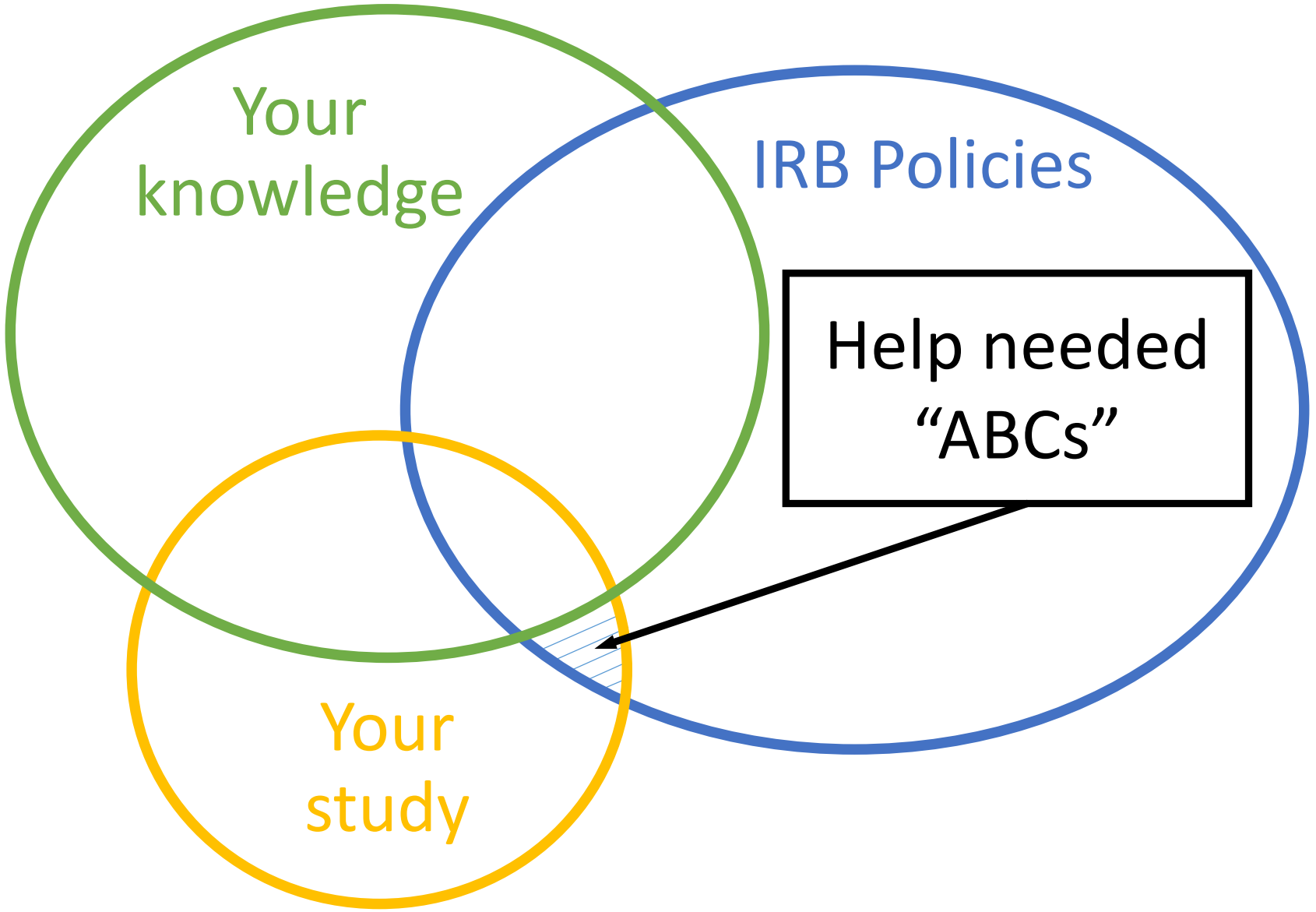
Why You Need Help

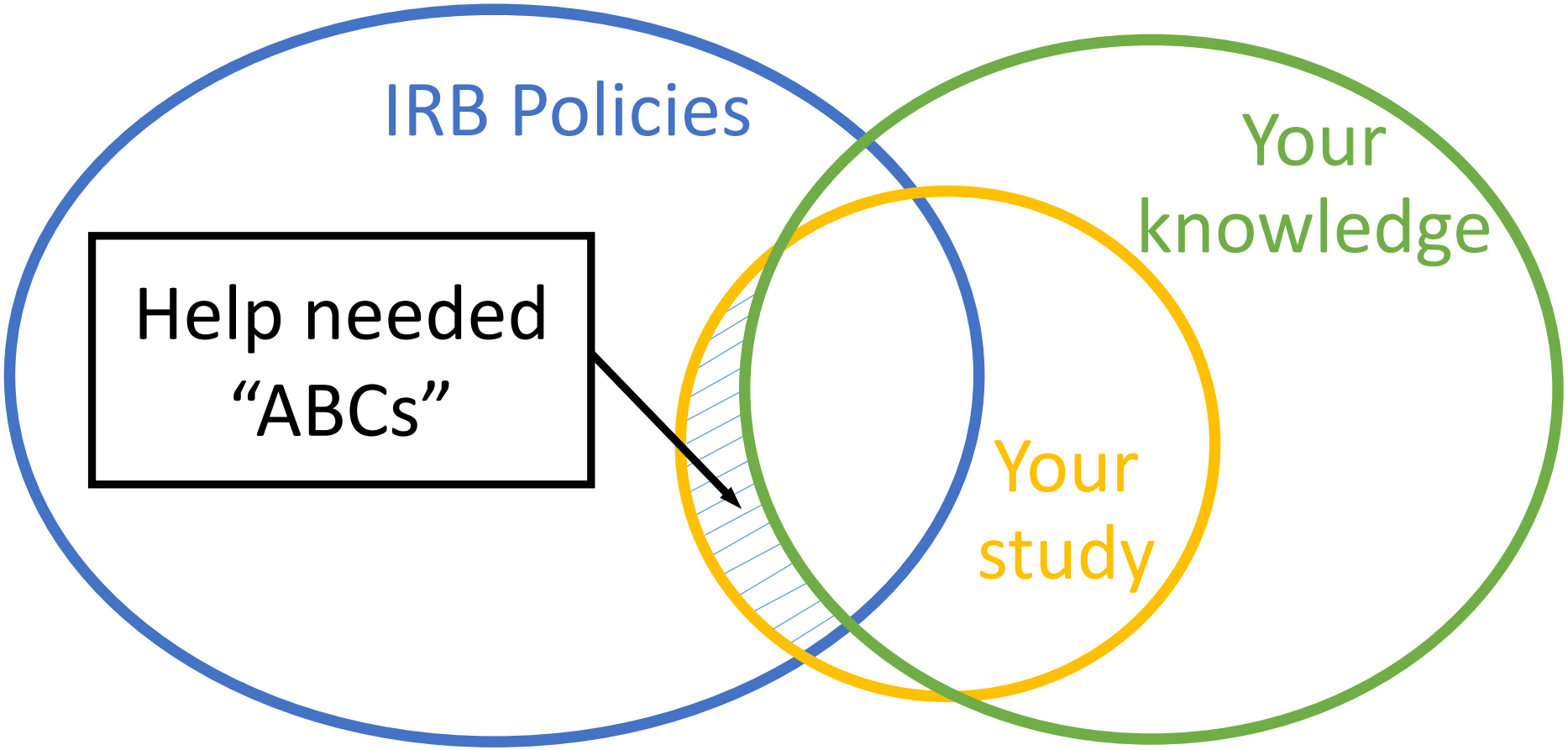
IRB requirements are:

- Complicated
- Study-specific
- Changing
  - 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


Your knowledge
IRB Policies
Help needed "ABCs"
Your study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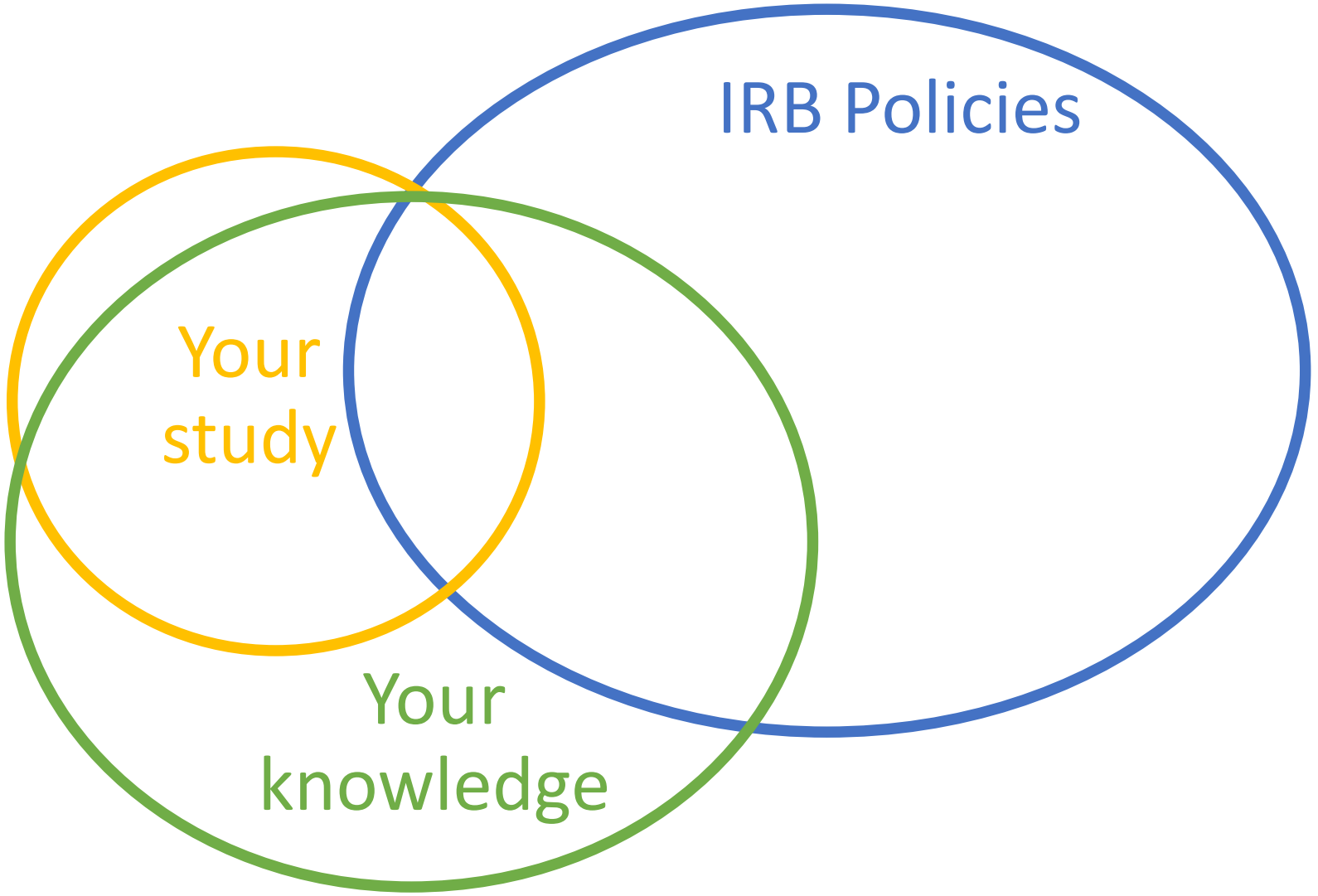
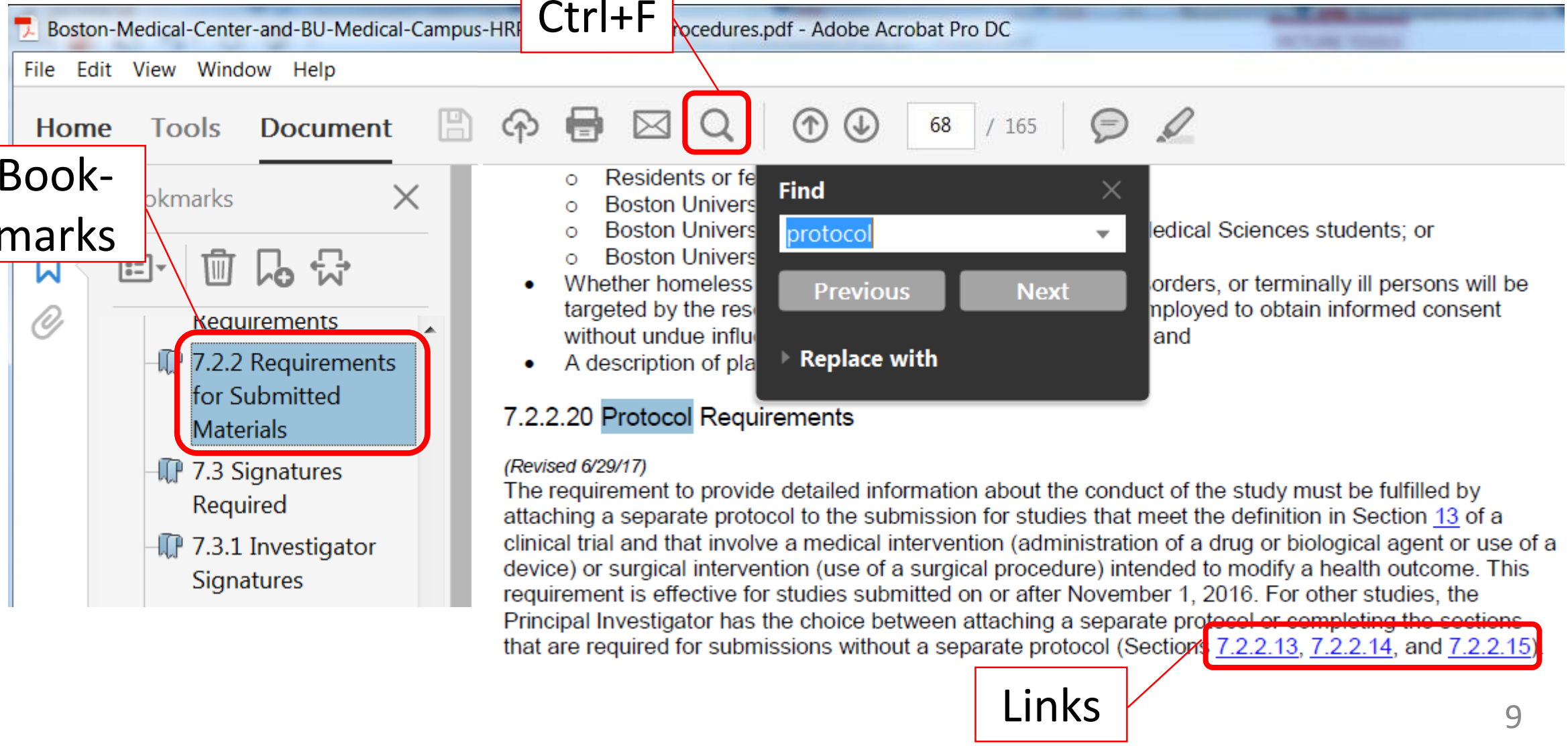

IRB Policies
Your study
Your knowledge

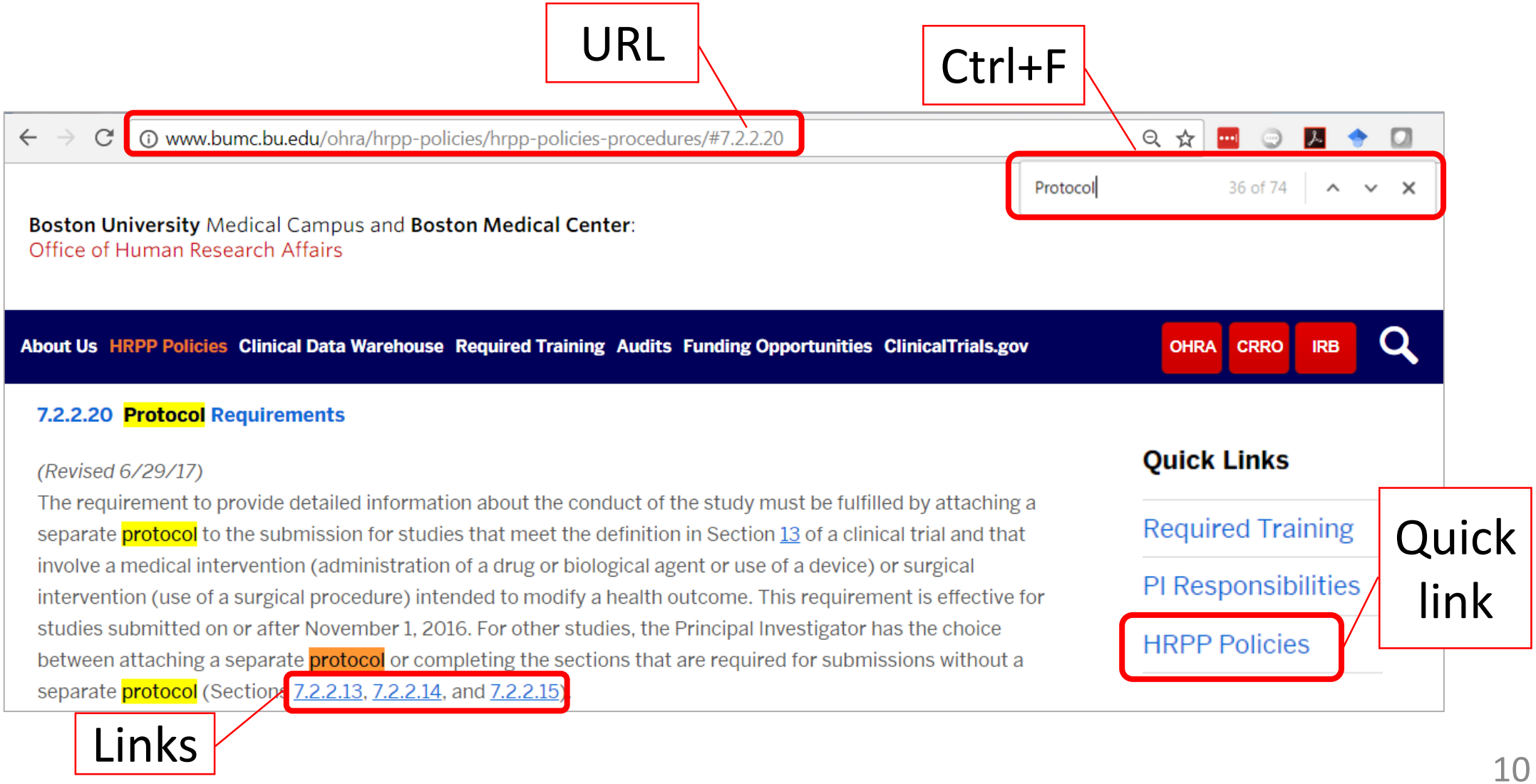
IRB Requirements

- 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 – pdf Version



Policies & Procedures – Webpage Version



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

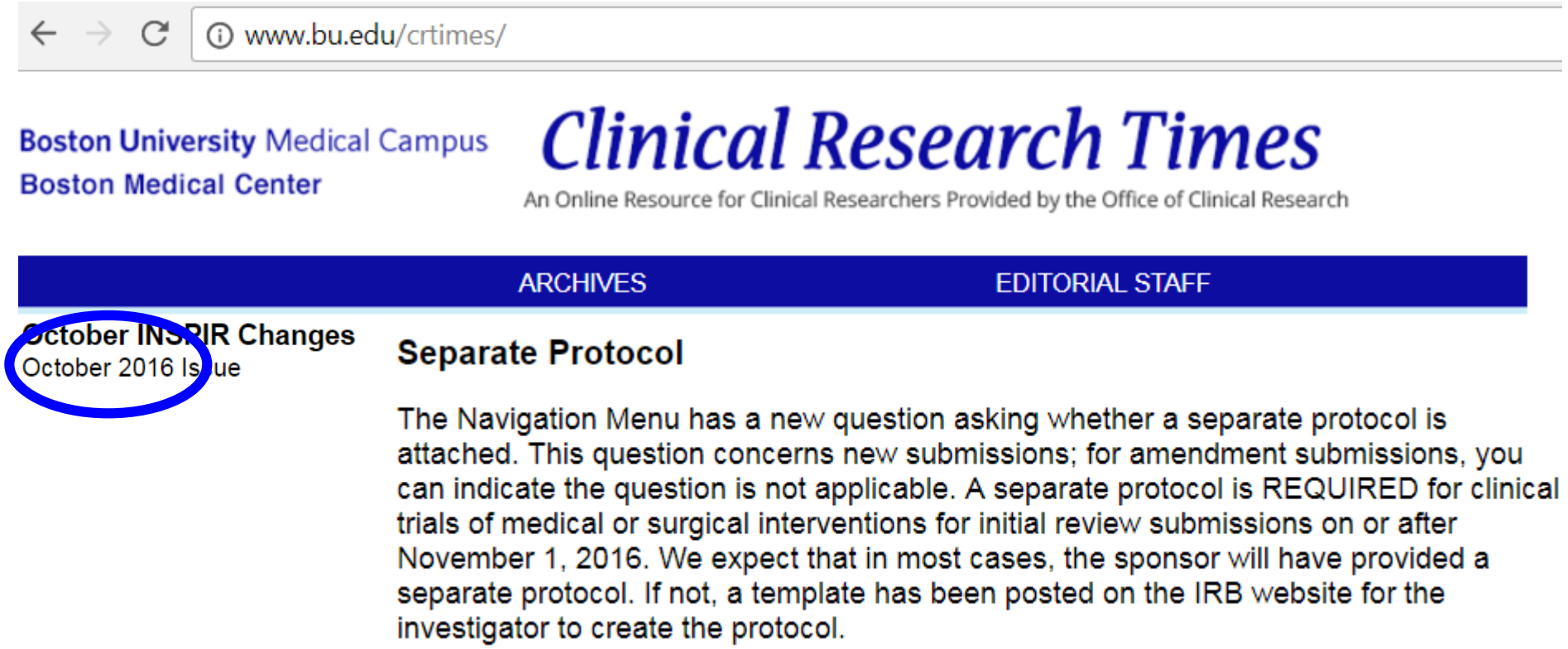
Version number and date

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



CRRO Seminars

http://www.bumc.bu.edu/crro/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

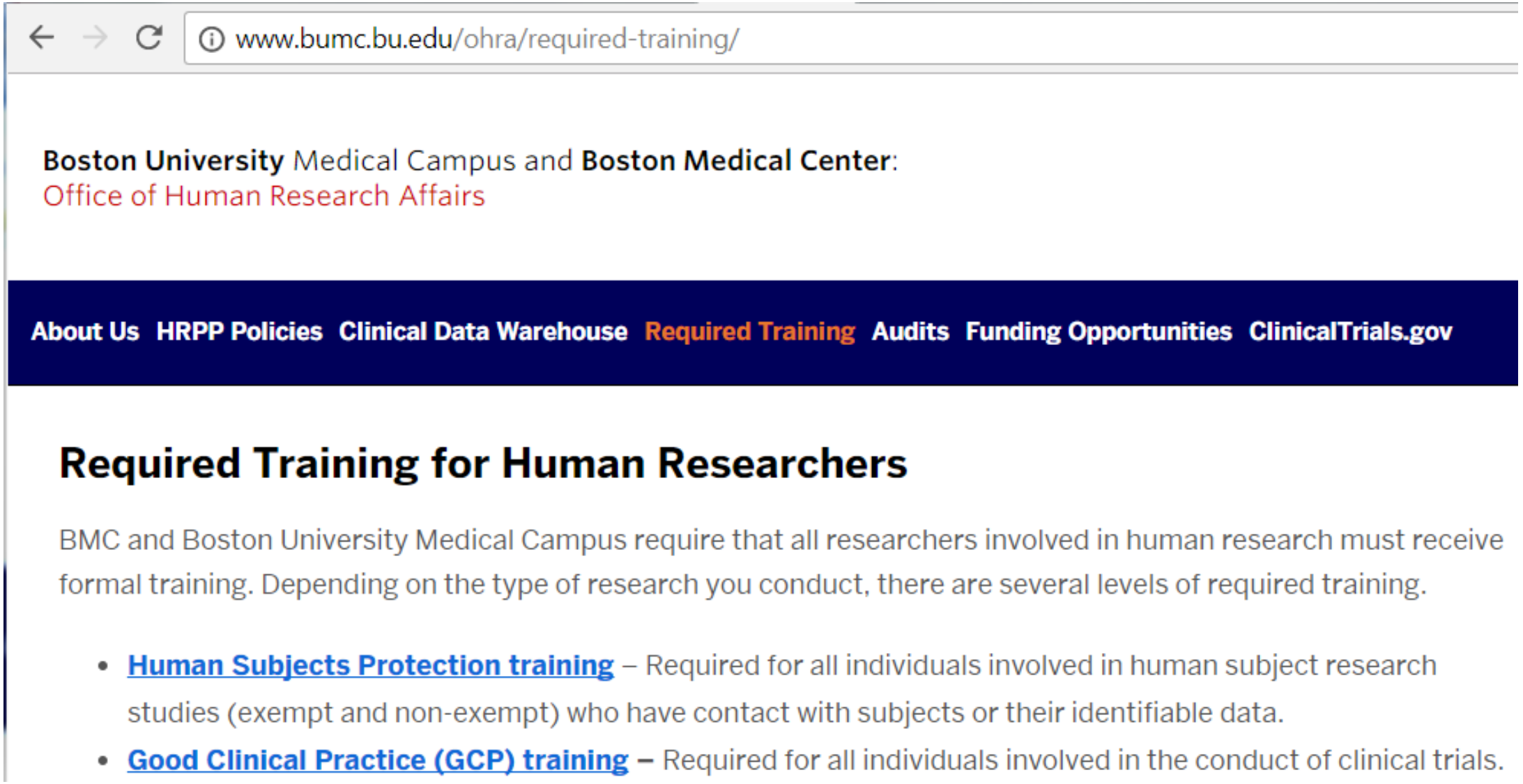
INSPIR Application

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**.


www.bumc.bu.edu/ohra/required-training/
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

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)

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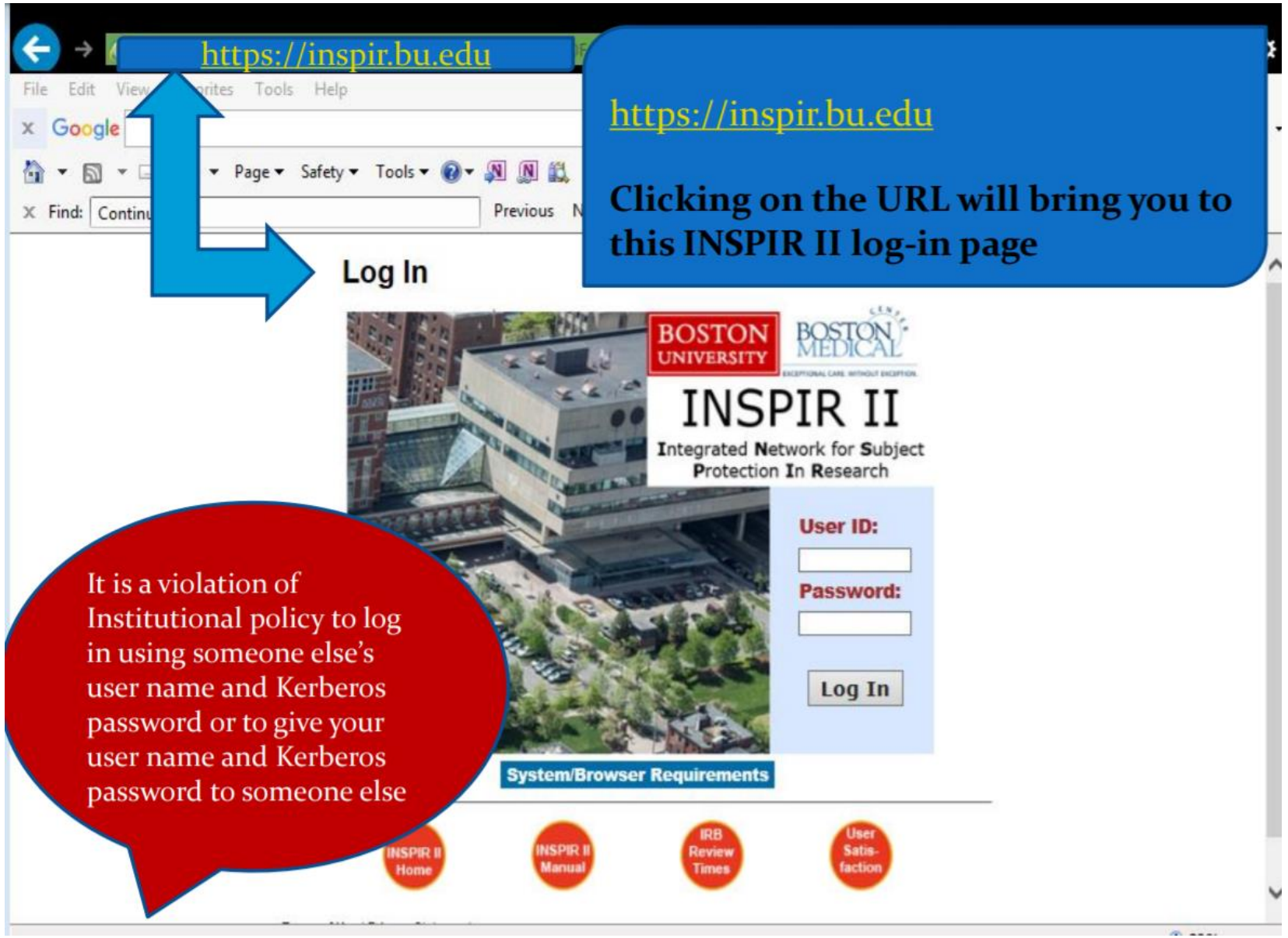
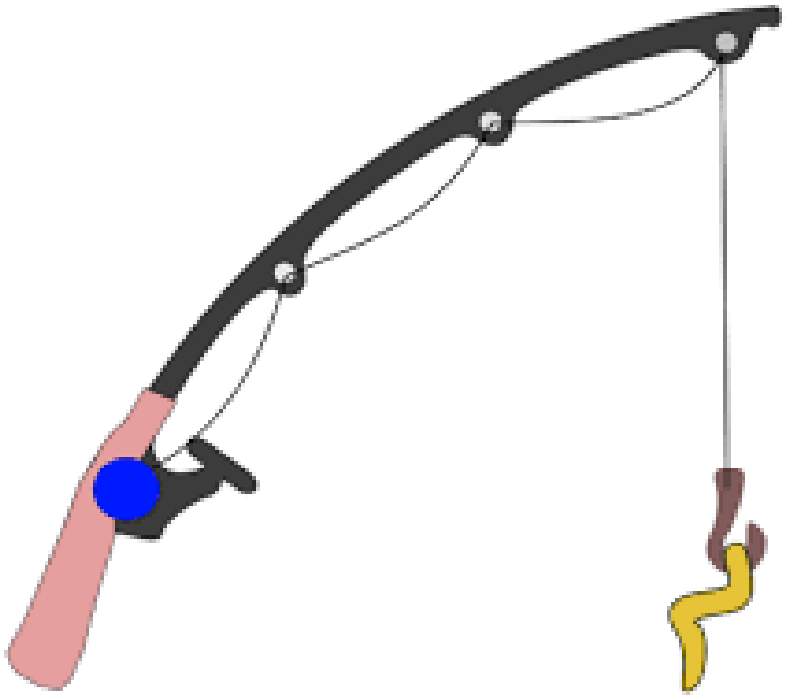
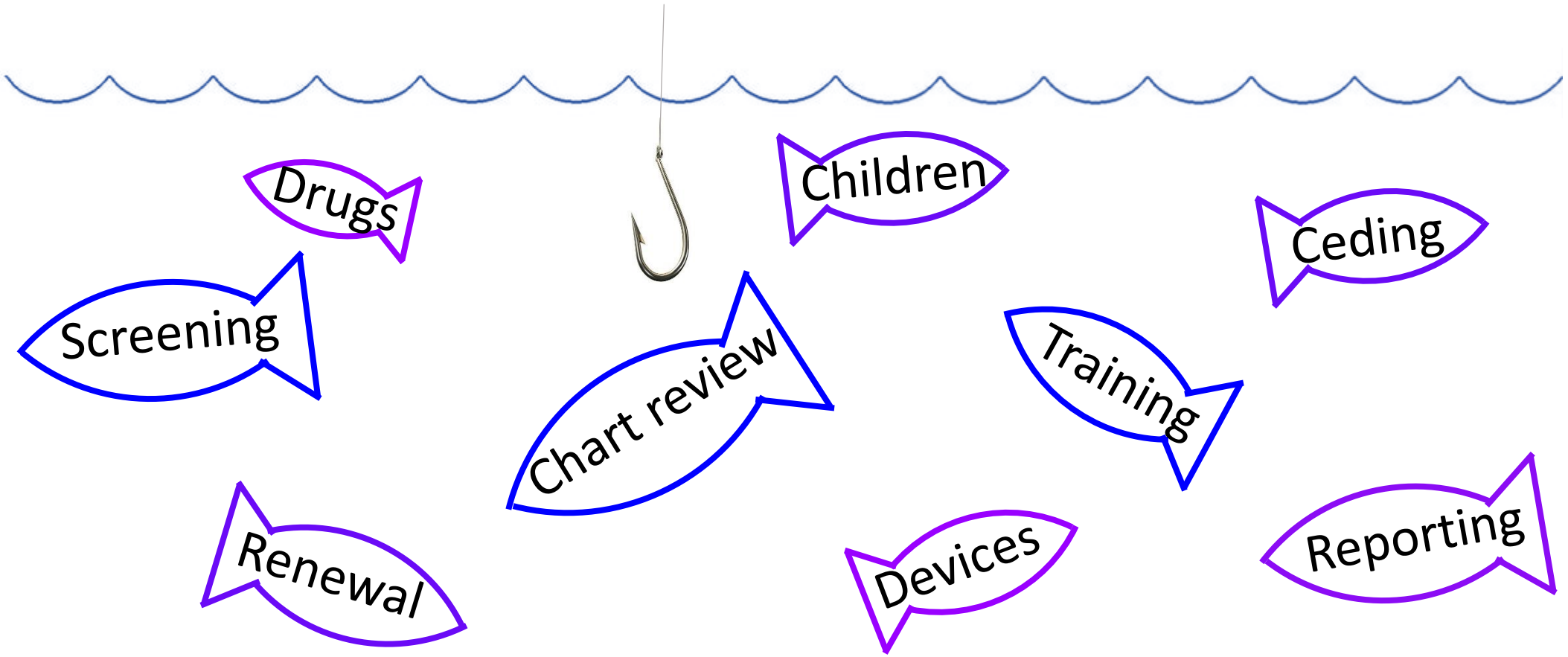

https://inspir.bu.edu
https://inspir.bu.edu
Clicking on the URL will bring you to this INSPIR II log-in page
Log In
BOSTON UNIVERSITY
BOSTON MEDICAL
INSPIR II
Integrated Network for Subject Protection In Research
User ID:
Password:
Log In
System/Browser Requirements
INSPIR II Home
INSPIR II Manual
IRB Review Times
User Satis-faction
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

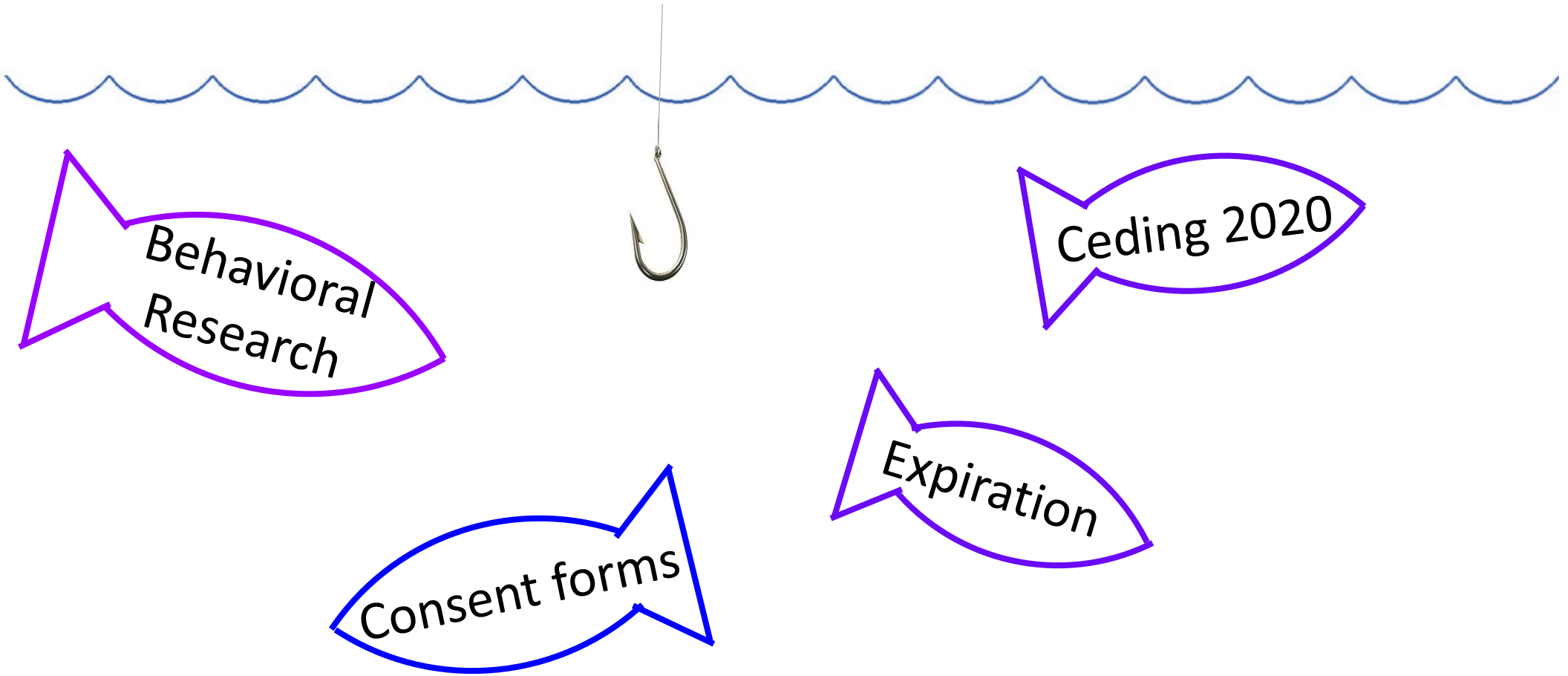
Your Turn



Now


Drugs
Children
Ceding
Screening
Chart review
Training
Renewal
Devices
Reporting

Coming in January 2018



Thank you!