Important Updates about the OHRA, IRB, CRRO and RPN, and the 2018 Common Rule

John Ennever, MD PhD CIP, ***Director, Office of Human Research Affairs***

Matt Ogrodnik, MS CIP, ***Director, BUMC/BMC IRB***

Mary-Tara Roth, RN MN MPH, ***Director, Clinical Research and Resources Office***

Objectives

- Understand what is different and the same between the IRB and OHRA
- Review the expected changes that will occur next January related to the Common Rule 2018
- Describe what you need to do when another IRB will be the IRB for your study
- Learn about new and upcoming developments at the IRB
- Provide updates on the CRRO (including educational offerings), QA Reviews, and the RPN

BOSTON UNIVERSITY

BOSTON MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Updates: OHRP, IRB, CRRO, RPN and Common Rule

John F. Ennever, MD, PhD
Director Office of Human Research Affairs
Boston Medical Center and Boston University Medical Campus

Learning Objectives

Understand

- What is different with OHRA and the IRB – and what is the same
- What are the changes that will occur next January
- What you need to do when another IRB will be the IRB for your study

What is different in OHRA and the IRB

- Tom Moore has retired for Boston University
- I have taken over some of his responsibilities – namely as Director of OHRA
- Matthew Ogrodnik is now the IRB director
- Lin Themelis has been promoted to IRB Administrator

What is the same in OHRA and the IRB

- Tom Moore is still gives me advice on how to handle problems
- I am still available to give advice to Matt and IRB staff
- I am still available to research staff and investigators – although I will probably defer to Matt and his staff when appropriate
- We are continuing to tweak our policies and procedures – just not as rapidly as before

What are the changes that will occur next January

- On January 21, 2019 the new (revised) Common Rule will go into effect
- New consent form requirements
  - Our current templates are structured to meet all of the new requirements
  - Some uncertainty about the new introductory section – a concise and focused presentation of the key information

What you need to do when another IRB will be the IRB for your study

- When you are using another IRB, you are still required to submit an abbreviated application in INSPIR
- Most reviewing IRBs will require a document describing any local issues related to the specific research – this is something that you and the IRB staff work on together

What you need to do when another IRB will be the IRB for your study – Part 2

- Single IRB review (as mandated by NIH) is very new for us as well as most of the other academic IRBs – please be patient
- Do not assume that we can be the IRB of record for you multi-center trial – we usually cannot

Updates: OHRP, IRB, CRRO, RPN and Common Rule

MATTHEW OGRODNIK, MS, CIP

DIRECTOR INSTITUTIONAL REVIEW BOARD

BOSTON MEDICAL CENTER AND BOSTON UNIVERSITY MEDICAL CAMPUS

IRB Updates

Learning Objectives

- What is the new minimal risk exempt category?
- How can I remove someone from multiple studies?
- Who should I contact at the IRB office for questions?

IRB Updates: Exempt Category

- New Exempt “Catch-All” Minimal Risk Category

(13) Minimal risk research without external funding with adult subjects able to provide abbreviated consent where the research does not qualify for categories (7) through (12)

IRB Updates: Exempt Category

- This category can be used when the study qualifies for our "equivalent protections"
- This category **cannot** be used for research that includes:
  - Children
  - Prisoners
  - Adults with diminished decision-making capacity

IRB Updates: Exempt Category

- What research will qualify?
  - Studies with an intervention/method(s) that goes beyond surveys, interviews, and/focus groups, and is not a benign behavioral intervention (category 7)
  - Examples:
    - Effect of a text messaging system on medication adherence
    - Randomized trial of enhanced v SOC patient navigation

IRB Updates: Exempt Category

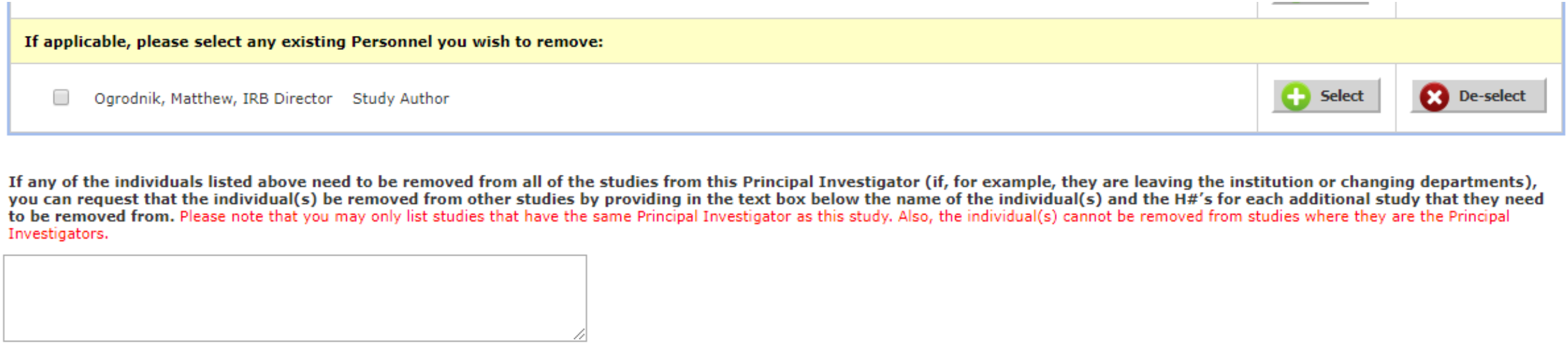
- Benefits of Exemption:
  - Use of Exempt Information Sheet
  - 3 year approval and status check-in
  - Amendments only needed if changes affect exempt determination

IRB Updates: CHCs

- New recruitment letter policy:
  - No signed Project Summary needed from Boston Healthnet if only posting recruitment flyers
  - New BHCHP Policy:
    - All research at BHCHP requires consultation with BHCHP administration prior to IRB submision

IRB Updates: Removing Personnel

New Option for Removing Internal Personnel



IRB Updates: Staff Assignments

As John noted, there have been some staffing changes

- IRB Administrators
  - Lin Themelis
  - Jamie Merrill
    - Please reach out to them (or myself) for questions about new greater than minimal risk studies

Recent IRB Changes

- IRB Analysts: In general, for questions on already-approved studies:
  - Blue- Kathryn Jones
  - Green- Robert Terrano
  - Orange- Emily Assarian
  - Cede Review- Roz Schomer and Jackson Norton

- If your study is Panel Red, please reach out to the analyst who sent the last approval letter

Recent IRB Changes

- Open Office Hours:
  - Weekly drop-in hours, alternating Tuesdays 2-3:30 and Wednesdays 10-11:30 (Calendar on IRB Website)
- medirb@bu.edu or maogrodn@bu.edu

REMINDER: When planning multi-site studies or thinking about ceding review, reach out to IRB early in the process!

Updates: OHRP, IRB, CRRO, RPN and Common Rule

Mary-Tara Roth, RN, MSN, MPH
Director, Clinical Research Resources Office
Asst. Director, Office of Human Research Affairs
Boston Medical Center and Boston University Medical Campus

BOSTON MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

BU Clinical & Translational Science Institute

BOSTON UNIVERSITY MEDICAL CAMPUS

CRRO Clinical Research Resources Office

Supported by the BU CTSI and the Office of Human Research Affairs
Serving all BMC and BU Medical Campus Clinical/human Researchers

Regulatory Service and Education Program

- Consultation services
  - Study implementation
  - IRB application submission
  - Support for sponsor-investigators of FDA regulated research
- Tools and Resources *(web-site based)*
- Education programs for all levels of the research team
- Clinicaltrials.gov support
- Research Professionals Network (RPN)

See our website: www.bumc.bu.edu/crro
See BU CTSI website: https://www.bu.edu/ctsi/

CRRO and OHRA Staff

- Karla Damus: Consultations, Clinicaltrials.gov, education
- Gina Daniels: RPN and Quality Assurance
- Fiona Rice: Quality Assurance
- Abdalla Abdussamad: Quality Assurance

CRRO Trainings

- **Fundamentals training** now 5 hours (not 8), and over one day (not two)
  - Sept 27, 2018, 9:30am – 2:30pm
  - Jan 8, 2018, 9:30am – 2:30pm
  - May 1, 2019, 9:30am – 2:30pm
- **PI training** now 3 hours (not 4.5)
  - Oct 26, 2018, 8:30am – 11:30am
  - Feb 5, 2019, 8:30am – 11:30am
  - June 5, 2019, 8:30am – 11:30am
- Both trainings now $25

http://www.bumc.bu.edu/crro/training-education/

Research Professionals Network (RPN)

- Launched Dec. 2016; membership now at 250!
- RPN Initiatives include:

Ongoing

- RPN Website
- Annual needs assessment/satisfaction survey
- On-going development of study management tools
- Peer-led, Competency-based Workshops
- Web-based discussion forum on Zoho Connect
- Annual networking event
- Mentoring program

Upcoming

- Professional certification test prep
- On-boarding reference guide
- Standardized job descriptions to define a career ladder at BU and BMC

Research Professionals Network

- RPN Workshops
  - 11 new workshops for AY 2018/19
  - 2 levels: Fundamental and Advanced
  - Workshops now offer ACRP and SoCRA credits
  - New collaboration with University of Vermont (one of our CTSI partners)
    - ½ of sessions co-led by UVM staff

AY 2018/19 RPN Workshop Calendar

(http://www.bumc.bu.edu/crro/research-professional-network/resources-programs/rpn-workshops/)

Date	Topic	Presenter	Level*
Sep 18 2:00pm	Why Do We Need IRB Review?	Melanie Locher (UVM) and Donna Silver (UVM)	Fundamental
Oct 16 3:00pm	Single IRB and Reliance Agreements	Kim Luebbers (UVM), Matthew Ogrodnik (BU), Janet Seo (BMC), and Donna Silver (UVM)	Fundamental
Nov 27 2:00pm	Research Design and Data Analysis	Abby Crocker (UVM), Sarah Qin (BMC), and Nellie Shippen (BMC)	Fundamental
Dec 17 2:00pm	Developing Effective Data Collection Tools	Alana Ewen (BMC)	Fundamental
January	Having Difficult Conversations/Words Matter	Alix Rubio (BMC), Nellie Shippen (BMC), and Emily Tarleton (UVM)	Advanced
February	Clinicaltrials.gov	TBD	Advanced
March	Protocol Compliance	Michelle St. Paul (BU)	Fundamental
April	SOP Development	Jessica Howard (BU) and Kimberly Parker (BMC)	Advanced
May	Drugs/Devices (IND/IDE)	TBD	Advanced
June	Preparing for an FDA Audit/Audit Preparedness	Thomas Cheng (BU)	Fundamental
July	Developing Effective Corrective and Preventative Action Plans (CAPAs)	Mary-Tara Roth (BU)	Advanced

Research Professionals Network

- **2nd annual RPN luncheon!**
  - Th. Oct. 4, 12 – 2pm, Hiebert Lounge *(RSVP by Sept. 28)*
  - Recognizing and appreciating the amazing work of our research professionals at BMC/BU Medical Campus
  - Updates on the RPN and awards to two outstanding members of our RPN: a “Rising Star” and an “All Star”

OHRA Quality Assurance Reviews

- Process updated and refined in 2017 w new QA staff
- Triage new studies by a risk-based “tiering system”
- Early stage QA reviews
  - Consultative in nature; emphasis on staff education
- Written report, meeting with PI and staff, follow-up on any required reporting
- Brief Survey of QA Review experience – New this month!

Questions and Discussion

Thank You

for attending the Clinical Research Seminar