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*
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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
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 giving 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 submission
IRB Updates: Removing Personnel

New Option for Removing Internal Personnel

If applicable, please select any existing Personnel you wish to remove:

- Ogrodnik, Matthew, IRB Director
- Study Author

If any of the individuals listed above need to be removed from all of the studies from this Principal Investigator (if, for example, they are leaving the institution or changing departments), you can request that the individual(s) be removed from other studies by providing in the text box below the name of the individual(s) and the H#’s for each additional study that they need to be removed from. Please note that you may only list studies that have the same Principal Investigator as this study. Also, the individual(s) cannot be removed from studies where they are the Principal Investigators.
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
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/corro](http://www.bumc.bu.edu/corro)
See BU CTSI website: [https://www.bu.edu/ctsi/](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
<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Presenter</th>
<th>Level*</th>
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<tbody>
<tr>
<td>Sep 18 2:00pm</td>
<td><strong>Why Do We Need IRB Review?</strong></td>
<td>Melanie Locher (UVM) and Donna Silver (UVM)</td>
<td>Fundamental</td>
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<td>Oct 16 3:00pm</td>
<td><strong>Single IRB and Reliance Agreements</strong></td>
<td>Kim Luebbers (UVM), Matthew Ogrodnik (BU), Janet Seo (BMC), and Donna Silver (UVM)</td>
<td>Fundamental</td>
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<td>Nov 27 2:00pm</td>
<td><strong>Research Design and Data Analysis</strong></td>
<td>Abby Crocker (UVM), Sarah Qin (BMC), and Nellie Shippen (BMC)</td>
<td>Fundamental</td>
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<td>Dec 17 2:00pm</td>
<td><strong>Developing Effective Data Collection Tools</strong></td>
<td>Alana Ewen (BMC)</td>
<td>Fundamental</td>
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<td>January</td>
<td>Having Difficult Conversations/Words Matter</td>
<td>Alix Rubio (BMC), Nellie Shippen (BMC), and Emily Tarleton (UVM)</td>
<td>Advanced</td>
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<td>February</td>
<td>Clinicaltrials.gov</td>
<td>TBD</td>
<td>Advanced</td>
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<tr>
<td>March</td>
<td>Protocol Compliance</td>
<td>Michelle St. Paul (BU)</td>
<td>Fundamental</td>
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<td>April</td>
<td>SOP Development</td>
<td>Jessica Howard (BU) and Kimberly Parker (BMC)</td>
<td>Advanced</td>
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<td>May</td>
<td>Drugs/Devices (IND/IDE)</td>
<td>TBD</td>
<td>Advanced</td>
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<td>June</td>
<td>Preparing for an FDA Audit/Audit Preparedness</td>
<td>Thomas Cheng (BU)</td>
<td>Fundamental</td>
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<tr>
<td>July</td>
<td>Developing Effective Corrective and Preventative Action Plans (CAPAs)</td>
<td>Mary-Tara Roth (BU)</td>
<td>Advanced</td>
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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 with 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