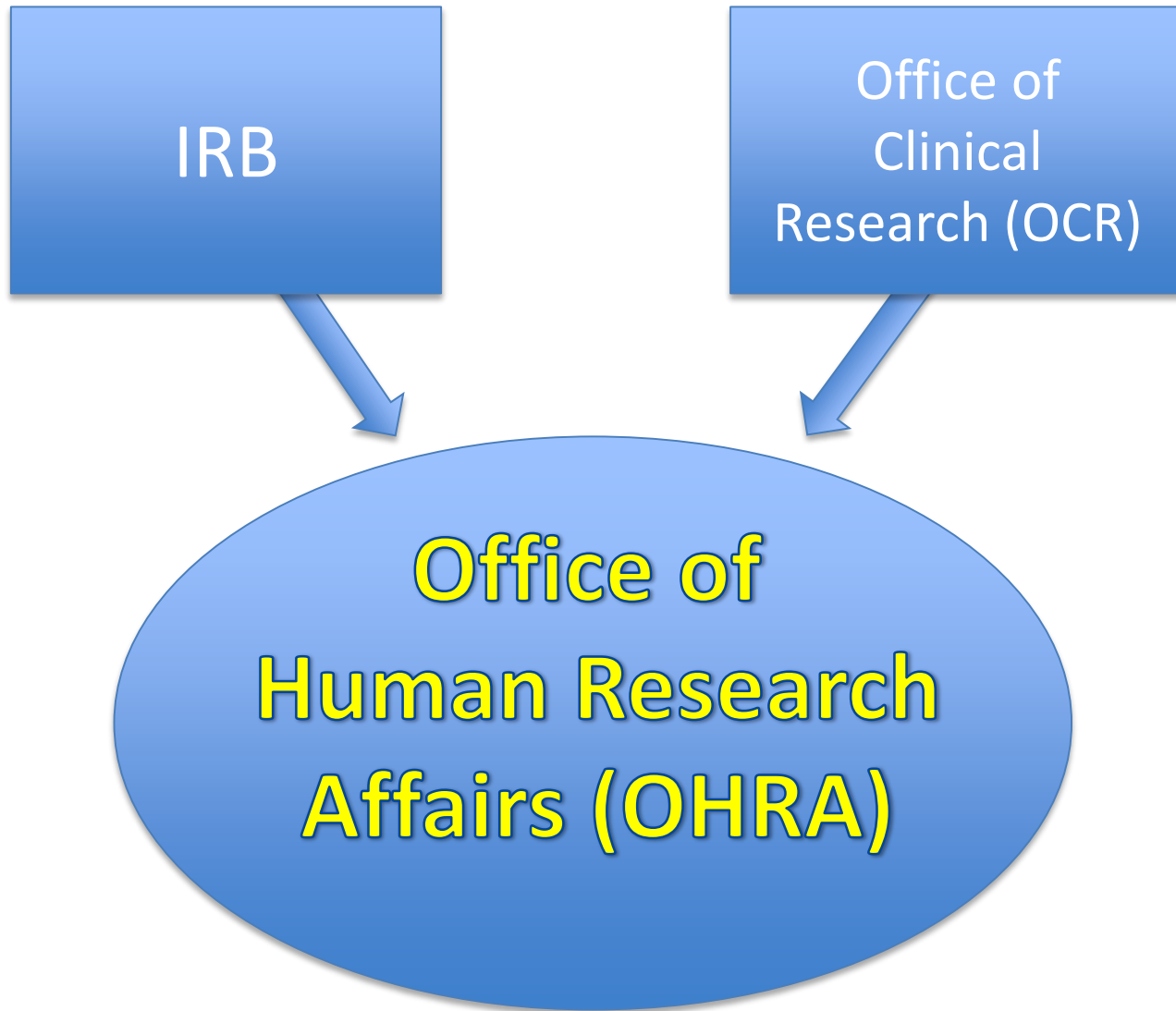# Recent Changes in Oversight of Human Research at BU Medical Campus and BMC: What Do They Mean for You?

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Consolidation

IRB

Office of Clinical Research (OCR)

Office of Human Research Affairs (OHRA)

OHRA

Research infrastructure
Industry-sponsored research
Research clinical data warehouse

HRPP

Serves BU med
campus and BMC

Elements of Our Human Research Protection Program (HRPP)

- IRB
- Human research certification and re-certification
- *Clinical Research Times* newsletter
- IRB Internship
- Clinical Research Monthly Seminars
- Human researcher education
  - Individual consultations
  - Group training
- Quality assurance assessments
- For-cause audits
- Research pharmacy
- BMC's research compliance officer

Are You a BU or a BMC Investigator?

- Your institutional allocation determines where your grants are submitted.

- Lab research—is the lab in BU or BMC space

- Human research—the primary location where the research study team is based

"where research team is based" means the location of the offices where the PI and team write grants, analyze data, and write manuscripts.

It does NOT mean where research visits are conducted.

CRRO Clinical Research Resources Office

Supported by the BU CTSI and OHRA
Serving all BU Medical Campus and BMC Clinical Researchers

Regulatory Service and Education Program

- Consultation services

- Tools and Resources *(web-site based)*

- Education programs for all levels of the research team

- Support for sponsor-investigators of FDA regulated research

- Quality Assurance assessments

- StudyFinder

See our website: www.bumc.bu.edu/crro

Changes to the Required Human Subjects Protection Training

- Initial certification through Collaborative Institutional Training Initiative (CITI)
  - Choice of Biomedical or Sociobehavioral course.
  - Expiration/recertification 3 years after completion.
- Recertification through CITI refresher modules
  - Available automatically prior to CITI expiration
  - Individuals who have current/active certification through BU/BMC outside of CITI, need to attest to their status prior to taking refresher module.
  - Expiration/recertification every 3 years.

New Requirements for GCP Training

- Intro-level GCP training will be integrated into the Basic CITI Human Subjects Protection course.

- For those conducting clinical trials, GCP training will be **mandatory**; 2 ways to fulfill requirement:
    - CITI GCP Course
    - Those taking the "Fundamentals in the Conduct of Clinical Research" in-person training given by the CRRO
        - *fulfilling the requirement this way is coming soon*

QA Assessments

- Any BU Medical Campus /BMC study (including those reviewed by any external IRB) may be selected for a random quality assurance assessment.

- Priority is on (but not limited to):
  - Investigator-initiated
  - Greater than minimal risk
  - Intervention studies

A few additional CRRO updates

- New staff person:
  - Regulatory Education Manager
- Coordinator Network

Industry-sponsored clinical trials

- BMC now negotiates and administers industry-sponsored trials for BMC Investigators (Clinical Trial Office)

- BU negotiates and administers industry-sponsored trials for BU Investigators (BU Office of Sponsored Programs)

Clinical Trial Office

- Component of BMC Research Operations
- Supports BMC clinical trials and clinical research that utilize BMC clinical infrastructure
- For BMC industry-sponsored trials, the CTO is responsible for contract and budget negotiation, financial and billing management, reporting and auditing, account reconciliation and closeout

Clinical Trial Office (2)

- Has primary responsibility for assuring billing compliance for BMC services done as part of research
  - BMC <u>and</u> BU studies
  - Funded <u>or</u> unfunded
- Performs "Medicare coverage analysis" for all research studies that utilize BMC services

How Do Studies Find Their Way to the Clinical Trial Office?

- For sponsored BMC studies involvement of CTO is part of the process
- For all other studies that utilize BMC clinical services investigators submit a VelosCT Pre-qualification checklist to the CTO
- The INSPIR application asks if such a checklist has been submitted and if not, whether any of a list of BMC services will be utilized
  - If no checklist has been submitted and services are used, the application will be routed to the CTO

Separate FWA

- Boston Medical Center FWA – 00023612
  - Components
    - Boston Medical Center
    - Roslindale Medical and Dental Center
  - Institutional Official – Dr. Ravin Davidoff

- Boston University Medical Campus FWA – 00000301
  - Components
    - School of Medicine
    - School of Public Health
    - School of Dental Medicine
  - Institutional Official - Dr. Thomas Moore

AAHRPP Accreditation

- Reasons for seeking accreditation
  - De facto standard (nearly all CTSAs)
    - Increasingly institutions will cede review only to other accredited IRBs
  - Opportunity to carefully evaluate what we are doing and how we are doing it
  - Becomes a continuous process of on-going evaluation and improvement

AAHRPP (2)

- Evaluates three domains
  - Organization
  - IRB
  - Researcher and Research Staff

AAHRPP (3)

- Process
  - Self evaluation of how to meet AAHRPP standards for each domain
  - Assemble written documentation and submit for AAHRPP pre-review
  - AAHRPP site visit to confirm that we are doing what we stated in our documentation
  - AAHRPP Council reviews documentation and the report from site visitors and issues the accreditation

- Cambridge-based, AAHRPP-accredited IRB
- Founded by BU SOM and BCH graduate
- High-quality board members
- Simplified process for submission directly through INSPIR – no requirement for separate application
- Initially optional (can still use WIRB)
- Protocols currently at WIRB stay with WIRB