# Clinical Research Resources Office

**Regulatory Education and Consultation**

**Recruitment Services Program**

**Research Quality Program**

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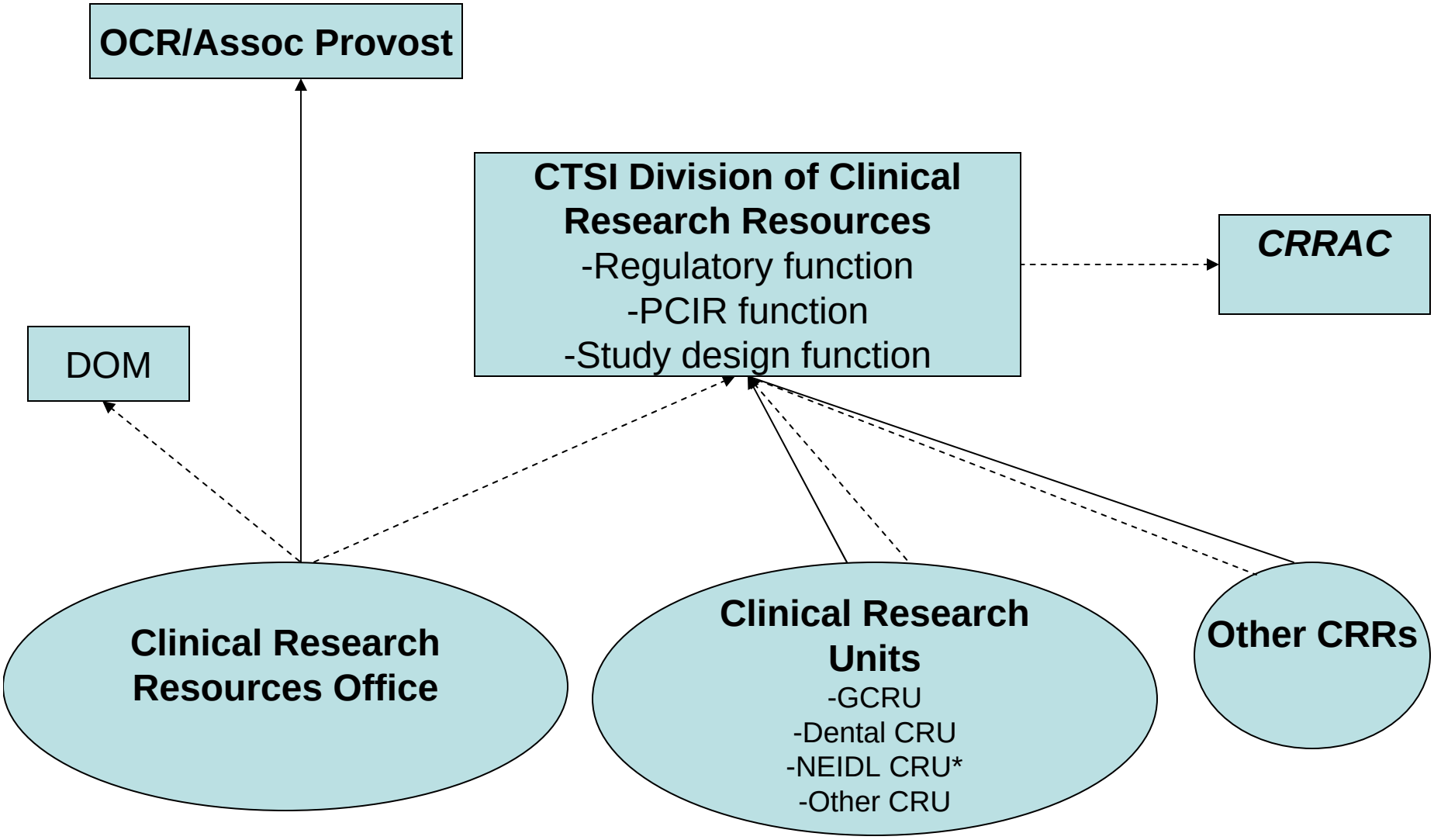


*reports to NEIDL (New England Infectious Diseases Laboratory)
CRR=Clinical Research Resources
CRRAC=Clinical Research Resources Advisory Committee
CRU=Clinical Research Unit
CTSI=Clinical Translational Science Institute
DOM=Department of Medicine
OCR=Office of Clinical Research
PCIR=Participant Clinical Interactions Resources

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# *CRRO Mission:*

*The mission of the Clinical Research Resources Office is to facilitate the design and conduct of ethical and scientifically valid clinical research by providing a range of services, resources and guidance to support BUMC clinical researchers in planning, submitting, conducting and analyzing their research.*

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# *CRRO Goals:*

- ***Facilitate research*** by providing guidance and tools that are relevant, focused, accessible, and current.
- ***Be responsive to needs*** of the BUMC clinical research community, the needs of research participants, and the changes in regulations and policies guiding clinical research.
- ***Centralize expertise and support*** for conduct of clinical research.
- ***Foster Research Participant Advocacy*** by promotion of best practices to ensure safe and ethical conduct of research.

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# *CRRO Staff:*

- **Mary-Tara Roth, RN, MSN, MPH**

  *Director*

- **Kimberly Russell-Lucas, MPH, CCRC**

  *Clinical Research Recruitment Manager*

- **Russell Gontar**

  *Quality Assurance Manager*

- **Linda C. Rosen, MSEE**

  *Clinical Data Warehouse Research Manager*

- **Coming soon**

  *Clinical Research Regulatory and Education Manager*

- **Coming soon**

  *2 Recruitment Specialists*

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# *What we do:*

- **Regulatory Education and Consultation**
- Recruitment Services Program
- Research Quality Program

  - Consultation regarding IRB submissions and study implementation:
    - Pre-review of protocol, DSMP/DSMB development/implementation, consent, recruitment plan, study documentation, etc.

  - Education and guidance on regulatory issues:
    - In formats that are accessible: the info you need, when you need it.
      - Researcher-initiated questions;
      - Seminars (research community, coordinators, new PIs, etc.);
      - Web-based links to guidance and tools;
      - Small group instruction (as determined by needs of study team).

  - Facilitate access to experts:
    Study design, biostatistics, international, pharmacy, IP, clinical areas, etc.

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# *What we do:*

- Regulatory Education and Consultation
- **Recruitment Services Program**
- Research Quality Program
  - Consultation services: Guidance, consultation and tools to assist researchers in developing protocol-specific recruitment plans and completing the IRB application.
    - ReSPECT Website
  - ReSPECT Registry of potential research participants.
  - Web-based list of current studies for researchers (for collaboration) and potential subjects and their clinicians (for recruitment) .
  - Community Outreach & Research Education.

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# *What we do:*

- Regulatory Education and Consultation
- Recruitment Services Program
- **Research Quality Program**
  - Early-stage Quality Assessments.
    - Focus is on assisting studies at an early point in conduct.
    - Identify potential deficiencies before they affect the safety of participants and/or integrity of the study data.
    - Educational/consultative - reports go to PI only.
  - Consultation for preparation for sponsor audit/ FDA inspection.
  - Directed audits as necessary (e.g. requested by IRB).
  - On-going monitoring services for Sponsor-investigators to fulfill FDA sponsor monitoring requirements (21 CFR 312.56; FDA Guidance 1/88, 11/98).*

** Future service offering*

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# *Some examples:*

- How do I write a Charter for a DSMB?
- How do I create a DSMP for a high-risk, 1st in human study?
- What kind of on-going site monitoring do I need to set up to fulfill my obligation as sponsor in an FDA-regulated trial?
- How do I determine if my study requires an IND? And if it does, what do I do?
- How do I develop source document worksheets for my study?
- The FDA has notified us of upcoming inspection… what's involved in an inspection, and what should we do to prepare?

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# *More examples:*

- The IRB has asked me to develop a Corrective Action Plan for a group of protocol deviations… what goes into such a plan?
- How do I define Stopping rules for my study?
- How do I define Adverse Events for a study with a low-risk behavioral intervention?
- How should I organize regulatory files for my study?
- I need to include a DSMP in my NIH grant application… what is a DSMP and how do I develop it?
- What are requirements for documenting my study?

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# Questions?

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