Researchers Take Advantage of the
CTSC Research Concierge Services
Carolyn Apperson-Hansen, Director

How can we help you?
Reaching out for new ideas and collaborations!

The Research Concierge Service (RCS) is the “Front Door” or entryway to all elements of the CTSC program. Through this “Front Door,” researchers from all partner institutions can more easily identify and access the CTSC’s vast resources, both well-established but perhaps unknown and those newly developed. To the uninitiated researcher, and even to clinical research veterans, the complexities of modern clinical research present burdensome, ever-changing regulatory requirements and place ever increasing demands on the researcher and the researcher’s study team.

The services of the RCS currently provide both in-person and virtually:

- **At the initial project design stage**, facilitate and strategize the path forward including
  - Identifying primary, secondary, and safety endpoints to meet the study aims
  - Establish sample size justification needed (i.e., clinical or statistical significance)
  - Address data needs (i.e., data flow diagram, database, research data management, user requirements for data, regulation compliance needs)
  - Address statistical needs
  - Provide tips for Informed Consent Form (i.e., Research team at one site or multiple sites, data storage)

- **Match researchers** to core resources as well as researchers with specialized expertise

- **Identify potential collaborators** (i.e., link researchers across disciplines and institutions)

- **Education**
  - In general, the research process
  - Roles and responsibilities of the study team
  - Navigating multi-disciplinary research processes
  - Proposal development
  - 21 CFR Part 11 requirements for FDA Regulated Studies
  - Development of policies, procedures, and work instructions
• **Once a grant is received**, facilitate and advise on establishing the nuts and bolts of getting a study underway (e.g., discussing formats and sections for protocols, data tools, managing data, locating needed data resources)

• **Provide guidance on regulatory requirements** as well as data safety and monitoring

• **Respond to ad hoc requests** from researchers (e.g., building prototype of adapted blood pressure cuff for preemies)

• **Facilitate data transfer** needs of the institutions when a researcher leaves the institution

• **Facilitate data use agreements** (DUAs) for researchers who need to move data from one institution to another

• **Facilitate establishment** of a DSMB Charter

• **Develop/Maintain a ‘library’ of templates** a researcher can use to get studies up and running quicker and efficiently

• **For researchers new to the institution(s)**, facilitate introduction for doing research at the institution

**Contact the RCS:**

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