

**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:**

[ctsc-research-concierge@case.edu](mailto:ctsc-research-concierge@case.edu)

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Carolyn Apperson-Hansen, Director  
Katie Sturgis, Administrative Assistant

[cva9@case.edu](mailto:cva9@case.edu)  
[kls150@case.edu](mailto:kls150@case.edu)

216 368-0035  
216 368-4669