

Utilizing the CER Strategic Initiative Team

Step 1) Set up a consultation with the CER Strategic Initiative team

- Send an email to cer_si@schsr.unc.edu with information on the following components of your project:

Component	Relevant Questions
Population	What is the patient population of interest? What subgroups will be considered in terms of age, gender, ethnicity, etc.? Do you anticipate that the intervention effects will differ among the subgroups?
Intervention	What is the intervention of interest (e.g., a drug, device, procedure, or test)?
Comparator	What are the alternatives?
Outcomes	What are the outcomes and endpoints of interest?
Timing	What is the time frame of interest for assessing outcomes? Are stakeholders interested in short-term or long-term outcomes?
Setting	What is the clinical setting of interest (e.g., hospital, private practice, community health center, etc.)?
Databases	What database (if any) will you examine? If you are not sure, indicate so.

Upon receipt of your email, the CER Strategic Initiative team will set up a time to discuss your research proposal. A few of the issues that may be discussed during the consultation include:

- Identifying the appropriate study design and data resources for your research question;
- Assessing the advantages and disadvantages of various study designs and data sources;
- Providing information about data use agreement requirements; and
- Providing advice about other TraCS resources.

As you proceed with development of your research plan, keep in mind that the CER Strategic Initiative team can function as either consultants or collaborators for your project. As consultants, we will provide advice about your research plan and assist in the identification and preparation of a database applicable to your research question. As collaborators, our role may include study design, analysis planning, programming assistance, and/or interpreting results.

Step 2) If applying for a TraCS pilot grant, complete your application

- After your consultation with the CER strategic initiative team, complete the application and submit it using the NC TraCS [online system](#).

Step 3) Once any necessary funding is in place, complete the appropriate data use agreement (DUA) and IRB applications

- If your project is using a database available at UNC, it is possible your project may fall under an existing data use agreement (DUA). If your project is not covered by a current DUA (likely for projects using Medicare or Medicaid data), an application for a new DUA will be needed. The CER Strategic Initiative team can assist with the application process. The time from application to approval of the DUA will vary depending on the data source. DUAs for the use of data from The Centers for Medicare and Medicaid Services (CMS) take the longest (approximately 4 months). The exact amount of time will depend on the scope of the DUA and CMS. The one-year project period will not begin until the data use agreement (and any other approvals such as IRB) are in place.
- All projects using the databases available at UNC require IRB approval.