

CRSO: IN THE KNOW

Creating Research Registries
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Navigating the regulations and requirements related to clinical data and research data can be confusing. Registries (i.e. databases, repositories) can be valuable tools for understanding both clinical and research data. Unlike a clinical registry, research registries or repositories involving data and/or specimens require IRB oversight.

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Clinical registries are commonly established for the purposes of diagnosis, treatment, billing, marketing, quality control, or public health surveillance of health-related conditions. Research registries are created and maintained for research purposes. However, clinical registries may be altered to facilitate research (e.g., through the addition of data fields not necessary for the core purpose of the database) and then be considered research registries. Recognizing when your registry represents “research” is very important.

Examples of research databases, registries or repositories include:

- A list of names, diagnosis, and contact information developed and maintained to identify prospective research subjects
- A collection of medical information and/or biological specimens intended for use in future research studies
- A collection of patients’ diagnosis, treatment, and follow-up information intended for and used to conduct generalizable studies on the effectiveness of particular treatment interventions

If you believe that your registry may qualify as research, be sure to submit an IRB application prior to initiating the registry. The requirements for IRB oversight depend on (1) whether or not the data and specimens in the registry or repository include or are linked to individually identifiable health information and (2) the terms of the informed consent under which the data and specimens were originally collected.

Data must always be stored in a manner that is consistent with UNC policies.

Resources Available

[NC TraCS Research Registry Toolkit](#)

The Toolkit includes registry-relevant content about recruitment and engagement, data, and regulatory topics, and focuses solely on registries used for research purposes.

