



Regulatory Guidance for Academic
Research of Drugs and Devices

about ReGARDD

The purpose of the Regulatory Guidance for Academic Research of Drugs and Devices (ReGARDD) Program is to provide a mechanism for academic researchers to seek guidance, education, and regulatory support for their ideas and concepts. Our focus is to move promising products and novel discoveries into clinical trials.

ReGARDD provides academic researchers with the regulatory tools and resources necessary to successfully navigate the pathway from discovery to clinical implementation of new drugs, biologics, and medical devices.

Through our shared website, we offer current best practices for preparing IND and IDE submissions to the FDA and provide easy access to protocol and submission templates, up-to-date federal regulations, and in-depth guidance concerning drug and device clinical research pathways.

By means of our Regional Regulatory Forum, we strengthen the regulatory affairs workforce at each of our affiliate institutions by providing exposure to a broad array of regulatory knowledge. The Forum provides a platform to share best practices, enables discussion of complex regulatory issues, and allows us to benefit from our collective regulatory expertise.

The program, launched in 2015, is a collaboration between the regulatory affairs specialists and experts from North Carolina institutions that receive funding from the NIH Clinical and Translational Science Awards (CTSA) Program.

These CTSA hub institutions currently are the University of North Carolina at Chapel Hill and partner RTI International, Duke University, and the Wake Forest School of Medicine.

Combining the regulatory talents from the North Carolina CTSA hubs and the Research Triangle Park (RTP) area enables sharing of ideas, lessons learned, historical information, and the development of successful strategies to assist the academic researcher in navigating an increasingly complex regulatory environment.

**To learn more about ReGARDD
and to access helpful tools and
resources, see our website at
regardd.org**