



Until every child is well

Institutional Centers for Clinical and Translational Research
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HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

Announcement Office of Research Regulatory Support, Education, and Quality

As opportunities in clinical and translational research have increased, and studies have become more complex and competitive, the Institutional Centers for Clinical and Translational Research (ICCTR) has created the Office of Research Regulatory Support, Education and Quality (ORRSEQ). ICCTR undertook this action in response to the recently approved Research Strategic Plan to support our clinical research community.

The ORRSEQ staff will provide in-person and online resources to investigators in the following three major clinical research areas:

Regulatory Support

In light of the growing number of translational and early phase studies being conducted at BCH, ORRSEQ will oversee regulatory support, investigator support and operational assistance for FDA-regulated studies and studies where the investigator serves as the sponsor. Regulatory tools, templates, SOPs, and policies will be available to help sponsor-investigators navigate the complex pathways that accompany clinical and translational research. This effort will allow BCH to maintain clinical research compliance with Good Clinical Practice, Massachusetts law, institutional policies, and government regulations.

Education

Education opportunities that cover a variety of clinical research topics will be available to BCH clinical research professionals, research nurses, investigators and trainees. These include live presentations and interactive sessions, as well as video recordings so that learners can access the education when it is convenient for them. Available video recordings and upcoming educational offerings can be found on the Institutional Centers for Clinical and Translational (ICCTR) website.

Quality

ORRSEQ's commitment to continuous quality improvement of clinical research conducted at BCH is imperative. The ORRSEQ staff will develop and promote the use of tools, templates, SOPs, and research practice guidelines.

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