

Navigating the Clinical Research Maze at Northwestern University

Objectives

- To introduce all the offices involved in approving clinical research studies at NU
- To explain how the approval process works for each office
- To provide information on what to submit, what to expect, and who to call when you have a question

Departments Involved in Clinical Research at NU

- **OPRS** – Office for the Protection of Research Subjects
- **IRB** – Institutional Review Board
- **OSR** – Office for Sponsored Research
- **ORI** – Office for Research Integrity
- **GCRC** – General Clinical Research Center
- **NM Office of Research** – Northwestern Memorial Healthcare Office of Research
- **NUCATS Institute** – Northwestern University Clinical and Translational Sciences Institute
- **CRO** – Clinical Research Office of the Robert H. Lurie Comprehensive Cancer Center

The Basic Requirements

- At least two approvals need to be gained for any new clinical research study at NU:
 - The Institutional Review Board (IRB) approval
 - acceptable human subject protections in the protocol and consent/assent processes, ethical soundness (requires scientific validity)
 - The Office for Sponsored Research's (OSR) approval
 - financially and contractually acceptable to NU

Other Possible Requirements

- If your study involves other groups on campus (such as Northwestern Memorial Hospital or the General Clinical Research Center), you will need approval for your study from each of these groups as well
- The Institutional Review Board and the Office for Sponsored Research generally will not approve a study until it has already been approved by all of the groups that will be taking part