



# Research in the Works



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## Central IRBs: Enhanced Protections for Research Participants

Institutional Review Boards (IRBs) play a critical role in research, and assure safety and fairness to participants enrolled in research studies. The IRB, made up of researchers, administrative staff, and community members, must make decisions about the safety and fairness of research procedures consistent with:

- Federal regulations;
- State regulations;
- Ethical guidelines; and
- Rules specific to each institution where the research will take place.

As such, the IRB research review can be complicated and lengthy. When the same research study is conducted at multiple sites, the IRB review process is often increasingly complex, costly, and may excessively delay the start of the research study. Multisite studies are often reviewed by multiple IRBs (an IRB review at each site participating in the study), which can slow down study approval, result in duplication of effort, and occasionally produce contradictory decisions by different IRBs. To address these problems, the federal government has promoted the use of single IRBs (referred to as Central IRBs or CIRBs), where a single IRB is responsible for the review of all sites where the research study is conducted. For instance, if a research study will involve the enrollment of participants at all five campus locations in the University of Massachusetts system, only the IRB at the University of Massachusetts Medical School (UMMS) will review the study on behalf of all the locations.

This CIRB process is new and requires careful study to understand its pitfalls and benefits. As such, UMMS and Columbia University received a National Institutes of Health (NIH) grant to study how different institutions conduct reviews of research involving multiple sites. We've completed over 100 interviews with IRB administrators, department chairs, research reviewers, and staff about their



experiences using a Central IRB. Additionally, we have attended IRB meetings around the country where a CIRB method was used. We are now in the process of reviewing, organizing, and coding data from these interviews and site visits.

Our study comes at a critical point, as NIH has recently announced that beginning in 2017 all research conducted at multiple sites must be reviewed by a CIRB. We believe our work will:

- Inform the current NIH mandate of CIRB review;
- Document what works and what doesn't with existing CIRB procedures;
- Highlight potential obstacles faced by IRBs as they transition towards centralized review; and
- Offer solutions to help institutions develop methods to use a CIRB approach.

The ethics of research is of vital importance to all research participants, but even more so for at-risk and disenfranchised individuals who may require additional protections and safety procedures for enrollment in research. We hope our work will result in the development of more efficient, ethical, and safe procedures for reviewing of the ethics of clinical research.

This study is conducted by researchers in the Systems and Psychosocial Advances Research Center (SPARC) in the Department of Psychiatry at the University of Massachusetts Medical School (UMMS) and Columbia University. The team at SPARC is led by Charles Lidz, Ph.D., Professor Emeritus, and includes Ekaterina Pivovarov, Ph.D., Assistant Professor, and Research Coordinators' Alexandra Murray, M.P.A. and Debbie Truong, M.A. Our collaborators at Columbia University include Paul Appelbaum, M.D., Dollard Professor of Psychiatry, Medicine, and Law; Robert Klitzman, M.D., Professor of Clinical Psychiatry; and, Deborah Stiles, J.D., Vice President for Research Operations.

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