Righting Research Wrongs: How US IRBs Respond to Participant Complaints, Concerns, and Injuries
Kristen Underhill, JD, DPhil, Yale University
Stephanie Boegeman, BS, MA, Yale University
Celia Fisher, PhD, Fordham University

Submission Type: Scientific
Topic Area: IRB Operations
Poster Number: 75

Problem Statement: Under US federal regulations, individuals providing informed consent to participate in research must receive information regarding whom to contact in case of a research-related injury or complaint. Informed consent protocols routinely direct participants to contact IRBs with concerns, but there has been little empirical study of participants' research-related grievances and the strategies that institutions use to resolve them. Formal resolution methods such as litigation and insurance are often unavailable or inadequate for addressing the range of research participants and research-related disputes. Research is needed to understand alternative venues for resolving research-related conflicts. This project presents an empirical study of the dispute resolution mechanisms that US research institutions use to address participant complaints, concerns, and injuries.

Methods: This poster presents results of 30 in-depth interviews with IRB chairs and directors at federally funded US hospitals and academic institutions. Interviews took place during 2013-2014 and elicited data on frequency and types of research-related complaints, institutional practices for responding to participants' concerns, options for complaint resolution, involvement of legal counsel, availability of compensation for injuries, and institutional experiences with research-related litigation.

Results: Interviews identified a range of participant complaints and institutional practices for resolution, as well as concerns about accessibility, conflicts of interest, and gaps in federal guidance. Across institutions, IRB personnel suggested that effective institutional dispute resolution practices can protect participants, minimize exposure to litigation, and safeguard relationships with participant communities. Interviewees described institutional practices using procedural justice themes, such as voice, transparency, courtesy, neutrality, and providing participants and research staff opportunities to be heard. Uptake of dispute resolution processes by participants, however, may be low due to discomfort or lack of knowledge; process evaluation was rare; and process development typically did not solicit input from participant or community representatives.

Limitations: This study used qualitative methods and a relatively small sample size; inclusion was limited to hospitals and academic centers; and findings cannot provide generalizable numerical estimates of the frequency and types of participant complaints or dispute resolution mechanisms across institutions.

Conclusions/Next Steps: Research institutions provide a variety of ways for resolving participants' concerns, complaints, and injuries, although these mechanisms may be underutilized by participants. This field may benefit from consulting research on workplace grievances and medical malpractice disputes. Further research is needed to understand how participants and investigators experience research-related disputes.