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## **A New Consortium to Study, Measure, and Improve the Effectiveness of HRPPs and IRBs**

A lot has been written about the fact that we don't have good means of measuring the effectiveness of IRB review, but there have been few systematic efforts to address this evidence gap. That may soon change.

In May 2018, Holly Fernandez Lynch, JD, MBE, Assistant Professor of Medical Ethics at the University of Pennsylvania's Perelman School of Medicine, and colleagues launched the [Consortium to Advance Effective Research Ethics Oversight](#) (AEREO) to make progress on this issue. AEREO's mission is to "improve the effectiveness of Institutional Review Boards (IRBs) and Human Research Protection Programs (HRPPs) in fulfilling their purpose of appropriately protecting the rights and welfare of research participants and achieving other ethical goals," such as promoting justice in research, fostering a culture of ethical concern among researchers, promoting trust in the research enterprise, and facilitating socially valuable, scientifically valid, ethical research.

AEREO brings together [members](#) from 21 leading academic, healthcare, and government institutions and independent IRBs, each participating in his or her individual capacity, with the aim of carrying out empirical research to evaluate the effectiveness of the current system of research ethics oversight and developing evidence-based policies and best practices for effective IRBs and HRPPs.

This project has received support from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), which will permit accredited organizations to use participation in AEREO activities to meet accreditation Standard 1-5, Element 1.5.B, which requires organizations to demonstrate continuous quality improvement.

PRIM&R also endorses this initiative as a means for advancing ethical research. Elisa Hurley, PRIM&R's executive director and a member of the AEREO Consortium, notes that, "a project like this is long overdue, and we're excited to be a part of it. We should all be interested in identifying and promoting research oversight practices that effectively and successfully protect the rights and welfare of research participants and promote ethical research."

We interviewed Professor Fernandez Lynch to learn more about AEREO and how those in our community can support this exciting and important project.

### **What is the problem AEREO is trying to address? Why is this a good time for AEREO to take on this problem?**

At root, AEREO is a response to the fact that we lack good ways to define and measure whether and how well IRBs and HRPPs "work" to do the things they were created to do—most importantly protect research participants and advance ethical, socially valuable research. This is a widely recognized and long-standing concern in the research ethics literature and it means that IRBs and HRPPs cannot be sufficiently evidence-based in their policies and practices.

When we think about IRB quality, what typically gets measured are the things that can be measured with relative ease, such as turn-around times, regulatory compliance, variation between boards, the presence of certain SOPs, and the like. But these are structural and procedural factors that can't tell us whether IRBs are actually achieving the relevant outcomes of interest. Think of them as unvalidated, surrogate measures of the things we really care about.

AEREO seeks to address this problem by defining outcomes directly related to the goals of research ethics oversight and empirically evaluating whether and to what extent the current system is effective in achieving these outcomes. Recent policy changes, such as the revised Common Rule and the NIH single-IRB policy, combined with increasing attention to evidence-based policy and practice and learning health care systems more generally, provide a strong impetus for taking this work up now.

### **Why is AEREO's approach important to advancing ethical research?**

Imagine a drug that doctors have good reason to hypothesize works, but about which there is little to no direct evidence of safety and effectiveness. Patients taking the drug might be OK, but we might worry they will be harmed, or at least not helped—and this raises further questions about whether the burdens, risks, and costs associated with the drug are acceptable. In this case, we would call for rigorous empirical study.

The same should be true for IRBs and HRPPs. Without clear evidence regarding their effectiveness, it might be the case that things are mostly OK—hopefully participants are adequately protected and we're avoiding unethical research, implementing useful reforms, and optimizing efficient and necessary research oversight. But it might also be the case that at least some of those things are not true. And that is why AEREO's approach is important: it will help advance the type of empirical analysis necessary to answer these questions so that we can be confident that the goals of research ethics oversight are being satisfied and make necessary adjustments.

### **Why has it historically proven so difficult to evaluate HRPP/IRB effectiveness?**

One of the best ways to study IRB and HRPP effectiveness would be to conduct randomized controlled trials comparing oversight by these entities to its absence in various contexts. However, this would potentially require waiving applicable legal and ethical requirements and face a host of other hurdles. It can also be difficult to isolate the impact of IRBs and HRPPs given the involvement of other players, such as investigators and sponsors, with roles in subject protection.

Beyond methodological problems, another difficulty is figuring out how to go about measuring amorphous concepts, such as whether IRB oversight leads to an improved culture of research ethics at an institution. Without further specification, whether the relevant outcomes have been achieved may be subjective—for example, whether participants have been adequately protected in a context in which some adverse events are inevitable may necessitate an additional review similar to the one the IRB carried out in the first place. Overall, IRB and HRPP effectiveness are especially hard to measure compared to aspects that are easier and faster to see and quantify, such as procedural quality.

There's one more important barrier, which is that—for a variety of reasons—IRB and HRPP activities have not traditionally been very transparent. Answering these important questions about effectiveness will require collaboration on data collection activities and data sharing between IRBs and HRPPs across sites. All of this will require institutional commitment, trust, time, and money.

### **How does AEREO propose to approach and address this challenge?**

AEREO's first step has been to bring together members from a variety of institutions who are dedicated to evidence-based IRB/HRPP policy and practice and who acknowledge the importance

of studying effectiveness in research ethics oversight. Working together, we are thinking of ways to collaborate on empirical evaluation. Rather than starting with quantitative metrics of IRB and HRPP effectiveness, we plan to start with several qualitative projects. For example, what do patients want out of research ethics oversight, what value do investigators think IRBs/HRPPs add to their research, what value do IRB members and HRPP staff think they contribute to achieving ethical goals? If we can better understand what is important to each of these stakeholders, we can start to ask how well IRB and HRPP policies, practices, and outcomes align with these considerations.

We could also learn quite a bit from evaluating IRB and HRPP correspondence with investigators. What types of issues are raised, what types of changes are required, how closely do these changes track things we might expect to be related to participant protection, and would various stakeholders and experts agree? Other projects may entail seeking a better understanding of how IRBs interpret ambiguous regulatory terms important to protecting participant rights and welfare, such as what counts as practicable when it comes to meeting the criteria for waiver of informed consent or what counts as “special protection” for vulnerable populations, as well as testing different approaches to IRB and HRPP oversight. These projects may not directly measure IRB and HRPP effectiveness, but they are important steps along the way.

### **How do you plan to leverage what you learn through the AEREO project to effect real change in the field?**

One of the most important influences we hope AEREO will have is to draw greater attention to the need for empirical evaluation of IRB and HRPP effectiveness—not just their processes and efficiency. Our goal is to encourage institutions to come up with creative approaches to promote evidence-based practice. HRPPs often operate under resource constraints, and it is easy to focus on regulatory compliance at the expense of other things that matter. We’d like to shift the culture in this space to a vision of HRPPs and IRBs as learning systems committed to a cycle of continuous and collaborative data collection about what is and is not effective, evaluation and dissemination of those data, and application of what we learn to advance the field.

In the projects that we run through AEREO, we will take precisely this approach, developing empirically informed policies and best practices to promote effective research ethics oversight based on what we learn, encouraging implementation of those policies and practices, and carrying out further study.

### **How can the research ethics and oversight community support this project?**

We hope that the research ethics and oversight community will support and participate in AEREO’s work by identifying and collaborating with us on empirical research projects, collecting and sharing data from their institutions, and developing and testing new approaches. AEREO is at its early stages, which means we also need to think creatively about funding this important work.

If you are interested in collaborating on AEREO projects, or if you have a project idea related to empirical evaluation of IRB and HRPP effectiveness that you think the AEREO Consortium should consider, please reach out to [Professor Fernandez Lynch](#).

**Find more information about AEREO—including information about the steering committee, consortium members, related news and resources, and more—on the [AEREO website](#).**

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