

A Systematic Exploration of IRB Review and Oversight of Research On, About, and Including Vulnerable Populations

**Joseph B. Martin Conference Center
Boston, MA
April 30, 2018**

This full-day workshop provides a basic overview of the regulations that cover and explore vulnerable populations using an expanded definition of vulnerability. In this workshop we will discuss examples relevant to the federal regulations as well as examples of populations and situations that result in vulnerable-populations research such as homelessness, disability, substance use, gender and sexual diversity, undocumented residency, etc. This workshop will emphasize the risks in doing research with vulnerable populations, explore practical considerations for IRBs reviewing studies involving vulnerable populations, and provide examples of how to incorporate additional protections.

Learning Objectives:

- Provide an overview of the concept of vulnerability and provide an analytical framework learners can use to identify potentially vulnerable subjects
- Review the basic ethical principles and regulations that guide research with vulnerable populations
- Discuss case examples of different types of vulnerabilities and explore how to think about these examples in the context of clinical and social, behavioral, and educational research.
- Discuss the threshold questions an IRB should address when reviewing research that proposes to include vulnerable populations or situations
- Review the additional risks and burdens that might be imposed upon vulnerable subjects and discuss how to more thoroughly consider the risk/benefit ratio when conducting research with vulnerable populations
- Provide examples of how to incorporate additional protections into informed consent
- Examine the special considerations study teams should address when designing and conducting a study involving these populations and that IRBs should be aware of when reviewing these studies (e.g., payment and undue influence, recruitment, maintaining contact with subjects, confidentiality, etc.)
- Look ahead and review emerging issues and novel approaches to digital and mobile health research including vulnerable populations



PUBLIC RESPONSIBILITY IN
MEDICINE AND RESEARCH

SPEAKERS

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AGENDA

7:30-8:30 AM	<i>On-Site Check-In (breakfast on your own)</i>
8:30-9:15 AM	Welcome and introduction Defining vulnerability according to the regulations
9:15- 10:45 AM	Subpart determination Case examinations and discussion
10:45-11 AM	<i>Break</i>
11:00-12:30 PM	Beyond the regulations: populations on the edge
12:30-1:30 PM	<i>Lunch</i>
1:30-3:00 PM	Beyond the regulations: populations on the edge (continued)
3:00-3:15 PM	<i>Break</i>
3:15-4:30 PM	Digital health & vulnerable populations: novel approaches questions and answers
4:30 PM	<i>Adjournment</i>

Please note this agenda is subject to change.