

eScholarship@UMassChan

Judy Savageau on The IRB Process in Human Subject Research

Item Type	Blog Post
Authors	Savageau, Judith A.
Citation	Savageau J. A. (2012 May 30). Judy Savageau on The IRB Process in Human Subject Research. [Web Log Post]. Retrieved from http://aea365.org/blog/?p=6486.</p>
Download date	2025-04-27 13:00:51
Link to Item	https://hdl.handle.net/20.500.14038/34643

The IRB Process in Human Subject Research

Hello! I'm Judy Savageau, faculty, researcher, and IRB representative for the University of Massachusetts Center for Health Policy and Research. I want to bring attention to the need for us to be mindful that our stakeholder groups are often 'subjects' in our evaluation research.

Why are there ethical concerns? Like research, evaluation involves human subjects. Study participants, vital to our understanding and advancing knowledge related to particular issues and processes, may experience risks and inconveniences with no direct benefit. Most investigators conducting research (whether clinical, population-based, evaluation, educational, policy or the basic sciences) must have their studies approved by their Institutional Review Board (IRB). The IRB defines 'research' as 'a systematic investigation designed to develop or contribute to generalizable knowledge'. While much of our evaluation work may not need IRB approval, there are many instances where we need oversight.

Many stakeholder groups have their own internal review processes whether as a state agency, a clinical practice, local school district, or cultural group. Multiple approvals may be needed if working with many different stakeholder groups. IRBs are particularly cautious, yet can be very helpful, when we include vulnerable populations: children and teens, elders, pregnant women, inmates, persons with cognitive impairments, mental illness, or other disabling conditions. Human subject protection involves capacity to consent, freedom from coercion, and comprehension of possible risks and benefits. Challenges arise when subjects aren't aware of potential risks, or understand that their participation is voluntary and that they have the right to withdraw at any time.

The quintessential requirements for the ethical conduct of human subject research include:

- **Respect for persons** - recognizing and protecting autonomy of individuals through the informed consent process;
- **Beneficence** - protecting persons from harm by maximizing benefits and minimizing risks; and
- **Justice** - requiring that benefits and burdens of research are distributed fairly.

Hot Tips:

- Be mindful of recruitment incentives whether cash, gift cards, free services, raffle prizes, and more.
- Consider whether paid participants are recruited fairly, informed adequately, and paid appropriately
- Take into consideration the subjects' medical, employment, educational status, and their financial, emotional and community resources.
- Consider whether incentives constitute undue inducements or coercion. We want to acknowledge a person's time, travel costs, and other expenses but, we must ensure participation is truly voluntary.

Rad Resources:

- ♦ Academic institutions are guided by federal guidelines through the [Office of Human Research Protections](#). This website has historical information about human subjects research, plus many useful references and links.

- ◆ [Essentials of Research Ethics for Healthcare Professionals.](#)
- ◆ [Payment of Clinical Research Subjects.](#)
- ◆ [Ethics in Human Subjects Research: Do Incentives Matter?](#)
- ◆ [Human Subjects Issues and IRB Review in Practice-Based Research.](#)