

Equitable Selection of Subjects: Equality Versus Fairness?

Journal of Empirical Research on
Human Research Ethics
2017, Vol. 12(2) 124–125
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DOI: 10.1177/1556264617698127
journals.sagepub.com/home/jre



Dear Practical Ethicist,

Our institution serves a community that is generally poor and medically underserved. When our investigators conduct research, they recruit participants from our patient population and the local area. Some of our Institutional Review Board (IRB) members have expressed concern about this, feeling that recruiting from this community is not consistent with the principle of equitable subject selection. When we discuss this with investigators, though, they raise the reasonable question of how they can do research that may ultimately benefit our patients, if they can't do research involving patients they have access to. How should we think about this?

Sincerely,

Enrollment Questions Use All Language

Dear EQUAL,

A fundamental tenet of ethical research is that selection of subjects must be equitable. Determining whether this is true for a given research study is one of the most subjective and difficult decisions that IRB/Research Ethics Committee (REC) has to make.

Equitable selection is about fairly sharing the benefits and burdens (possibility of harm, inconveniences) of research. The benefits of research are the anticipated benefits to subjects as individuals, and the benefit of the knowledge expected to the population affected the results of the research. The burdens may apply to individual subjects, or may apply to a group of people, such as the residents of a county in which a research project is conducted. To consider the distribution of the benefits and burdens, the IRB/REC has to first make the analysis of the risks and potential benefits of the research.

Equitable does not mean equal. The *fair* sharing of the burdens and benefits of research does not necessarily mean *equal* sharing. If I wash the dishes and my friend dries the dishes and places them into the cabinets, we might say that we have equitably divided the work, but we have not equally divided the work. In the same way, the fair sharing of burdens and benefits does not necessarily mean the equal division of burdens and benefits. This is what makes the evaluation of equitable selection so challenging. Determining equalities is easy, but judging fairness is subjective.

Subjects who live in London might have access to research conducted at local universities that individuals in rural

Australia may not. Research conducted in a women's college might not enroll men. Research on therapies for prostate cancer will not enroll women. Research on improving the quality of magnetic resonance imaging (MRI) will not benefit populations who live in developing communities who struggle for clean drinking water and have no access to an MRI. However, we would not consider these inequalities to be unfair or to say that this research cannot proceed because everyone does not have equal access. Equitable selection should be assessed in the context of the purpose of the research and the setting in which the research is conducted. Consideration of the setting should also include consideration of the stage of the research and the rationale for eligibility criteria; there may be valid safety or scientific reasons to exclude populations such as women of child-bearing potential or persons with HIV infection, especially in early studies.

The assessment of equitable selection should also be proportional to potential risk and potential benefits. When research risk is minimal, there essentially cannot be unfair sharing of the burdens (risks) of the research. When research holds out no prospect of direct benefit to the research subjects, there essentially cannot be unfair sharing of the direct benefits of research to individual subjects. There can, however, be unfair sharing of societal benefits—for example, if “nontherapeutic research” such as pharmacokinetic studies of a drug in healthy volunteers were being performed in a population or community that will never have access to the benefits of the drug as a therapy. As risks and potential benefits increase, the degree of fairness required in the distribution of those burdens and benefits increase. When research involves an intervention that is available (and reasonably accessible) outside the research context, it is difficult to justify that individuals not chosen as subjects are deprived of the research benefits.

The effect of risks and potential benefit on fairness becomes especially nuanced when research involves populations vulnerable to coercion or undue influence. Common issues arise with research involving children, adults unable to consent, and prisoners. With greater than minimal risk research involving vulnerable populations, IRB/RECs typically insist on a very clear relationship between risks and potential benefits to find that there is equitable selection of participants. We allow autonomous adults to be altruistic and volunteer to take risks solely for the benefit of others with no possibility of direct benefit. We typically do not allow vulnerable populations to be

altruistic in the same way; for example, most IRB/RECs would not approve a nontherapeutic bioequivalence study in a subject population with advanced dementia. Research on vulnerable populations typically must provide a direct benefit to subjects or, if there is no benefit, have a high degree of potential scientific benefit that will benefit similar populations in the future.

In summary, to approve research, research ethics committees must determine that selection of subjects must be equitable. Equitable selection is about fairly sharing the burdens and benefits of research. The IRB/REC cannot make a determination about equitable selection until there has been an analysis of the risks and potential benefits of the research. With minimal risk research, there can be no unfair sharing of the burdens; in research with no direct benefits to participants, there can be no unfair sharing of direct benefits, although sharing of societal benefits should be considered. Fair does not mean equal and the context of the research in terms of setting, stage, and purpose affect the judgment of fairness. When research involves populations vulnerable to coercion or undue influence, the standard for risks and potential benefits is ratcheted up. Determining whether subject selection is equitable often raises tensions because we have different standards for fairness. However,

ethics committees should see this diversity as a positive part of the ethics review process.

P. Ethicist

Author Biographies

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Jeffrey A. Cooper, MD, MMM, is a physician, basic science investigator, clinical investigator, and manager with many years of ethical review experience as a member and chair of an IRB. He left medical practice in 2002 to help start the Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP), where he was responsible for the development and operation of the accreditation process. He is currently vice president of process and strategic improvement for the WIRB-Copernicus Group.

Lindsay McNair, MD, MPH, MSBioethics, is a physician, clinical investigator, and former academic IRB member who has spent most of her career working in clinical research for the pharmaceutical and biotechnology industry, with a specific interest in ethical drug development research. She is an adjunct faculty member at Boston University and is currently the chief medical officer for the WIRB-Copernicus Group.