Modern research ethics has generally centered around ensuring the priority of individual rights and welfare over society’s interest in pursuing medical knowledge. As the Declaration of Helsinki states, “in medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.”

This emphasis on protecting individuals emerged in part as a response to what the Belmont report called “troubling questions” raised “by reported abuses of human subjects in biomedical experiments.” However historically warranted, research ethics’ individualistic and subject orientation has left investigators, ethics committees, policy makers, and human subjects poorly equipped for negotiating the ethical problems that arise when clinical studies pose risks to nonsubjects. These nonsubjects (whom I will call “bystanders”) can include family members, caregivers, medical personnel, members of certain communities, unrelated third parties, or society in general.

As researchers pursue applications like gene transfer, xenotransplantation, or live-virus HIV vaccines, bystander risks are likely to occupy a more central position in ethical deliberations. Nevertheless, medical research has long involved bystander risks. In what follows, I survey various clinical research activities that involve burdens and risks for bystanders. Although research bystanders probably deserve some form of protection, doing so would generate numerous complications for research ethics. I close by urging a more sustained inquiry into the ethics of research involving bystander risk and provide a series of questions that may help guide that exploration.

Physical Risks

At least one high profile instance demonstrates that bystander risk in clinical research is hardly unique to today. This involved the Tuskegee Syphilis study, which prevented approximately 400 men with late-stage syphilis from obtaining treatment for their condition. Normally, late-stage syphilis is not contagious. However, two circumstances surrounding this study suggest that family members, children, and the sexual partners of the male subjects may have been at risk of contracting syphilis. First, medical historians have speculated that some of the men in the study might not have been in the late stage of syphilis. If so, they would have been contagious. Second, persons in the early phases of the late-stage syphilis are also contagious. Observations like these led one historian to conclude that “the most glaring gap in the data [collected during the Tuskegee study] is the lack of any investigation of the