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## The Legacy of the Tuskegee Syphilis Experiments for Emergency Exception From Informed Consent

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**See related article, p. 72.**

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In November 1996, the US Food and Drug Administration and the Department of Health and Human Services developed regulations allowing research to be performed with emergency exception to informed consent when the research participant is in a situation that is acutely life-threatening and a condition is being studied for which currently available treatments are untested or believed to be unsatisfactory. The regulations require the potential patient to be unable to consent because of the acute clinical condition, and there must not be time within the proposed therapeutic window to contact the legally authorized representative to obtain prospective consent. Furthermore, the possibility must exist that the patient will benefit from participation in the study. These regulations create a requirement for public notification and community consultation regarding the project before implementation.<sup>1</sup> Public notification is meant to ensure that the community is aware of the study before implementation, whereas community consultation is intended to provide the local community an opportunity to provide input to the institutional review board about the acceptability of the proposed research.<sup>2</sup> The rules were designed to balance the competing needs of respecting individual patient's rights with performing resuscitation research to better treat the community. How well they succeed will depend on

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researchers' willingness to listen to community concerns.

In this issue of *Annals*, Shah and Sugarman<sup>3</sup> report on experiences from 4 studies with efforts to inform the community and obtain community consultation when doing research using the new federal guidelines for exemption from consent for emergency research. They note important themes: community members are concerned about racial bias, and they want to know how to prospectively refuse participation in the study. The authors note that the concerns of minority patients being unfairly burdened may be legitimate because trauma centers (and academic health centers) are concentrated in inner cities, and minorities are disproportionately affected by violent crime. These themes raise questions about justice.

What is justice? Webster's dictionary defines justice as the upholding of what is right and lawful, especially fair treatment or punishment in accordance with honor, standards, or law.<sup>4</sup> Justice is related to the idea of human equality found in many traditions. The ancient Greeks saw all human beings as equal sparks of Zeus, whereas in Hindu traditions, human beings have an equal destiny through the cycles of reincarnation. Christianity is also based on human equality. In secular thought, Thomas Hobbes, Rene Descartes, and Karl Marx all consider equality a basic axiom. The US constitution and democratic principles are based on the idea of human equality (although, originally, this equality was limited to white men).<sup>5</sup>

Why justice? Justice is the principle that guides our actions in regard to others and is the ethical principle often evoked when the interests of individuals or groups compete. When we must make a decision that involves competing interests of individuals or groups, then justice should guide our actions. Research participants are being asked to participate in a study to gain knowledge that may benefit the community as a whole. There may or may not be any benefit to the individual participant. Thus, participation in research is primarily an altruistic act meant to benefit others.<sup>6</sup> Normally, the interests of the individual are protected by the use of prospective, informed consent. This allows the individual to decide

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whether or not he or she wants to participate, understanding that there may be no personal benefit. However, many emergency medicine and acute resuscitation research questions concern the initial management of unstable patients whose critical illness or injury renders them unable to give prospective informed consent for research.

Beauchamp and Childress<sup>7</sup> note that concerns about the relationship between economic and social classes of persons and the selection of human participants for research has been a long-standing issue related to justice. Enrollment in studies would be unjust if distinctions are made between classes of persons who are actually similar or if there is a failure to make distinctions between groups of people who are actually different.<sup>7</sup>

The legacy of the Tuskegee syphilis studies makes race a very real concern in any research study considering the use of exception from consent and raises serious questions about the application of justice or fair, equal treatment. Starting in the 1930s and not ending until 1972, the US Public Health Service studied 399 black men with tertiary syphilis from Macon County, AL. Most of the men were poor and illiterate. From the beginning, it was decided not to provide treatment for the disease in order to study its natural course. When penicillin became available as an effective treatment in the 1940s, it was again decided not to treat these men. There is no evidence that informed consent was ever obtained; in fact, it appears that many of the men believed that they were being treated, not just observed. As a natural consequence of this study and other historical events, black people in the United States have come to distrust the health care and research community. For example, a *New York Times* poll done in 1990 found that 35% of black church members believed that AIDS was a form of genocide and 10% believed that it was deliberately created in a laboratory to infect black people.<sup>8</sup> Levine<sup>9</sup> noted in 1983 that the Tuskegee studies placed black patients under the control of white physicians. This meant that "the socially franchised studied the socially disenfranchised."<sup>9</sup> In his article, Levine raised similar concerns about AIDS research and proposed that the homosexual community should be viewed as another

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disenfranchised minority. Shah and Sugarman<sup>3</sup> have shown that similar concerns exist in minority communities in 2002. With these concerns in mind, is it possible to design exception from consent research including community consultation and public notification in ways that might satisfy the concerns of minority groups? Maybe. Jones<sup>8</sup> ends his case study of the Tuskegee studies with the conclusion, "Hidden within the anger and anguish of those who decry the experiment is a plea for government authorities and medical officials to hear the fears of people whose faith has been damaged, to deal with their concerns directly, and to acknowledge the link between public health and community trust." Properly performed, sensitive community consultation and public notification for research that is truly designed to benefit individuals in all communities, including minorities, has a chance to restore that trust, but the concerns of minority groups and the legacy of the Tuskegee studies cannot be ignored. These very real concerns must be considered and addressed when designing research projects and the community consultation and notification that accompany those studies.

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