The Guatemalan Syphilis Trials, Community Engagement, and the Common Rule

Susan Reverby’s revelation of U.S. Public Health Service-sponsored studies of syphilis, chancroid, and gonorrhea in Guatemala in the 1940s rattled the science policy and ethics communities in both countries. The syphilis studies were particularly disturbing, as they involved the intentional infection of individuals: sex workers, prisoners, psychiatric patients, and Guatemalan soldiers, without rescue treatment. The studies were funded by agencies of the Public Health Service (PHS), namely, the National Institutes of Health, through grants to the Pan American Sanitary Bureau, and with the collaboration of major research institutions, including Johns Hopkins University and the Rockefeller Foundation.

The revelations gave rise to high-level government responses, including an apology from President Obama and two separate reports by the U.S. Presidential Commission for the Study of Bioethical Issues. The Guatemalan government prepared its own report. These documents allow for a fascinating comparison of perspectives on the studies by government commissions in the United States and Guatemala. A class-action lawsuit, launched by the research participants and their relatives against defendants, including the Rockefeller Foundation, Johns Hopkins University, and Bristol-Myers Squibb, is making its way through the U.S. courts. Coincidentally, the Guatemala studies came to light in the run-up to the revisions to the “Common Rule,” the U.S. regulations governing the protection of human subjects in federally funded research, revisions due to take full effect on January 21, 2019.

The current legal proceedings and implementation of the Common Rule revisions offer a rare opportunity for reflection on U.S. federal research ethics policy in light of the harms alleged in the Guatemala syphilis trials. Here, we examine whether the updated procedures and mechanisms of institutional accountability reflected in the revised Common Rule would render the harms experienced by the Guatemalan people in the 1940s “ethically impossible” now, as the title of one report by the U.S. presidential commission would suggest.

“Ethically Impossible”: STD Research in Guatemala from 1946 to 1948 describes harms to individual research subjects and violations of professional conduct standards, with emphasis on the inadequacy of consent, the vulnerability of the subjects, and the unacceptability of the risks they were subjected to, consistent with the individual and regulatory focus of the Common Rule. “Ethically Impossible” does not critically examine the social, economic, and political context that formed the backdrop for this research. In contrast, the Guatemalan report reflects a much broader interpretation of the harms incurred, noting, “While biomedical and psychological harm were caused, other dimensions exist such as the social harms whose roots are not immediately revealed, and which in the name of human justice and national dignity, require profound inquiry to fully understand.”

According to the Common Rule, consideration of the possible long-range effects attributable to research is beyond the scope of the risk-benefit assessments that institutional review boards are required to conduct. However, the U.S. presidential commission’s second report, Moral Science: Protecting Participants in Human Subjects Research, recognizes a potential pathway to re-
spect ethically relevant interests beyond the protection of individual research participants:

Effective community engagement provides an additional layer of safeguards by providing the community with opportunities to thoroughly weigh and accept or reject the risks and benefits of research activities, discover possible implications of research that might have unintended consequences to the host community, and independently debate the effectiveness of research protections. Interactive and ongoing dialogue between communities and research teams allows for the integration of community norms, beliefs, customs, and cultural sensitivities into research activities.9

This report reflects an intuition that there is something important about engaging in constructive dialogue and acknowledging and being responsive to the interests—many of which remain nonobvious in the absence of engagement—of legitimate stakeholders in the context of research projects, and that such actions have something to do with attempting to extend gestures of respect beyond individual human subjects.

There is steadily growing momentum in the research community to incorporate community engagement activities into research.10 Support for community engagement activities as a line item in research budgets began in 1990 when the National Institute of Allergy and Infectious Diseases (NIAID) funded community advisory boards as part of its HIV prevention trials program. The boards emerged as a mechanism to elicit input from the HIV/AIDS community in developing NIAID’s HIV/AIDS research strategy. These actions fundamentally improved the relationship between research funders and the communities they were engaged with, but the ways that research can affect broader stakeholder interests have not trickled down into the Common Rule regulatory apparatus.

The Common Rule aims to protect research participants and promote ethical conduct in research through institutional accountability, including prospective independent review of risks and potential benefits, detailed requirements for informed consent, and institutional responsibility for oversight of approved activities. Community engagement offers an extension to these core processes—like adding a wide-angle lens to a camera—allowing a view beyond the Common Rule’s boundary of implications for individual research participants to include implications and potential harms to other stakeholders. The U.S. presidential commission’s advocacy for community engagement suggests that other harms, such as the collective grief about the exploitation of the Guatemalan people that the Guatemala report emphasizes, should not be viewed as outside the scope of the world’s most dominant human subjects policy simply because they do not fit neatly into the individualistic architecture of the Common Rule. As the Guatemalan report articulates, “The experiments on human subjects conducted in Guatemala during the period of 1946 to 1948 constitute a violent assault on the human dignity of helpless individuals, the medical profession, and the country’s sovereignty, as well as the ethics of scientific research. It is an immoral act of large proportions and a crime against humanity.”11

It is pointless to speculate about whether a robust community engagement strategy might have prevented the ethical violations in the Guatemala syphilis trials. Indeed, a minimal form of community engagement was utilized in Guatemala: representatives of powerful governmental institutions from the U.S. and Guatemala explored common interests and negotiated shared benefits that enabled the studies to proceed.12 Missing, however, was any meaningful engagement with the research participants themselves or those who might have represented and defended their interests.

We know that our current system of protections is not a perfect guarantee for avoiding harms. The more urgent question is whether the types of harm articulated in the Guatemala national report, and those asserted in the current class action suits, can be prevented, or minimized, by some form of community engagement. These harms are all too familiar in the history of research, both domestic and international, and yet it remains doubtful that our research ethics strategies are fit for the purpose of preventing them. Even the prospect that this remains true should give us pause to examine whether the revisions to the Common Rule—which have also become a de facto standard in international research—are up to the task.

We still have much to learn about community engagement, what it means to conduct effective community engagement in a wide range of research contexts, and what kinds of ethical gains can be made for all stakeholders as a result.13 A fitting legacy for the Guate-
malian syphilis trials would be a serious commitment to improve our understanding of what makes community engagement effective and to more thoroughly explore how the ethical aims of community engagement can most effectively complement the provisions of the revised Common Rule.

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6. Ibid.
8. 45 C.F.R. 46.111(a)(2).