

► Public Health Service Research in Guatemala: *Toward New Scholarship*

Further research and scholarship into the Public Health Service sexually transmitted infection experiments, such as that done recently by Charlene Galarneau (“‘Ever Vigilant’ in ‘*Ethically Impossible*’: Structural Injustice and Responsibility in PHS Research in Guatemala,” May-June 2013) is critical to the ever-evolving understanding of the ethics of human research and the pedagogical value of the Guatemala experiments as a case study. Scholarship such as Galarneau’s is necessary to fully understand what happened in Guatemala from different academic perspectives as well as recognize the steps we need to take as research ethicists to protect current research participants. After releasing “*Ethically Impossible*”: *STD Research in Guatemala from 1946 to 1948*, the Presidential Commission for the Study of Bioethical Issues completed three follow-up projects worth highlighting in conjunction with Galarneau’s new article precisely because they enable such continuing bioethics scholarship.

First, the commission linked the electronically available *Ethically Impossible* endnotes of hundreds of original source citations back to redacted electronic versions of the original sources. While the National Archives and Record Administration has posted all of the records documenting the research to its website, the hyperlinked *Ethically Impossible* allows scholars immediate access to documents within the context provided by the report. Scholars therefore can examine primary sources and also pursue their

own analysis and interpretations of the rich source materials.

Second, the commission released the *Guatemala Subject Data Spreadsheet*, created from lead investigator Dr. John Cutler’s documents, to account for all of the subjects of the experiments. No full medical history of the subjects otherwise exists. Demographic information such as age, gender, and population is available alongside medical information such as disease status, STI exposure, and treatment. The data are sortable, so that a scholar can compare treatment of vulnerable populations, evaluate exposure techniques, and analyze treatment regimens—much like Galarneau did for her research with the sex worker data. The commission intends access to these data for ethical and educational use, as opposed to purely scientific. Finally, the commission released a *Study Guide to “Ethically Impossible” STD Experiments in Guatemala 1946 to 1948*. While *Ethically Impossible* focused on the fact-finding investigation that was President Obama’s charge, the commission developed the *Guide* for those who wish to focus on the ethical significance of these experiments. The report required chronological construction; the commission broke down the *Guide* by ethical topic, with discussion questions and further readings.

The commission commends the work of scholars such as Galarneau and hopes to increase the access to primary source and educational materials that make this type of work possible. All of the documents referenced above are currently available at bioethics.gov.

The commission is committed to the government transparency, academic scholarship, and ethics pedagogy that it believes will help researchers and bioethicists better understand the exploitation of some research subjects in the

past to protect the contribution of all research participants in the future.

Kayte Spector-Bagdady
Presidential Commission for the Study of Bioethical Issues

DOI: 10.1002/hast.181

► Fertility Treatment: *Medically Necessary?*

In their essay “Why We Should All Pay for Fertility Treatment: An Argument from Ethics and Policy” (March-April 2013), Josephine Johnston and Michael K. Gusmano advocate insurance coverage for in vitro fertilization (they do not really address fertility treatment broadly), but they do not attempt to fit their arguments into the standard for insurance coverage, which is medical necessity. Looking at IVF in the light of medical necessity, the article lacks data to support insurance coverage.

There are slight variations in the definition of medical necessity, but most would include the limits in the guidelines that Cigna Insurance gives its participating providers: “Medically necessary services are clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient’s illness, injury or disease and not primarily for the convenience of the patient or Physician, or other Physician, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.”¹

The first concern regarding a medical necessity argument for IVF is that the procedure be “considered effective.” The authors give success rates of 27 percent to 42 percent—that is, of actual