

Desperate Times: Protecting the Public From Research Without Consent or Oversight During Public Health Emergencies

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The coronavirus disease 2019 (COVID-19) pandemic demands a sweeping public health response. State governors have restricted the movement of private citizens with stay-at-home orders and have mandated business closures. We have collectively, necessarily, and—in many cases—willingly given up our personal freedoms for greater community benefit. Amid this crisis, however, preventing unnecessary sacrifice of fundamental human rights under the pretext of public health is critical.

One area where this concern arises is differentiating public health activities classified as *surveillance* from those that constitute *research*. Both are necessary in a pandemic for understanding disease epidemiology and transmission. In the 2018 revision of the federal regulations governing human subjects research (the “Common Rule”), public health surveillance activities that occur “during the course of an event or crisis that threatens public health” ([Table](#)) were specifically excluded from research regulation ([1](#)). One can hardly imagine a crisis that threatens public health more than COVID-19.

Yet, defining activities as public health surveillance has profound implications, because there is then no further ethical oversight, no legal requirement in the United States for informed consent, and no specific protection for vulnerable participants or communities. Protections for research

participants arose from human rights abuses, as in the Tuskegee syphilis study, in which researchers unethically justified sacrificing individual rights for public benefit. During the current pandemic, when fear, uncertainty, and the temptation to rebalance the public interest over the individual exist, it is paramount that research institutions heighten their vigilance and avoid repeating past mistakes.

As institutional review board (IRB) members, the authors are responsible for ensuring that research meets ethical, scientific, and regulatory standards. During this pandemic, we have seen an increase in requests for the IRB to determine that projects qualify as public health surveillance. Many of these projects have already been designated as public health surveillance by federal agencies and other IRBs, and have included long-term storage and undefined future use of biological specimens (related and unrelated to COVID-19), required submission of genetic information to publicly available databases (such as dbGaP), or incorporated a plan for the creation of cell lines. In some cases, participants would receive an information sheet; in others, no information would be provided to participants. Recently, as an IRB, we determined that informed consent was required before genomic data from a COVID-19 public health surveillance activity could be made publicly available, and were then informed by the federal sponsor that our investigator could not participate because of this requirement.

We believe the use of the Common Rule exclusion of public health surveillance activities from research protections amid this pandemic does not justify unlimited research activities without consent. At Johns Hopkins, we are particularly cognizant of this issue. In 1951, cervical cancer cells were collected without informed consent from a 31-year-old woman named Henrietta

Lacks. These became the HeLa cells, among the most widely used and important cell lines. This cell line was created without permission, thereby contributing to a deep distrust within the community that surrounds The Johns Hopkins Hospital and depends on it for clinical care. The Henrietta Lacks story exemplifies the potential damage to public trust that ensues when human tissue is used without consent.

The collection of data and biological specimens during this pandemic is extremely important for future research aimed at controlling the virus. Data and specimens may be collected, tested, and even stored for legitimate public health surveillance, but their use for subsequent research is not exempt from regulations governing human subjects research. This is consistent with guidance ([Table](#)) from the Office for Human Research Protections ([2](#)), the Centers for Disease Control ([3](#)), the World Health Organization ([4](#)), the United Kingdom's Health Research Authority ([5](#)), and the Nuffield Council on Bioethics ([6](#)). In many cases, specimens collected and stored as part of public health surveillance will be valuable for future research. If so, it should proceed *as research*—with IRB oversight. If consent is impracticable at that point, an IRB could grant a consent waiver. However, if researchers know in advance that specimens or data will be used for future research, such as creation of cell lines and submission of whole genome sequencing data to publicly available databases, then consent for these research activities must be obtained at the time of collection. Modern technology makes it increasingly impossible to truly deidentify biological specimens.

Obtaining informed consent may be impracticable in some public health surveillance activities. The ethical basis for using surveillance data without consent, particularly in emergency

situations, is that it serves a compelling common good (7). Many—including the authors—agree that public health activities should proceed without informed consent when it is not possible or would undermine effective public health response (7). However, in the absence of a legal requirement, consent should be considered if possible. Obtaining consent may *not* be difficult, especially when data are collected prospectively. Even if informed consent is impracticable, information about the scope and purpose of the surveillance should be available to participants and to the public (7).

There is a general sense that obtaining IRB approval is unnecessarily bureaucratic and could delay important public health response. We recognize the urgent need to collect data, as well as the importance of these data for future research. Combining a public health surveillance activity with a research activity by collecting additional data or storing samples for future use is in the public's interest and should proceed without unnecessary delay. Our institution, and many others, have responded to the urgent needs caused by this pandemic by streamlining IRB review processes and approving flexible methods for obtaining consent, including remote platforms and oral consent. If the desire for so broadly invoking a public health surveillance exception represents a need for speed, we recommend establishing rapid response IRB processes rather than sacrificing protections.

COVID-19 is an international public health emergency. However, we should not invoke the Common Rule's public health surveillance exclusion, under questionable pretenses, when there is clearly also a research intent, whether extant or downstream. Storage of data and biological specimens for future research should occur with informed consent. Activities that are truly

research should be regulated as such, and public health surveillance should be done with consent if possible. We must execute good governance of the public health surveillance and emergency response infrastructure to maintain the public trust and avoid repeating research abuses of the past.

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Table. Regulatory and Ethical Guidance on Public Health Surveillance and Informed Consent

Statute/Guidance	Text
45 CFR 46.102(l)(2)—Revised Common Rule Definition of Public Health Surveillance. As revised 19 January 2017 and amended on 22 January 2018 and 19 June 2018.	“Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).” (1)
Office for Human Research Protections. Activities Deemed Not to be Research: Public Health Surveillance 2018 Requirements. Published online 7 November 2018.	“If an activity is composed of multiple components, some of which are not public health surveillance, OHRP’s view is that only those components that serve to enable a public health authority to carry out one or more public health surveillance objectives should be considered potentially eligible for the public health surveillance activity exclusion under 45 CFR 46.102(l)(2).” (2)
Centers for Disease Control. Distinguishing Public Health Research and Public Health NonResearch. Published online 29 July 2010.	“Emergency response activities tend to be nonresearch ... however, an emergency response might have a research component if, for example, samples are stored for future use intended to generate generalizable knowledge or additional analyses are conducted beyond those needed to solve the immediate health problem.” (3)
World Health Organization Guidance for Managing Ethical Issues in Infectious Disease Outbreaks. 2016	“Before individuals are asked to provide biospecimens during an infectious disease outbreak, they should be given access to information about the purpose of the collection, whether their samples will be stored and, if so, the ways in which their specimens might be used in the future.... informed consent is particularly important if there is any possibility that the specimens may later be used for research.” (4)
World Health Organization Guidance on Ethical Issues in Public Health Surveillance. World Health Organization. 2017	“Whenever possible, individuals should be involved in decisions that affect them.” (7) “Seeking informed consent is often not feasible in practice, e.g. from large populations. It may be prohibitively costly and unwarranted when the risks are low (as in some epidemiological research in which CIOMS has allowed waiving of consent). In some cases, however, consent is the norm, such as in routine descriptive health surveys. It is the obligation of the public health authorities accountable for surveillance to assess the importance and feasibility of seeking informed consent.” (7) “Whether or not consent is sought, information about the nature and purpose of surveillance and about any risk for harm should be publicly accessible.” (7)
World Health Organization. Ethical Standards for Research During Public Health Emergencies: Distilling Existing Guidance to Support COVID-19 R&D. 29 March 2020.	“In all cases, research involving human participants requires independent ethics review.” (8) “Individual informed consent is a fundamental ethical requirement for research. Prospective research participants must be able to weigh the risks and benefits of participation.” (8)

CFR = Code of Federal Regulations; CIOMS = Council for International Organizations of Medical Sciences; COVID-19 = coronavirus disease 2019; OHRP = Office for Human Research Protections.