

Exception from general requirements for informed consent

General Comments: The enactment of this major rule change prior to public comment or airing is very disturbing, as is the vagueness of the examples to justify the need to eliminate obtaining the consent of patients who are conscious and able to decide whether or not to participate in experimental testing for unknown life-threatening chemical, biological, radiological, or nuclear agents.

Let me propose the following example: an “investigator,” a single person working in a lab may make the crucial decision to submit a patient’s specimen for investigational testing, without any proof of the validity or efficacy of the test, with essentially no meaningful oversight, except perhaps the agreement of a single “independent” physician. With 150 labs across the US able to refer specimens for investigational testing, this leaves much room for abuse of this process to waive informed consent.

- A great deal of power is given to two people whose expertise and neutrality are not defined or known and who can apparently appoint themselves as arbiters of which members of the public will be subjected to investigational testing, without any oversight required for 5 days. Then an IRB must be informed, but it is expected that the IRB will essentially be a rubber-stamp for whatever “research” has already occurred.
- IRBs have had a terrible track record of protecting patient privacy as detailed in GAO reports, so it is hard for consumers to have much confidence in oversight by IRBs, many of which are dominated by researchers, academics, and industries that have vested interests in conducting the research they are asked to oversee.

Recommendation 1): An open and clear process for choosing highly qualified individuals to be granted the extraordinary emergency power to waive informed consent should be designed with public comment and consumer collaboration input. Such momentous decisions should be made in concert with consumer privacy experts and medical ethicists, who are also chosen in an open process for their expertise. Cities, regions, and communities should know who these deciders-of-their-fates will be and have final approval of their appointments.

Continuing my example: a specimen from a conscious patient whose life is “threatened,” yet apparently has no outward signs of any serious medical illness, can be forcibly included in research of an experimental investigational test or device. That example cited in the Interim Final Rule makes no sense. In fact, it violates the Principles of medical ethics requiring consent.

- What kind of life-threatening illnesses show no outward signs of such extreme and sudden threat to life? I am a physician but cannot picture what sort of threats would fit this odd picture painted by the FDA.

- Generally, in the case of a rapidly fatal infection, patients are sick and are seeking help or already in treatment or hospitals—they are NOT unable to consent or agree to participate in research until they are in extremis (or their legal guardians can consent).
- In the case of a slower life threat, for example from exposure to radiation, there is clearly time to seek informed consent and these patients also will be seeking medical help and can be talked to.
- Because the test or device is unproven and the rate of false negatives and false positives is unknown, the risk of being diagnosed incorrectly is not known.

Recommendation 2) The previous rule this is designed to supercede, which requires that the human subject be unable to communicate (i.e., in a coma or unconscious) should be restored. There is no situation where a patient is awake that would justify this seizure of their bodily specimens and justify the forcible participation in investigational research. The kind of city/regional/community experts I described in Recommendation #1 should be appointed to make critical decisions about waiving informed consent when patients are unconscious, as in the prior rule, which is consistent with the principles of medical ethics.

Continuing my example: There is something that is glossed over in the FDA's example, when patients give consent for treatment and testing, such as for infectious agents, they follow their physician's recommendations about which tests should be performed, or there would not be any specimens in the first place. We are talking about cooperative patients They expect that any and all needed tests will be performed, so if the routine tests do not reveal the agent, patients who still feel sick typically want to have further tests to find out what's wrong. The FDA example implies that in this life-threatening emergency there is no time, yet the patient is not so sick as to be in a coma or in extremis so they can fully cooperate with the research and investigation if they wish. Why must they be forced to participate?

What if you are forced to be tested and the test result is positive for a chemical, biological, radiological, or nuclear substance, but a biopsy or further test is required to confirm the diagnosis? This rule could give "investigators" or the President the power to require more invasive testing, require treatment of unknown efficacy, and/or require people to be quarantined. The President has already invoked his powers to require members of the armed forces be given experimental vaccinations and treatments. Should he have that power over civilians too? Do we want "investigators" and/or the President determining what tests and medical treatment we will have?

Recommendation 3) The results of investigational tests and devices could profoundly impact people's lives, so they must have the right to decide to participate in such research. If you are believed to have a potentially fatal illness you should have the right to decide whether or not to be tested. This entire subject, the taking of rights in response to terrorist threats has not received nearly the kind of public discussion and debate we have had before we took other major steps as a society to enact health measures for the

public good. The nation agrees that in cases of violence against children, women, and the elderly, their medical privacy must be breached and their names must be reported for the good of all. That kind of widespread public knowledge and support does not exist for this extraordinary elimination of the right of informed consent by the FDA.

Continuing my example: Who decides exactly how great the threat to life must be before patients' rights to give informed consent are taken away? Should people's rights to give informed consent be stripped if the threat of death is 10% from a particular chemical, biological, radiological, or nuclear agent? What if the threat of death is 45%?

Recommendation 4): After a vigorous national public discussion and debate, Congress should set the standards for what level of threat to life justifies the elimination of fundamental human rights to privacy and self-determination. Agency officials must never have the power to determine Americans' fundamental human and Constitutional rights to privacy, which are so essential to our liberty and Democracy.

The FDA asserts that this rule change applies to a "narrow" set of circumstances, but by its very construction gives many unknown individuals of unspecified qualifications, who are known to the public, immense powers over their life and death. There is nothing narrow about this rule and its interpretation will be subject to the whims of people the public has not has any say in appointing or overseeing.

This Interim Rule is a massive elimination of patients' rights to privacy, justified by an extremely weak example that makes no sense. This elimination of fundamental privacy rights is being justified by invoking the threat of terrorism and fear, it is not based on public debate or discussion or agreement.

Deborah C. Peel, MD
Comments on behalf of the Patient Privacy Rights Foundation
PO Box 248
Austin, TX 78767
512-732-0033