They Can’t Force You: The Truth About Informed Consent Transcript

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Introduction to informed consent

This is the most important legal information you need to know in order to get through your health care journeys without being taken advantage of. What is informed consent?

There is a legal definition. There are four tenants to it. This was written by Dr. James Lyons Wheeler. He and I have talked a few times. he's one of the smartest people I've ever met.

We had lunch. I talked to him about B1. So I'm giving him some very valuable information and he has given us this incredibly valuable. word-for-word because I don't want to mess it up.

That's how important this is. There are four things required by the U. S. Code of Federal Regulations for informed consent. Written by James Layans Wheeler, Ph. D., February 10, 2026, modern medicine driven by financial incentives and institutional pressure has quietly abandoned informed-consent and ethical restraint, transforming care into compliance enforcement while convincing itself it is acting in patients' best interests.

That's why one of the first papers I wrote was for the interagency harmonization on informed consent across all HHS agencies, so the Department of Health and Human Services has 27 agencies.

Until those regulating informed consents do it right, nothing will change in medicine and public health. While HHS has many important competing agendas, this one ranks very high.

Proper and legally obtained informed consent per US CFR, which is US Code of Federal Regulations, requires all four of the following to be in place. Number one, statements of benefits and risks of any medical procedure, drug, or device.

Two, an attempt by the physician to determine if the patient understands the benefits or risks.

Legal definition and four requirements

Number three, an explanation of medically reasonable alternatives. Number four, and absence of any threat of negative consequences to the continuance of care to patient if they decline to provide consent, permission, parent, or assent, minors.

Ascent means agreement. Not an electronic tablet shoved in your face with, quote, sign here, unquote. These facts are supported by binding US federal law and long-standing bioethics doctrine, not opinion.

Here is the evidentiary foundation, point by point, grounded in US code of federal regulations and controlling legal standards. Informed consent is a protected human right in U. S.

law. Now remember, people refused the COVID shot and they got fired from their job. New York City teachers, military people, and the sued afterwards and won minimum $1 million.

Some people $5 million dollars. So you can't break informed consent. Informed consent is not a courtesy workflow step or administrative checkbox. It is a legal and ethical prerequisite to medical intervention, grounded in constitutional bodily autonomy and codified in federal regulation.

Two regulatory frameworks govern informed consent in the United States. Number one, 45 CFR 46, common rule HHS regulated research, public health programs and federally funded activities.

and the second one is 21 CFR 50, FDA regulated drugs, biologics, and devices. Both impose substantive

requirements that cannot be satisfied by electronic signature alone.

Number one, disclosure of risks and benefits is mandatory. Federal law requires explicit disclosure, of both risks, an expected benefits in language understandable to the subject.

45 CFR requires, quote, a description of any reasonably foreseeable risks or discomforts to the subject. Also requires quote a, description any benefits to this subject or to others that may reasonably be expected.

Unquote. Similarly, 21 CF-R mandates the same disclosures for FDA regulated products. Failure to disclose known risks, minimization of risks or overstatement of benefits invalidates consent as a matter of law.

It has to be informed consent, so if they give you bad information, then you're not being informed. Courts have repeatedly held that omission or distortion of material risk constitutes battery, not merely negligence.

The definition of battery in law is intentional unlawful touching or application of force to another person without their consent resulting in harmful or offensive contact.

This contact can include hitting, pushing, spitting, or even touching someone's clothing as long as it is intentional and offensive to a reasonable person.

Battery differs from assault, which involves the threat or apprehension of imminent harm without actual contact.

Risk disclosure and patient understanding

battery completes the act. It is the actual physical contact In criminal law, it is a misdemeanor, but it can be elevated to a felony if serious injury or deadly weapon or specific aggravated factors are involved.

Number two, the physician must assess patient understanding. Consent is not valid unless the clinician makes a good faith effort to determine comprehension.

45 CFR requires information be presented, quote, in language understandable to the subject, unquote. This requirement is now satisfied by presentation alone.

Federal guidance clarifies that investigators and clinicians must ensure actual understanding, not passive receipt. The Belmont Report from 1979, which underlies the common rule, states explicitly, quote, an agreement to participate in research is valid only if voluntarily given by a subject who is adequately informed and has comprehended the information, unquote.

Courts have reinforced this standard in Canterbury versus Spence, 1972, the court held that informed consent requires information conveyed, quote, in terms the patient can understand, unquote, not merely disclosed.

A tablet signature with no interaction, no questioning, and no comprehension check fails this standard. Number three, medically reasonable alternatives must be explained.

This is not negotiable. Federal regulations require disclosure of reasonable alternative, including the option of no intervention. 45 CFR requires, quote, a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

21 CFL contains the identical requirement. Courts consistently rule that failure to disclose alternatives, especially when risks differ materially, vitiates consent.

Vitiate means spoils or lessens. Importantly, alternatives include delayed treatment, conservative management, non-pharmacologic options, declining the intervention entirely.

If alternatives are omitted, consent is legally defective even if risks are disclosed. Number four, absence of coercion

or penalty is a core requirement of informed consent.

Federal law explicitly forbids coercions, undue influence, or a penalty for refusal. 45 CFR common rule requires that informed consents be sought, quote, under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate, and that minimize the possibility of corrosion or undued influence.

Alternatives, coercion, and refusal rights

Unquote. This is not limited to overt force. Federal guidance defines coercion broadly to include implicit threats, power imbalance, and loss of access to benefits or services.

So there are pediatricians that will refuse to see a patient if the mom decides not to vaccinate. That is against federal law. Crucially, 45 requires disclosure of, quote, a statement that participation is voluntary.

Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, unquote. So the physician must state that.

You can decide not to take our care or our therapy. I won't fire you as a patient. This clause is dispositive. That means it settles disputes or property.

If refusal to participate in the medical therapy leads to dismissal from a practice, denial of unrelated care, delayed treatment, labeling as noncompliant, threats of school exclusion, employment consequences, or medical abandonment, then consent is legally void.

So they can't kick out of the school if you're not vaccinated. They can't kick you out of work if you don't do some medical treatment and your medical doctor can abandon you just because you disagree with the therapy that they're recommending FDA regulations mirror this requirement verbatim 21 CFR states quote no informed consent may include any exculpatory language through which the subject is made to waive or appear to wave any of the subjects legal rights." Unquote.

So there's no giving up your rights. The hospital can't write up some paragraphs and you sign a document saying, I give up my rights, they can do that.

And 21 CFR requires, quote, a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled." So during COVID, it totally felt like medicine became the police state.

And if you didn't obey what their demands were, you get fired, You couldn't leave your house. You can go to work, et cetera, etc. That is a total police date that is unconstitutional.

It is completely federally unlawful. There is no governor, there's no politician that had any right to make you stay at home, to lose your job, lose medical care, or not go to the hospital.

Loss of access to care is a loss of benefit, threatening dismissal from care for refusal constitutes undue influence under FDA rules. OHRP, which is the Office for Human Research Protections under the Department of Health and Human Services has this guidance, refusal cannot affect access to care.

So the HHS Office for Human Research Protections has repeatedly clarified subjects should not be pressured to participate and should be threatened with loss of benefits or services to which they are otherwise entitled.

This includes medical care, especially when the physician controls access. A physician who conditions ongoing care on acceptance of a procedure invalidates consent by definition.

So if they require you take their procedure or do their therapy, and they say, if you do this, I'll keep seeing you, then

that is not informed consent.

Minors. Coercion is even more tightly prohibited. This is very interesting. For children, federal regulations are stricter, not looser. 45 CFR requires parental permission and child assent, where appropriate.

Assent means agreement. 45 CFR makes clear that dissent by a child must be respected unless a narrowly defined life-saving exception applies.

Electronic consent, legal consequences, and closing advice

Threatening a children with school exclusion when no mandate exists, loss of care, authority-based pressure constitutes coercion of a vulnerable population, which is an ethical red line.

Courts treat coerced consent as no consent at all. U. S. courts consistently hold that consent obtained under threat or pressure is invalid. In Canterbury v.

Spence, 1972, the court emphasized that informed consent requires free choice, not acquiescence to authority. More broadly, consent obtain under duress converts a medical intervention into battery, regardless of intent.

This is why modern lawsuits correctly frame these cases as battery, false imprisonment, fraud, not malpractice. Why, quote, sign here or find another doctor, unquote, fails legally.

Dismissal threats exploit a power imbalance. Physician controls access. Patient is dependent. Refusal carries consequences. that is undue influence even if spoken politely.

A consent process that includes any threat, explicit or implied, of negative consequences to continued care is not informed consent under U. S. law. Electronic consent does not replace substantive consent.

HHS guidance is explicit that electronic or written consent doesn't substitute for the informed-consent process itself. HHS OHRP guidance from 2016 states, informed consent is a process, not a form.

The clinician remains responsible for explanation, assessment of understanding, opportunity for questions, absence of coercion or undue influence. A tablet signed here workflow satisfies documentation, no consent.

legal consequence of failure, battery not paperwork error. When informed consent requirements are not met, courts treat the intervention as unauthorized touching.

This is why modern lawsuits correctly are pivoting away from injury causation and toward battery, fraud, false imprisonment, deprivation of civil rights.

These claims do not require proof of injury, only proof that consent was invalid. Bottom line, legally and ethically, informed consent is a human right embedded in U. S.

federal law. It requires disclosure, comprehension, and alternatives. Anything less is coercion dressed up as care. Until HHS agencies harmonize enforcement of 45 CFR 46 and 21 CF R 50, as written, rather than as administratively convenient, Medicine will continue to drift toward institutional authority over patient autonomy.

And no amount of cause for convenience for healthcare workers, providers, medical professionals, technology, or public messaging can override that reality.

How you can help right now share this with a loved one. So this is on Substack. The name of this sub stack is called Popular Rationalism by Dr. James Lyons Wheeler.

So we never get to the point where you sign an informed consent form. Make sure you read it and understand it. Ask the administrative staff or the doctor, what am I signing?

What does this say? I have a question on this line. Don't be rushed through this. I know as Americans, we're so trained to just sign documents, like when you buy a large purchase like a house, you can sign document for 45 minutes.

And we are trained just to go on and on like that. But when it comes to your physical body, what else is more important than your health? Know exactly what you're signing.

If they threaten you, oh if you don't sign that, then you won't get your care that you need, or we aren't going to see you anymore, that's battery. That's not legal at all.

Informed consent is how you keep the autonomy of your body in control. It's your own body. Nobody else has any right over it or to force any kind of therapy on you.

If you can't control your whole body, what else is there? R. F. K. Jr. says, a sick person has one dream. A well person, has a thousand. And the more medications you're on, the sicker you get.

That means you're going to die sooner and you are sicker because of the medications. All medications are poison. They're designed to block receptor sites and destroy enzymes and they do things that stop.

they don't do anything to enhance or to nourish or build or make healthier or stronger. The more you take, the sickier you get. That's the bottom line.

Take your power back. I hope this helps.