## 21 CFR 50.22(c): National Security Threat

**At Bottom:** President Biden's FDA promulgated a rule it never proposed and publicly stated it would not enact.[1] The rule effectively claims Americans as chattel,[2] permitting an estimated 30,000 entities to conduct clinical investigations on the American people without obtaining their "legally effective informed consent" (21 CFR 50.22) or notifying them before, during, or after the investigation of their involvement, even if injury occurs. Additionally, it permits the creation of secret medical files on Americans to be shared with unknown persons for unknown reasons and for an unknown duration.

**Clinical investigation** "means any experiment that involves a test article and one or more human subjects…" (21 CFR 50.3(c)) (emphasis added).

**Test article** "means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act." (21 CFR 50.3(j)).

The FDA further states that a clinical investigation "means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug (i.e., FDA-licensed) in the course of medical practice." (21 CFR § 312.3).

**Human subject** "means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient." (21 CFR 50.3(g))

Therefore, clinical investigations under 21 C.F.R. § 50.22 always involve activities that expose Americans to experimental drugs, biologics, devices, and other testing articles to study their effects on the body's structure or function, or to collect biometric data and biospecimens for secondary research purposes[3] by involving them as test subjects without their consent or knowledge.

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[1] The rule in question is specifically 21 CFR § 50.22(c), whose language was added to a final rule change despite the FDA publicly stating they would not add that language.

[2] Chattel in the context of slavery refers to a specific form of enslavement known as chattel slavery, where enslaved individuals are legally treated as movable personal property (chattel) that can be bought, sold, owned, inherited, or traded like any other commodity, such as livestock. This FDA, under 21 CFR 50.22, has assumed ownership over the lives of the American people, granting unto itself absolute control over their bodies and biometric data, stripping them of all legal rights or protections as human beings, notifying an estimated 30,000 entities that they can do unto the American people as they deem practicable without their consent.

[3] Secondary research involves using data or biospecimens (such as medical records or tissue samples) originally collected for a different purpose. For example, a hospital may collect a

"**Legally effective informed consent**" means that the potential participant must never be pressured to participate in a federally funded investigational product or related activity, nor be penalized for refusing such participation (45 CFR 46.116)("Common Rule"). This consent standard is required by Congress under 42 USC 289 to protect the rights of the American people involved in clinical investigations.

Although the FDA stated that harmonizing with the Common Rule was the reason for the changes, the Rule does not harmonize with the Common Rule for non-physical risks (e.g., data/biospecimen use) because it permits access to an individual's identifiable private information without consent involving invasive procedures. Furthermore, it deviates substantially from the Common Rule when applied to direct exposure to the test article.

In effect, the Rule permits one member of society to covertly touch another member of society or their biospecimens with experimental testing articles that affect the body's structure, thereby depriving them of their constitutional guarantees of bodily autonomy, privacy, and due process. Therefore, it remains unclear how the Rule can apply to investigations requiring physical administration or invasive procedures without implicating battery,[4] as no IRB waiver can override fundamental common-law protections against unconsented bodily contact or invasion of privacy. This tension deprives subjects of constitutional and common-law guarantees of bodily autonomy and privacy because the FDA empowers a sponsor of the clinical investigation to engage in offensive conduct under the guise of lawful authority—conduct that meets the legal threshold of battery in all US States and Territories.

**The Rule:** On November 11, 2018, the FDA proposed a new rule ("Rule") titled, 'Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations,"[5] to implement "a provision of the 21st Century Cures

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newborn's blood to determine the newborn's blood type, but under the Rule, the blood is sent off for a secondary research purpose: obtaining the newborn's DNA. Secondary research involves minimal physical risk, but it can never be considered minimal risk with respect to the citizen's constitutional right to privacy and personal property.

[4] In most U.S. jurisdictions, battery is defined as the intentional infliction of harmful or offensive physical contact upon another person without their consent. While such contact often results in emotional or physical injury, proof of actual injury is not required; the harmful or offensive nature of the contact itself suffices to establish the tort, entitling the plaintiff to at least nominal damages. Conduct involving unauthorized medical procedures, treatments, or invasions of the body—such as administering substances without permission, or secretly obtaining biospecimens through invasive means—meets the threshold of battery because a reasonable person would find such contact offensive.

[5] 2018-24822 (83 FR 57378)

Act (Cures Act)."[6] It is from this proposed 2018 rule that the FDA issued its final 2024 Rule.[7]

The agency stated in the proposed Rule that:

- The Common Rule's fifth criterion of exemption from informed consent states that, **'if the research involves using identifiable private information ("IPI") or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format**.'" [8]

- "At this time, **we are not proposing to adopt the new fifth criterion** in the revised Common Rule, which has a general compliance date of January 21, 2019; however, we invite comments on this issue." (Id).

Five years later, on December 21, 2023, the agency issued its final Rule[9] that specifically allowed persons to conduct clinical investigations on Americans even when "the research involves using identifiable private information or identifiable biospecimens." The Rule, 21 C.F.R. § 50.22(c), states that investigators are permitted to waive the informed consent rights of Americans "If the clinical investigation **involves using identifiable private information or identifiable biospecimens**, the clinical investigation **could not practicably be carried out without using such information or biospecimens in an identifiable format**."

The agency promised not to include the very language in 2018, yet it did so in 2023. This conduct constitutes a form of deceptive implicature known as time displacement, and it is morally repugnant in a civil society.

By introducing § 50.22(c) in the final rule without explicitly proposing it earlier, the FDA engaged in bait-and-switch rulemaking. The agency solicited public comments on a narrower set of criteria but implemented a broader exemption, undermining transparency and public trust. The FDA abused its "discretion" (§ 706(1)(A)) in issuing the final Rule by failing to provide stakeholders with notice of a proposed rule that would subject the American people to covert biomedical experimentation and the creation of secret medical files on their lives.

Notably, the agency did not provide a single example of how the Rule could be applied without violating the rights of the American people. Furthermore, no clinical investigation can ensure minimal risk when a subject's IPI is known but collected covertly, as this knowledge introduces legal, financial, religious, privacy, and other

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[6] https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf
[7] 2023-27935 (88 FR 88228)
[8] https://www.federalregister.gov/d/2018-24822/p-53
[9] 2023-27935 (88 FR 88228)

risks to the subject's welfare that are not accounted for during informed consent. The new Rule permits investigators to gather an individual's biometric data,[10] extract biospecimens, expose the individual to testing articles for study, and link the subject's IPI to this data to create a secret medical record for permanent storage and retrieval without the individual's awareness. If the research data were leaked, stolen, or sold, it could pose reputational, civil, or criminal risks to the subject.

The Rule is **extremely dangerous**: The MalaCards Human Disease Database[11] identifies over 19,000 known diseases. The FDA regulates approximately 23,000 approved prescription drugs, 7,000 medical devices, 1,600 animal products, 753 biological products, and 100,000 tobacco products.[12] However, the number of test articles used in clinical investigations remains unknown, as does the number of studies conducted by the 30,000 entities operating under a Federalwide Assurance agreement,[13] each involving an unspecified number of investigators and investigations. A clinical study[14] revealed that, on average, each U.S.-licensed drug carries 4.6 absolute contraindications[15] and 1.54 relative contraindications.[16] A National Institutes of Health study reported that 54% of prescription drugs have at least one known contraindication.

Additionally, a study on anaphylaxis identified drugs as the leading cause of anaphylactic reactions in adults.[17] Furthermore, the CDC reports that 1 in 3 adults suffers from some allergy.[18] Assessing whether an investigation exceeds minimal risk

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[10] Examples of biometric data include DNA, voice, fingerprints, facial recognition, digital signature, hand geometry, gait, iris, retina, biological biometrics, keystroke patterns and rhythms, and other behavioral biometrics.

[11] MalaCards - human disease database. Malacards.org. Published 2017. https://www.malacards.org/

[12] *FDA Regulated Products and Facilities*. Accessed June 6, 2025. https://www.fda.gov/media/182749/download

[13] An FWA agreement is a contract between an entity and HHS that uses federal funding or its authority to involve humans in investigational medical products and related activities. https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html

[14] Then MI, Wahram Andrikyan, Fromm MF, Maas R. Comprehensibility of Contraindications in German, UK and US Summaries of Product Characteristics/Prescribing Information—A Comparative Qualitative and Quantitative Analysis. *Journal of Clinical Medicine*. 2022;11(14):4167-4167. doi:https://doi.org/10.3390/jcm11144167

[15] "An absolute contraindication is a situation which makes a particular treatment or procedure absolutely inadvisable." Medical Definition of Contraindication. RxList.

[16] "A relative contraindication is a condition which makes a particular treatment or procedure possibly inadvisable." (*Id*.)

[17] Wood RA, Camargo CA, Lieberman P, et al. Anaphylaxis in America: The prevalence and characteristics of anaphylaxis in the United States. *Journal of Allergy and Clinical Immunology*. 2013;133(2):461-467. doi:https://doi.org/10.1016/j.jaci.2013.08.016

[18] Ng A, Boersma P. Diagnosed Allergic Conditions in Adults: United States, 2021. *PubMed*. Published online December 17, 2022. doi:https://doi.org/10.15620/cdc:122809

when covertly exposing a subject to a test article involving an astronomical number of potential adverse reactions relating to an unknown number of combinations of drugs, foods, diseases, and medical products is literally incalculable. While a test article or its associated invasive procedure may be deemed to pose minimal risk under current medical standards, its interaction with other factors unknown to the sponsor of the activity, because they are not involved in the informed consent process of the subject, who alone can inform them of such conditions, can never be assumed to pose only minimal risk. **The lack of informed consent creates conditions exceeding minimal risk.**

For the first time in the biomedical research industry, a federal agency permits an investigator to expose humans or their biospecimens to test articles when their IPI is known, without obtaining their legally effective informed consent. Because this statement is true, the Rule **violates** Constitutional guarantees, federal laws, and ratified treaties, such as:

1. The Fourth Amendment's guarantee of privacy. "Wherever a man may be, he is entitled to know that he will remain free from unreasonable searches and seizures" (*Katz v. United States,* 389 U.S. 347 (1967)). The Rule permits the creation of secret medical files for the first time because the investigator is permitted to conduct such experiments on persons whose IPI is known, and the research data is attached to that IPI without the subject's consent.

2. The Fifth Amendment's Due Process Clause to Bodily Integrity. "[n]o right is held more sacred or is more carefully guarded by the common law than the right of every individual to the possession and control of his own person, free from all restraint or interference of others unless by clear and unquestionable authority of law." (Union Pacific Railway Co. v. Botsford, 141 U.S. 250 (1891)); "forced medication [i]s a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment, our assumption was entirely consistent with this Nation's history and constitutional traditions" (Washington v. Glucksberg, 521 U.S. 702 (1997)); "On balance, the right to self-determination ordinarily outweighs any countervailing state interests, and competent persons generally are permitted to refuse medical treatment, even at the risk of death" because "The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment." (Cruzan v. Director, Missouri Dep't of Health, 497 U.S. 261, 273 (1990)); "[t]he protections of substantive due process have for the most part been accorded to matters relating to marriage, family, procreation, and the right to bodily integrity." (Albright v. Oliver, 510 U.S. 266, 272 (1994)).

3. The Rule permits clinical investigators to take an individual's biometric and biospecimens (i.e., private property) for the benefit of others, violating the

**Takings Clause**. "Government action that physically appropriates property is no less a physical taking because it arises from a regulation." (*Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063 (2021))

4. The Thirteenth Amendment protects Americans from involuntary servitude. *In United States v. Kozminski*, 487 U.S. 931 (1988), the Supreme Court defined "involuntary servitude" as "a condition of servitude in which the victim is forced to work for the defendant by the use or threat of physical restraint or physical injury, or by the use or threat of coercion through law or the legal process" (emphasis added). Here, the Rule's authorization of covert enrollment exploits legal processes to bypass consent, effectively coercing individuals into involuntary servitude by denying them the choice to refuse participation. By leveraging regulatory mechanisms to conceal the labor-intensive experiment, the Rule mirrors the coercive legal coercion *Kozminski* condemns, as individuals are stripped of autonomy over their bodies and data for corporate gain. Such covert conscription into medical experimentation, without meaningful choice or transparency, violates the Thirteenth Amendment's prohibition on involuntary servitude by transforming individuals into unwitting tools of corporate research without regard for their dignity or agency.

5. The Rule violates 42 U.S.C. § 2000bb-1(a), the Religious Freedom Restoration Act (RFRA), by permitting federally authorized persons to covertly expose Christians, Jews, Muslims, and other persons of faith and creed to fetal-derived cell lines, such as HEK-293 or PER.C6, or porcine (i.e., pig) tissues or cell lines, such as PK-15 (derived from a pig's kidney) or porcine islet cells, in ways that violate their faith and creed.

6. Article VII of the International Covenant on Civil and Political Rights Treaty (ICCPR) states, "no one shall be subjected without his free consent to medical or scientific experimentation."

7. Due Process for injuries: No mandatory post-injury notification (50.22(e)) prevents redress, causing the victim to unjustly bear the physical, legal, and financial burden alone.

8. The Rule violates 42 USC § 289 because it does not protect the "rights" of the American people when involving them in experimental drugs, biologics, devices, and related activities. A regulation cannot violate a federal law without violating the Separation of Powers doctrine.

The Rule, as applied to exempt informed consent research activities when the subject's IPI is known, permits investigators to conduct such research in our public schools, universities, hospitals, nursing homes, and doctors' offices, involving

unsuspecting citizens. The Rule uses the legal process to waive the constitutional protections of an entire nation, posing a national security threat. It is for this reason that the FDA never proposed enacting 21 CFR § 50.22(c), because it is impossible to conduct minimal risk research involving a subject's constitutional protections when their IPI is known or could be known.

**NOTABLY:** The rule permits investigators to access "leftover samples" from "clinical care" (i.e., routine medical care). These samples include blood, saliva, hair follicles, and skin from surgeries, doctor's visits, physicals, etc., and can now be used in clinical investigations, with the research data linked to the owner's IPI. This data can then be shared, sold, or used for profit-oriented purposes at the owner's expense and without the owner's knowledge.

The Rule is physically dangerous, constitutionally impermissible, poses unquantifiable risks, operates under *ultra vires* power, and should be vacated, with mandatory disclosures of who was involved in such investigations and what was done to or taken from them.

This Rule is only the tip of the iceberg regarding how Americans are being stripped of their constitutional rights by federal agencies and the federal judiciary. I stand ready to assist in resolving this matter on behalf of the American people.

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