

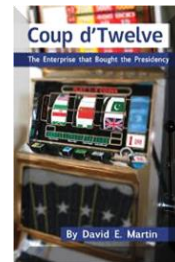
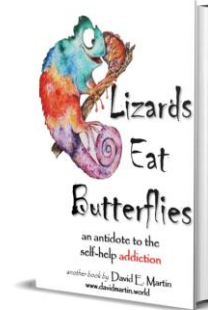
David E. Martin

Speaker, Author, Fully Human

Informed Consent:

YOU'RE A LAB

RAT...



'Butterfly' of the Week:

www.davidmartin.world

Rules on Informed Consent

Relevant Laws:

- 21 Code of Federal Regulations
 - *§50.20 – Except as provided in 50.23 and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.*
 - §50.23 – waiver for DOD and in “emergency”
 - §50.24 – suspended “with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation”

Why This Matters

- During “declared emergencies”, the medical industry is exempted from liability: *“provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving “willful misconduct” as defined in the PREP Act.”*

<https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>

- A must read... When Human Experimentation is Criminal by L. Song Richardson <https://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=7314&context=jclc>

The Case... U.S. v. Stanley, 479 U.S. 1005 (1986)

- **Justice Brennan** - *The Court confers absolute immunity from money damages on federal officials (military and civilian alike) without consideration of longstanding case law establishing the general rule that such officials are liable for damages caused by their intentional violations of well-established constitutional rights.*
- **Justice O'Connor** - *No judicially crafted rule should insulate from liability the involuntary and unknowing human experimentation alleged to have occurred in this case. Indeed, as JUSTICE BRENNAN observes, the United States military played an instrumental role in the criminal prosecution of Nazi officials who experimented with human subjects during the Second World War, ante, at 687, and the standards that the Nuremberg Military Tribunals developed to judge the behavior of the defendants stated that the "voluntary consent of the human subject is absolutely essential . . . to satisfy moral, ethical and legal concepts." United States v. Brandt (The Medical Case), 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, p. 181 (1949). If this principle is violated the very least that society can do is to see that the victims are compensated, as best they can be, by the perpetrators. I am prepared to say that our Constitution's promise of due process of law guarantees this much. Accordingly, I would permit James Stanley's Bivens action to go forward, and I therefore dissent.*

<https://biotech.law.lsu.edu/cases/research/stanley.htm>

You can take action

US Department of Health and Human Services
Office of the General Counsel
200 Independence Ave. S.W.
Washington, D.C. 20201

<https://www.aoc.gov/sites/default/files/pdf/TortFormSF95.pdf>