



Why do they get to tell us what to do? OHRP & FDA

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Agenda

- ▶ Why do they get to tell us what to do?
 - ▶ FDA
 - ▶ OHRP
 - ▶ Federalwide Assurance (FWA) & Common Rule
- ▶ References

Why does the FDA get to tell us what to do?

- ▶ Federal Law: United States Code Title 21- Food & Drugs, Chapter 29 - Federal Food, Drug, and Cosmetic Act
 - ▶ Interstate Commerce Clause of the US Constitution
 - ▶ FDA has jurisdiction over articles introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce
 - ▶ Any component of the article can bring the entire article into jurisdiction
 - ▶ Doesn't matter if manufacturer is US-based or not
 - ▶ Can Impose criminal as well as civil penalties

Why does OHRP get to tell us what to do?

- ▶ It is a condition for receiving federal funding for human research:
 - ▶ Obtain Federalwide Assurance (FWA)
 - ▶ Apply Common Rule to non-exempt human research funded by federal agencies



What is a Federalwide Assurance (FWA)?

- ▶ An assurance of compliance
 - ▶ Through the assurance of compliance, an institution commits to HHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR part 46 as well as the Terms of Assurance.
 - ▶ The Federalwide Assurance is the only type of assurance of compliance accepted and approved by OHRP.
 - ▶ The FWA covers all non-exempt human subjects research at the submitting institution that is HHS-conducted or -supported or funded by any other federal department or agency that has adopted the Common Rule and relies upon the FWA. It is not project specific.

More about FWAs

- ▶ University of California policy applies the *Common Rule* or commensurate protections to all human subjects research in which UC San Diego is engaged, regardless of funding source, funding status, the location, or scale of the research.
- ▶ “Checking the box”
 - ▶ Institutions may voluntarily extend their FWA to cover all human subjects research at the institution regardless of the source of support for the particular research activity.
- ▶ UCSD has “unchecked” the box, in compliance with UC policy, to enable flexibility for research that is not federally funded (e.g., FLEX categories for exempt studies)

References

- ▶ USC Title 21, Chapter 29
- ▶ 21 CFR 50
- ▶ 45 CFR 56
- ▶ [OHRP's FWA webpage](#)
- ▶ UCSD PPM 100-5