Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Start here. Is it research?

Activity is research. Does the research involve human subjects?

Does the research involve obtaining information about living individuals? [45 CFR 46.102(f)]

Does the research involve intervention or interaction with the individuals? [45 CFR 46.102(f)(1), (2)]

Activity is research involving human subjects. Is it covered by the regulations?

Is it conducted or supported by HHS? [45 CFR 46.101(a)(1)]

Does the institution hold an FWA under which it applies 45 CFR 46 to all of its human subjects research regardless of the source of support?

The research involving human subjects is covered by the regulations.

Go to Chart 2

The research involving human subjects is NOT covered by the regulations.

Activity is not research, so 45 CFR part 46 does not apply.

The research is not research involving human subjects, and 45 CFR part 46 does not apply.

Is the information individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)]

Is the information private? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.) [45 CFR 46.102(f)(2)]

Unless exempt under 45 CFR 46.101(b), 45 CFR part 46, subpart A applies to the research, and as appropriate subparts B, C, and D also apply.

Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]

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