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

Start here.

Is the activity a systematic investigation **designed** to develop or contribute to **generalizable** knowledge? [45 CFR 46.102(d)]

**NO**

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

**YES**

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

**NO**

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

**YES**

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

**NO**

**NO**

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)]

**NO**

**BUT**

Activity is research involving human subjects. Is it **conducted or supported by HHS**? [45 CFR 46.101(a)(1)]

**NO**

**NO**

**BUT**

Is the research covered by an applicable OHRP approved assurance created under 45 CFR 46.103?

**YES**

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

**NO**

**NO**

Go to Chart 2

AND

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