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

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1. Start here.

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

   YES

   Activity is research. Does the research involve obtaining information about living individuals? [45 CFR 46.102(f)(2)]

       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

           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

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               YES

               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)]

                   NO

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

                   YES

                   Go to Chart 2

                   NO

       YES

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

           NO

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

               NO

               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. [45 CFR 46.102(f)(2)]

               YES

               Go to Chart 2

   NO

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