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 not 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** 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

    - **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)]

      - BUT

      - **YES** Go to Chart 2

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

  - **NO**

  - **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.

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

  - **YES** Go to Chart 2

  - **NO** Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]
Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

Has HHS prohibited exemption of the human subjects research? (All research involving prisoners, some research involving children.) [Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]

NO

Will the only involvement of human subjects be in one or more of the following categories?

- Research conducted in established or commonly accepted educational settings, involving normal education practices?
  - YES
  - Exemption 45 CFR 46.101(b)(1) may apply.
  - Go to Chart 3

- AND/OR

- Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior?
  - YES
  - Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply.
  - Go to Chart 4

- AND/OR

- Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens?
  - YES
  - Exemption 45 CFR 46.101(b)(4) may apply.
  - Go to Chart 5

- AND/OR

- Research studying, evaluating, or examining public benefit or service programs?
  - YES
  - Exemption 45 CFR 46.101(b)(5) may apply.
  - Go to Chart 6

- AND/OR

- Research involving taste and food quality evaluation or consumer acceptance studies?
  - YES
  - Exemption 45 CFR 46.101(b)(6) may apply.
  - Go to Chart 7

NO

No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.

September 24, 2004

**“Only”** means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.