Chart 2: Is the Human Subjects Research Eligible for Exemption? View text version of Chart 2

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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
  - If not exempt under (b)(1)

- 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
  - If not exempt under (b)(2) or (b)(3)

- Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimen?
  - YES → Exemption 45 CFR 46.101(b)(4) may apply → Go to Chart 5
  - If not exempt under (b)(4)

- Research studying, evaluating, or examining public benefit or service programs?
  - YES → Exemption 45 CFR 46.101(b)(5) may apply → Go to Chart 6
  - If not exempt under (b)(5)

- 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
  - If not exempt under (b)(6)

YES

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.

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is **not** exempt.
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

View text version of Chart 3

From Chart 2

Is the research **only** conducted in *established or commonly accepted* educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)

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

NO

Research is not eligible for 45 CFR 46.101(b)(1) exemption.

Next

YES

Does the research study involve only *normal education practices*? (Such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)

NO

Return to Chart 2 and consider whether 45 CFR 46.101(b)(2) exemption applies.

YES

Research is eligible for 45 CFR 46.101(b)(1) exemption from 45 CFR part 46 requirements.

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**Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?**

From Chart 2

Does the research involve only** the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? *("Existing" means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)*

**YES**

Are these sources publicly available?

**YES**

Research is eligible for exemption under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

**NO**

Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

**YES**

Return to Chart 2 and consider whether 45 CFR 46.101(b)(5) exemption applies

**NO**

Research is not eligible for exemption under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

**Note:** See OHRP guidance on research use of stored data or tissues and on stem cells at [http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-research-involving-stem-cells/index.html](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-research-involving-stem-cells/index.html), and on coded data or specimens at [http://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html) for further information on those topics.

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Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply? View text version of Chart 6

From Chart 2

Is the research or demonstration project conducted or approved by the Department or Agency Head?

YES

Does the research or demonstration project involve only** the study, evaluation, or examination of:

Public benefit or service programs;

NO

**Procedures** for obtaining benefits or services under public benefit or service programs;

NO

Possible changes in or alternatives to public benefit or service programs or to procedures for obtaining benefits or services under public benefit or service programs;

NO

Possible changes in methods or levels of payment for benefits or services under those public benefit or service programs?

YES

Research is not eligible for exemption under 45 CFR 46.101(b)(5).

NO

Research is eligible for exemption under 45 CFR 46.101(b)(5) from 45 CFR part 46 requirements.*

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


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Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply? [View text version of Chart 7]

From Chart 2

Does the research involve only** a taste and food quality evaluation or a food consumer acceptance study?

- **YES**
  - Are wholesome foods without additives consumed?
    - **YES**
      - Research is eligible for exemption under 45 CFR 46.101(b)(6) from 45 CFR part 46 requirements. Other Federal, State, and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]
    - **NO**
      - Is food consumed that contains a food ingredient, agricultural chemical, or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture?
        - **YES**
          - Research is not eligible for exemption under 45 CFR 46.101(b)(6).
        - **NO**
          - Go to Chart 8

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

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