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(j), 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.

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

Project does not qualify for Exempt status
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

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.)

NO → Research is not exempt under 45 CFR 46.101(b)(1).

NO → Project does not qualify for Exempt status

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 → Research is exempt under 45 CFR 46.101(b)(1) from all 45 CFR part 46 requirements.

YES → Project does not qualify for Exempt status

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Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

From Chart 2

Does the research involve only the use of educational tests, survey procedures, interview procedures, or observation of public behavior?

YES

Does the research involve children to whom 45 CFR part 46, subpart D applies?

NO

Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?

NO

NO

Research is not exempt under 45 CFR 46.101(b)(2).

However, the 45 CFR 46.101(b)(3) exemption might apply.

Are the human subjects elected or appointed public officials or candidates for public office? (Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)

NO

NO

Research is not exempt under 45 CFR 46.101(b)(2) or (b)(3).

Project does not qualify for Exempt status

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YES

Does any Federal statute require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?

YES

Research is exempt under 45 CFR 46.101(b)(3) from all 45 CFR part 46 requirements.

NO
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents 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 exempt under 45 CFR 46.101(b)(4) from all 45 CFR part 46 requirements.

NO

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

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

NO

Project does not qualify for Exempt status

* Note: See OHRP guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/policy/index.html#tissues and #stem, and on coded data or specimens at #coded 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?

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:

YES

Public benefit or service programs;

NO

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

YES

Research is exempt under 45 CFR 46.101(b)(5) from all 45 CFR part 46 requirements.*

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;

YES

NO

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

YES

NO

Research is not exempt under 45 CFR 46.101(b)(5).

* Note: See OHRP guidance on exemptions at http://www.hhs.gov/ohrp/policy/index.html#exempt for further description of requirements for this exemption.

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Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

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 exempt under 45 CFR 46.101(b)(6) from all 45 CFR part 46 requirements.

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

NO

Research is not exempt under 45 CFR 46.101(b)(6).

Project does not qualify for Exempt status

September 24 2004