This worksheet is used to determine whether "Human Research" is exempt from regulation.

1. Exemption Categories (The research must fit into one or more of the following categories) 45 CFR §46.401(a)
   
   1. The research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
   
2. One of the following is true: 45 CFR §46.401(b)
   
   a. The research does not involve <Children> as subjects
   
   b. The research is not subject to DHS, DOD, ED, EPA, HHS, or VA regulation
   
   c. The research is limited to educational tests and observation of public behavior where the investigator(s) do not participate in the activities being observed

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2, if (i) the human subjects are elected or appointed public officials or candidates for public office, or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the investigator records the information in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects (see Footnote 1)

5. All of the following are true:
   
   a. The research is conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. In addition: OPRR Guidance on 45 CFR 46.101(b)(6)
   
   b. The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act)
   
   c. The research or demonstration project is conducted pursuant to specific federal statutory authority
   
   d. There is no statutory requirement that the project be reviewed by an IRB
   
   e. The research involves no significant physical invasions or intrusions upon the privacy of participants
   
   f. The funding department or agency concurs that this exemption applies

6. (a) Taste and food quality evaluation and consumer acceptance studies, (1) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or 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.

2. Additional Criteria (all must be met)
   
   1. The research is not FDA-regulated. (See WORKSHEET: Human Research)
   
   2. One of the following is true: 45 CFR §46.301(c)
      
      a. The research does not involve <Prisoners> as subjects
      
      b. There is no interaction or intervention with subjects and the research is not subject to DHS, DOD, ED, HHS, or VA regulation
      
   2.1 The research involves no more than minimal risk to subjects
   
   2.2 There are adequate provisions to maintain the privacy interests of subjects
   
   2.3 The research includes sufficient protections for any vulnerable populations
   
   2.4 A consent process is unnecessary for the research
   
   2.5 The research involves an appropriate consent process that is appropriate:
      
      a. Provides sufficient opportunity to consider whether to participate and minimizes the possibility of coercion or undue influence
      
      b. Does not include exculpatory language
      
      c. Discloses sufficient information to make a decision in understandable language, such as:
         
         *(The study involves research) *(The expected duration of the subject's participation)
         
         *(The extent, if any, to which confidentiality will be maintained)
         
         *(That participation is voluntary) *(Whom to contact for questions about the research)

3. Notes

4. Footnotes

4.1 For research conducted, funded, or otherwise subject to regulation by any US federal department or agency "existing" means "existing at the time the research is proposed." Otherwise, it means "existing at the time the research is proposed or will exist in the future for non-research purposes."

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