**PURPOSE and SCOPE**

The purpose of this worksheet is to provide support for Designated Reviewers granting exemption determinations. This worksheet is to be used. It does not need to be completed or retained.

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| **1 GENERAL EXCLUSIONS FROM EXEMPTIONS** (Check if **“Yes”**. If either is checked, the research is not exempt.) | | |
|  | The research is FDA-regulated.[[1]](#endnote-2) | |
|  | The research involves Prisoners and is conducted or funded by DHHS or Dept. of Defense (DOD). | |
|  | The research involves Prisoners, and is inappropriate for the prison population being studied or involves interactions with Prisoners. | |
| **2 The research falls into one or more of the following categories** (One or more categories must be checked.) | | |
|  | 1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. | |
|  | 2. Research that **only** includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: | |
|  | The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or |
|  | Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or |
|  |  | The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7) |
|  |  | If the research involves children and is conducted, funded, or subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), or Environmental Protection Agency (EPA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed and (2) the use of educational tests. **(“N/A” if the research does not involve children or is not conducted, funded, or otherwise subject to regulation by these agencies.)** |
|  | 3. Research involving benign behavioral interventions[[2]](#endnote-3) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively[[3]](#endnote-4) agrees to the intervention and information collection and at least one of the following criteria is met: | |
|  | The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or |
|  | Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or |
|  | The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7) |
|  | 4. [[4]](#endnote-5) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: | |
|  |  | The identifiable private information or identifiable biospecimens are publicly available; or |
|  |  | Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; or |
|  |  | The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or |
|  |  | The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. |
|  | 5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. In addition: (Check if **“Yes”**. All must be checked) | |
|  | The program under study delivers a public benefit[[5]](#endnote-6) or service[[6]](#endnote-7). |
|  | The research or demonstration project is conducted pursuant to specific federal statutory authority. |
|  | There is no statutory requirement that the project be reviewed by an IRB. |
|  | The project does not involve significant physical invasions or intrusions upon the privacy of subjects. |
|  | The funding agency concurs with the exemption. |
|  |  | The research or demonstration project must be published on the appropriate publicly accessible Federally maintained list prior to commencing the research involving human subjects. [[7]](#endnote-8) |
|  | 6. [[8]](#endnote-9) Taste and food quality evaluation and consumer acceptance studies, (i) 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 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 Dept. of Agriculture. | |
| **3 Criteria for approval of exempt research** (Check if **“Yes”**) | | |
|  | The research involves no more than Minimal Riskto subjects. **(Must be checked.)** | |
|  | Selection of subjects is equitable. **(Must be checked.)** | |
|  | If there is recording of identifiable information: **(If checked, the following must be checked.)** | |
|  |  | There are adequate provisions to maintain the privacy interests of subjects. |
|  |  | There are adequate provisions to maintain the confidentiality of the data. |
|  | There are interactions with subjects: **(if checked, the following must be checked.)** | |
|  |  | There will be a consent process. |
|  |  | The consent process will disclose that the activities involve research. |
|  |  | The consent process will disclose the procedures to be performed. |
|  |  | The consent process will disclose that participation is voluntary. |
|  |  | The consent process will disclose the name and contact information for the investigator. |
|  |  | There are adequate provisions to maintain the privacy interests of subjects. [[9]](#endnote-10) |

1. The organization’s policy is to not grant exemptions to FDA-regulated research in category (6). [↑](#endnote-ref-2)
2. Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. [↑](#endnote-ref-3)
3. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. [↑](#endnote-ref-4)
4. “If these sources are publicly available” was removed because public data cannot be private, and if there is no collection of private identifiable information, there can be no Human Subjects. [↑](#endnote-ref-5)
5. For example, financial or medical benefits as provided under the Social Security Act. [↑](#endnote-ref-6)
6. For example, social, supportive, or nutritional services as provided under the Older Americans Act. [↑](#endnote-ref-7)
7. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. [↑](#endnote-ref-8)
8. Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR §50. If an organization’s policy is to grant exemptions to FDA-regulated research in category (6), then additional criteria for such exemptions would be that consent will be obtained in accordance with 32 CFR §50.20 and §50.25, and the consent will be either documented in writing in accordance with 21 CFR §50.27 or waived in accordance with 21 CFR §56.109(c)(1). [↑](#endnote-ref-9)
9. [↑](#endnote-ref-10)