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| The purpose of this Checklist is to provide support for Designated Reviewers granting exemption determinations. This checklist is to be used. It does not have to be uploaded into the electronic system unless a limited IRB review is required. This checklist, or equivalent information, must be uploaded into the electronic system if a limited IRB review is required. | | | | |
| 1. GENERAL EXCEPTIONS :   (Check if “YES”. If checked, STOP, the research is not exempt.) | | | | | |
|  | The Research is subject to FDA Jurisdiction | | | |
|  | The research involves more than Minimal Risk to subjects. | | | |
|  | The Research involves access to Medical Records | | | |
|  | The Research involves deception, unless the subjects are told that deception is involved. | | | |
|  | The research involves Prisoners and is conducted or funded by DHHS, Dept. of Defense (DOD), Veterans Administration (VA), National Science Foundation (NSF), or Department of Education (ED). | | | |
| 1. gENERAL Criteria for approval of exempt research:   (Check if “Yes”) | | | | |
|  | Selection of subjects is equitable. (That is, the research is appropriate for the population being studied.) ***(Must be checked.)*** | | | |
|  | If identifiable information will be recorded (***One of the following must be checked***):  Recording of identifiable data is justified;  There are adequate provisions to maintain the confidentiality of the data  Not applicable | | | |
|  | There are adequate provisions to maintain the privacy interests of subjects. | | | |
|  | ***One of the following must be checked.***  The requirements for a waiver of consent under Checklist HRP 410 Waiver of Consent are met.  If there is a prospective interaction with subjects, there is a consent process which includes ***(all must be checked):***  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.  If the study is NIH-funded, the Certificate of Confidentiality template language is included. | | |
| 1. The research falls into one or more of the following categories:   (One or more categories must be checked) | | | | |
|  | **1. Educational Research**  Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices. This exemption 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. ***Both of the following must be checked:*** | | | |
|  |  | The research is not likely to adversely impact students’ opportunity to learn required educational content. | | |
|  |  | The research is not likely to adversely impact the assessment of educators who provide instruction. | | |
|  | **2. Educational Tests, Surveys, Interviews, Observation**  Research that includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording). | | | |
|  |  | 1. At least one of the following must be checked. ***(If none are checked, research is not exempt):***   This research does not include children as defined by 45 CFR 46.402(a)  This research is not subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), Environmental Protection Agency (EPA), or Veterans Administration (VA), US Department of Agriculture (USDA).  The procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed’ and/or (2) the use of educational tests. | | |
|  |  | 1. 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 subject. ***(If checked, exemption requirement is met.)*** | | |
|  |  | 1. 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; ***(If checked, exemption requirement is met.)*** | | |
|  |  | 1. 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. ***(If checked, the box below (e) must also be checked)*** | | |
|  |  | 1. Limited Review is complete and the following determination has been made: When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data | | |
|  | **3. Research involving benign behavioral interventions with adult subjects**  Research involving benign behavioral interventions[[1]](#footnote-1) in conjunction with the collection of information from a subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection***.*** | | | |
|  |  | 1. ***All the following must be met:***   This research only involves the participation of adults.  The research is a behavioral intervention[[2]](#footnote-2).  The participants have adequate decision-making capacity[[3]](#footnote-3) to agree to participate in the research.  The subjects prospectively agree to participate in the procedures.  If the study involves deception, the subjects are told that deception is involved.  The data collection is limited to 1) Verbal (oral) or written responses by the subject, 2) Data entry by the subject, 3) Observation of the subject, including audiovisual recording.  The research intervention is benign[[4]](#footnote-4).  The intervention is brief in duration[[5]](#footnote-5). | | |
|  |  | 1. 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; ***(If checked, exemption requirement met.)*** | | |
|  |  | 1. 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; ***(If checked, exemption requirement is met.)*** | | |
|  |  | 1. 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. ***(If checked, the box below (e) must also be checked)*** | | |
|  |  | 1. Limited Review is complete and the following determination has been made: When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. | | |
|  | **4. Secondary research for which consent is not required**  Secondary research uses of identifiable private information or identifiable biospecimens. ***At least one of the following must be checked to qualify for this exemption*** | | | |
|  |  | | The identifiable private information/biospecimens are publicly available. | |
|  |  | | Information is recorded by the investigator in such a manner that:   * The identity of the 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. | |
|  | **5. Research and demonstration projects conducted or supported by a Federal department or agency**  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 designee 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. The research or demonstration project is published on the department or agency’s list of research and demonstration projects that the department or agency conducts or supports under this provision. | | | |
|  | **6. Taste and food quality evaluation and consumer acceptance studies**  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 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 Dept. of Agriculture. ***At least one of the following must be checked to qualify for this exemption:*** | | | |
|  |  | The food contains only food ingredients at or below the level and for a use found to be safe | | |
|  |  | The food contains agricultural chemical or environmental contaminants 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. | | |

1. [↑](#footnote-ref-1)
2. The term behavioral intervention is used in the language of the regulations to define research procedures that are employed in the study of psychological states and processes, cognition, ideas and attitudes, or behavior. [↑](#footnote-ref-2)
3. Research requiring decision-making on behalf of the participant by a legally authorized representative would not qualify for the exemption. [↑](#footnote-ref-3)
4. Does not include physical (bodily) tasks or physical manipulations (e.g., range of motion activities, physical exercise) unless these are minor activities that are incident to the behavioral intervention and do not increase risk. Cannot be physically invasive- no instruments, substances or energy into body, harmful, painful, or distressing – no extremes of heat, cold, noise or light. Cannot introduce risks of harm, physical or emotional discomfort, offense, or embarrassment. [↑](#footnote-ref-4)
5. Generally refers to the intervention as opposed to the data collection activities if they are separable. Intervention can last a few minutes to a few hours, may occur in several sessions. [↑](#footnote-ref-5)