Initial Review  Review of Contingencies  Change in Protocols

REVIEWER'S CHECKLIST FOR EXEMPT PROTOCOLS

**IRB #**

**Reviewer:**

**Date:**

**Investigator:**

**Due Date**:

Enclosed is a **HUMAN RESEARCH PROTOCOL** for review. Please address each of the categories numbered below. As you review the study, please check if the information is adequate. Please use the second checklist below while reviewing each element of the **RECRUITMENT STATEMENT/COVER LETTER** (if applicable). Organize your written comments/suggestions below or on additional pages using the same numbers as used for each category.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **YES** | **NO** | **NA** |
| **Initial review materials received** |  |  |  |
| 1. IRB Cover Sheet, *required* (summary email is sufficient) |  |  |  |
| 1. IRB Exempt Review Application, *required*  * The first page of the IRB application must be signed by all investigators |  |  |  |
| 1. Proposed informed consent document, required |  |  |  |
| 1. Survey instrument(s) and/or experimental procedure as applicable, required |  |  |  |
| 1. Recruitment materials for subjects, required |  |  |  |
| 1. Human Subjects training completion certificates for ALL investigators, required |  |  |  |
| 1. Letter(s) of Approval from cooperating entities (Letter from district or principal if conducting research in schools), if applicable |  |  |  |
| 1. Relevant grant applications, if applicable |  |  |  |
| 1. Investigators brochure (a comprehensive document summarizing the body of information about an investigational product), if one exists |  |  |  |
| 1. If study is supported by the Department of Health & Human Services, a copy of the HHS approved sample, informed consent form, and HHS protocol, if they exist |  |  |  |
| **If any of the applicable review materials have not been received, please notify the principal investigator in writing. The review should only continue once all applicable review materials have been received.** |  |  |  |

**YES NO NA**

|  |  |  |  |
| --- | --- | --- | --- |
| **1. Funding source/conflict of interest** |  |  |  |
| 1. Researcher identifies funding sources (if any) |  |  |  |
| 1. There is no conflict of interest between funding sources and the project |  |  |  |
| **2. Appropriate category for research** |  |  |  |
| 1. Application is for exempt research |  |  |  |
| **3. Recruitment** |  |  |  |
| 1. Researcher has provided sufficient information on recruitment methods (including copies of any recruitment materials) |  |  |  |
| **4. Participants** |  |  |  |
| 1. Researcher has identified the approximate number of research subjects/records/specimens to be examined |  |  |  |
| 1. Subjects are over age 18 and under age 89 |  |  |  |
| 1. Any targeted groups are identified (age, gender, etc). |  |  |  |
| **5. Consent** |  |  |  |
| 1. Method(s) for obtaining consent are appropriate |  |  |  |
| 1. If requested, waiver of consent is appropriate |  |  |  |
| 1. Consent form or written script for consent is included with proposal and is suitable |  |  |  |
| **6. Compensation** |  |  |  |
| 1. Type/amount of compensation (if any) is described |  |  |  |
| 1. If class credit is part of compensation, alternative method(s) for obtaining credit are acceptable |  |  |  |
| **7. Data protection** |  |  |  |
| 1. Data will be kept in a secure location or on a password-protected computer |  |  |  |
| 1. Health information is not collected ***or*** health information is collected and a HIPAA De-Identification Certification form is attached |  |  |  |
| **8. Abstract** |  |  |  |
| 1. Abstract addresses exemption categories selected (e.g., type of data collected is appropriate, subject categories are acceptable, etc.) |  |  |  |
| 1. Abstract describes study procedures sufficiently |  |  |  |
| 1. Abstract describes duration of project (including time subjects will take part) |  |  |  |
| 1. Abstract describes benefits/risks of research to subjects and society |  |  |  |
| 1. Abstract describes how confidentiality/anonymity of subjects will be maintained |  |  |  |
| Do the benefits of the research outweigh the risks? |  |  |  |

RECRUITMENT STATEMENT/COVER LETTER/CONSENT FORM YES NO

|  |  |  |
| --- | --- | --- |
| 1. Investigator's names ***and*** ranks |  |  |
| 2. Explanation of purpose ***and*** justification of research |  |  |
| 3. Description of subject's participation ***and*** duration |  |  |
| 4. Description of risks ***and*** minimization of risks |  |  |
| 5. Explanation of how confidentiality/anonymity is protected |  |  |
| 6. Description of benefits to subject/society |  |  |
| 7. Explanation of voluntary participation |  |  |
| 9. Statement naming investigator who will answer questions ***and*** phone  number |  |  |
| Is the letter clearly written and in lay language? |  |  |

Comments:

|  |
| --- |
| **The following two statements MUST be true for the study to be exempt** The research does not involve prisoners.  The **ONLY** involvement of human subjects will be in research activities that fall under one or more of the  exempt categories.  **At least one set of the following statements must be true for the study to be exempt**  **Exempt category #1:**  1a) The research is conducted in a commonly accepted educational setting **AND**  1b) involves normal educational practices  **Exempt category #2:**  1a) The research involves educational tests or survey/interview procedures **AND**  1b) the research **does not** include children OR 2a) The research involves observation of public behavior **AND**  2b) if the research involves children where there is observation of public behavior, the investigator will not participate in activities being observed AND 3a) Information is recorded anonymously **OR**  3b) if identifiers are used, disclosure of responses will not be harmful to subjects  **Exempt category #3**  1a) The research involves 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  **AND**  2a) the human subjects are elected or appointed public officials or candidates for public office **OR**  2b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter  **Exempt category #4:**  1) The research involves data or specimens that are existing (on the shelf) at the start of the study AND 2a) Information will be recorded anonymously (no identifiers) **OR**  2b) the source is publicly available  **Exempt category #5:**  1) Projects which are conducted by or subject to the approval of department or agency heads,  **AND**  The project will study/evaluate  2a) Public benefit/service programs **OR**  2b) procedures for obtaining benefits or services under public benefit/service programs; **OR**  2c) possible changes in or alternatives to those public benefit/service programs or procedures; **OR**  2d) possible changes in methods or levels of payment for benefits or services under those public benefit/service programs.  **Exempt category #6:**  1) The study involves taste and food quality evaluation and consumer acceptance studies AND 2a) Wholesome food without additives are consumed **OR**  2b) 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. |

**I have reviewed the enclosed protocol and recommend:**

**Full Approval:** The study meets the criteria for exempt category(ies) # **\_\_\_\_\_\_\_\_\_\_**

**Contingent Approval:** Comments/suggestions/objections are listed or are attached.

**Rejection:** Comments/suggestions/objections are listed or are attached.

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**Signature of Reviewer Date**