EXEMPTION DETERMINATION SUBMISSION FORM

**INSTRUCTIONS**:

Please respond fully to each of the questions below when a research project is submitted for EXEMPTION DETERMINATION from OHRP regulations. The submitter should sign and date this form and return a PDF copy with the submission. Please submit the below applicable study documents with this completed and signed form to Pearl IRB for review.

Study documents may include:

Study protocol

Case report forms

De-identification SOP if data are not previously de-identified

\* PLEASE NOTE: Research that otherwise would be exempt by federal regulations that raises ethical concerns or requires measures to protect subjects may be denied and/or moved to a higher level of review (i.e. expedited or full IRB review).

**GENERAL GUIDANCE:**

Research activities are exempt from regulations for the protection of human research subjects when they are considered minimal risk (the probability or magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102.i)] and the ONLY involvement of human subjects falls within one or more of the exempt categories listed below.

Please be aware that the exempt categories outlined below do not apply to research involving prisoners or research involving a test article regulated by the FDA, unless the research meets the criteria for exemption taste and food quality evaluation and consumer acceptance studies:

* If wholesome foods without additives are consumed or
* 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, as described in 45 CFR 46.101(b)(6) and 21 CFR 56.104(d).

|  |
| --- |
| **STUDY/PRINCIPAL INVESTIGATOR CONTACT INFORMATION** |
| **Protocol Number:**  | **Protocol Title:**  |
| **Central IRB Submission:**  | **Single IRB Submission:**  |
| **Sponsor Name:**  |
| **Sponsor Contact Name:**  |
| **Street Address:**  |
| **Street Address:**  |
| **City:**  | **State:**  | **Postal Code:**  |
| **Phone:**  | **Email:**  |
| **Principal Investigator Name:** **(If this is a Central IRB review, please add remaining PI/site information at the end of this form)\*** |
| **Street Address:**  |
| **Street Address:**  |
| **City:**  | **State:**  | **Postal Code:**  |
| **\*Site Address:**  |
| **\*Additional Site Contact Name:**  |
| **City:**  | **State:**  | **Postal Code:**  |
| **Phone:**  | **Email:**  |
| **STUDY OF EXISTING DATA** |
| [ ]  Yes[ ]  No[ ]  N/A(move on to EXEMPTION CATEGORIES FOR HUMAN SUBJECT STUDIES).From       to      [ ]  Medical or Patient Records[ ]  Other (describe)[ ]  Yes, I will submit the form with this application[ ]  No. | 1. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [45CFR46.101(b)(4)]**To qualify for this exemption, data, documents, records, or specimens must exist at the time the research is proposed and not prospectively collected.** When was the original data collected or created? \*(i.e. the dates must be in the past; if you will use any data that was collected in the current year, please list the month as well)What is the source of the data?If medical or patient records are used - Please note if you are VIEWING medical records you must not record 16 specified identifiers that are listed in the regulations, including: name, street address, telephone and fax numbers, e-mail address, social security number, certificate/license number, vehicle identifiers and serial numbers, URLs and IP addresses, and full face photos and other comparable images. Information that could be used the following identifiable information: admission, discharge, and service dates, date of death, age (including age 90 and older), and five-digit zip code.If ‘OTHER’ answered please respond here:      Will you be using a data collection form (or CRF)?If ‘NO’ was answered list the data points (for example test scores, sex, race, age, etc.) that will be collected: |
| **EXEMPTION CATEGORIES FOR HUMAN SUBJECT STUDIES** |
| [ ]  Yes[ ]  No[ ]  N/A (Please explain):       | 2. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:* Research on regular and special educational instructional strategies, or
* Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. [45CFR46.101(b)(1)]
 |
| [ ]  Yes[ ]  No[ ]  N/A (Please explain):       | 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior  **unless:*** Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
* 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. [45CFR46.101(b)(2)]
 |
| [ ]  Yes[ ]  No[ ]  N/A (Please explain):      | 4. 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 #2 above:* Human subjects are elected or appointed public officials or candidates for public office; or
* Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. [45CFR46.101(b)(3)]
 |
| [ ]  Yes[ ]  No[ ]  N/A (Please explain):       | 5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:* Public benefit or service programs;
* 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. [45CFR46.101 (b)(5)].
 |
| [ ]  Yes[ ]  No[ ]  N/A (Please explain):       | 6. Taste and food quality evaluation and consumer acceptance studies:* If wholesome foods without additives are consumed; or
* 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. [45CFR46.101(b)(6) and 21 CFR 56.104(d)]
 |
| **ADDITIONAL QUESTIONS REGARDING STUDY** |
| [ ]  Yes[ ]  No | Do you intend to enroll PRISONERS as research participants?If you answered “yes”, the proposed research is not eligible for exemption (45CFR46.101.b). |
| **SUBMITTER CERTIFICATION AND SIGNATURE** |
| I certify that I have thoroughly reviewed the information provided on this exemption determination submission form and all additional forms submitted to Pearl IRB as true and accurate.Submitter Name (printed):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Submitter Signature: Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **IRB USE ONLY** |
| In addition to the regulations and answers provided by the client please consider the following questions and the when reviewing all documents for submission:* Are the ethical principles of respect for persons, beneficence and autonomy addressed?
* Will informed consent be obtained from subjects?
* Is the selection of subjects equitable?
* Are there adequate provisions to maintain the confidentiality of data?
 |
| **IRB Reviewer Determination:**[ ]  Submission *IS* considered exempt from IRB review. Please indicate appropriate regulatory category applied      .[ ]  Submission *IS NOT* considered exempt from IRB review. |
| Reviewed by (IRB member) name printed:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Reviewer Signature Review Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

\*If submission is determined to be a non-exempt study, the client may retain the option to request a non-exempt review.