**Exemption Request Form**

**Complete this form in its entirety. Do not add or delete any fields or form will be returned for correction.**

**Instructions:** Fill out this form to request an exemption from IRB approval/continuing review of research. Prior to submitting this form, please consult the **Exempt Research (E-20)** IRB policy on the McLeod intranet. The IRB consults this policy and all corresponding federal regulations when making a determination on any research exemption. **Information must be typed.**

**IRB USE ONLY:** Exempt Research? [ ]  Yes [ ]  No
 Exemption Review Date:

Date of Submission:

Project Title:

Principal Investigator:        Research Coordinator:

Address:

E-mail address:        Telephone:

Name and address of all facilities where project will be conducted:

**Type of exempt research** (primary investigation): [ ]  Procedural [ ]  Registry/Database

[ ]  Survey [ ]  Quality Improvement [ ]  Nursing [ ]  Other:

Length of study:        Expected number of subjects:

Expected results of the study:        How will the protocol be monitored?

**Will this research and its results be: [ ]  Published? [ ]  Presented outside of McLeod?**

*If so, submit a request for review to the Communications and Public Information Office at least 30 days prior to presenting or publishing your work. (Search “CPIO” on the McLeod intranet.)*

**Eligibility Requirements**

* 1. Is the research FDA-regulated (e.g. drug, device, or biologics)? [ ]  No [ ]  Yes
	2. Will or might the research involve vulnerable subjects (e.g. children, prisoners, mentally disabled persons, etc.)? [ ]  No [ ]  Yes (describe):

**Exemption Categories** [per 45 CFR 46.101(b)]. In the next section, please select all applicable exemption categories appropriate for your proposed research. If limited IRB review is required as part of the exemption, such review will take place after you submit this form. Finally, indicate how your study corresponds to that/those category(ies) using the Study Activities section.

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| --- | --- |
| [ ]  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: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;
2. 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
3. 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 review regarding the privacy of subjects and confidentiality of data.
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| [ ]  3. | Research involving benign behavioral interventions 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 agrees to the intervention and information collection and at least one of the following criteria is met: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;
2. 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
3. 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 review regarding the privacy of subjects and confidentiality of data.
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| [ ]  4.  | 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:1. The identifiable private information/biospecimens are publicly available;
2. 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;
3. The research involves only information collection and analysis involving the investigator’s use of identifiable health information as regulated under HIPAA for the purposes of “health care operations,” “research,” or “public health activities and purposes” [see 45 CFR 46.104 (d)(4)(iii) for details]; or
4. 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 in a federally lawful manner [see 45 CFR 46.104 (d)(4)(iv) for details].
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| [ ]  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. |
| [ ]  6. | Taste and food quality evaluation and consumer acceptance studies, if:1. Wholesome foods without additives are consumed, or
2. 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 FDA or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA).
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| [ ]  7. | Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited review regarding the obtaining and documenting of broad consent, along with privacy of subjects and confidentiality of data. |
| [ ]  8. | Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if all of the following criteria are met:1. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained appropriately [see 45 CFR 46.116 (d)];
2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117;
3. An IRB conducts a limited review regarding the privacy of subjects and confidentiality of data, and makes the determination that the research to be conducted is within the scope of the broad consent referenced in (i) above; and
4. The investigator does not include returning individual research results to subjects as part of the study plan, legal requirement notwithstanding.
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**Study Activities.** Using the space below, briefly clarify how the proposed project fits the selected exemption categories above. Describe the target population and/or how existing data/specimens will be accessed (if applicable). Attach any related study documents to this form, e.g. consent script, survey questions, Data Use Agreements, etc.

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**ALL FORMS MUST BE SIGNED BY THE PI.**

Principal Investigator (printed):

Principal Investigator Signature:        Date:

*Please send this original form along with any relevant supporting documentation\*\* to:*

Noah Kleckner, IRB Coordinator

McLeod Health - Research Department

(843) 777-2013

nkleckner@mcleodhealth.org

**\*\*PLEASE SEND ALL DOCUMENTS TO IRB COORDINATOR ELECTRONICALLY.**

**FOR IRB REVIEWER USE ONLY:**

**Comments:**     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Primary Reviewer (printed):    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Primary Reviewer Signature:   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    Date:

**FOR IRB OFFICE USE ONLY:** [ ]  Exempted [ ]  Deferred [ ]  Conditional Exemption

[ ]  Exemption Disapproved [ ]  Other

Acknowledgement Letter Sent Date:

[ ]  HIPAA Waiver of Authorization [ ]  HIPAA Authorization [ ]  IRB Waiver of Informed Consent

7/16, 4/17, 1/19