Community Healthcare System
Central Institutional Review Board
901 MacArthur Blvd., Munster, IN 46321
Phone: 219-836-6862

EXEMPT REVIEW DETERMINATION
(1/2019)

The Administrative staff (must be a member of the CHS CIRB) will review the Protocol Submission Form, Abbreviated Protocol Submission Form, or Protocol Renewal/Closure Form and/or any supporting documents related to the protocol to assess whether the study qualifies for Exempt Review.

The Administrative staff will document their findings on the Check List and file it with the acknowledgement letter to the investigator and the supporting documents in the protocol binder.

The Administrative staff will refer the request to the Chair of the CHS CIRB if an exempt status appears unclear. (Reference: Policy IRB 7.3: Exempt Review)

Protocol title:
Investigator:

General Exclusions from exemptions: Check if "Yes". If any are checked, the research is not exempt:

☐ **T**he resesearch is FDA-Regulated
☐ Research where there are interactions with prisoners
☐ Surveying or interviewing of children;
☐ Observations of public behavior of children when the investigator(s) participates in the activities being observed.

The research flls 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 education 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 or special educational instructional strategies, research on effectiveness of or the comparisons among instructional techniques, curricula, or classroom management methods.

☐ 2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures or observation of public behavior, (including visual or auditory recording) if ***at least one*** of the following criteria is met:

☐ 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;
☐ 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 subject's 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 45 CFR §46.111(a)(7)

NOTE: Document Limited Review below.

☐ 3. Research involving benign behavioral interventions in conjuction 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:

☐The information obtained is recorded by the investigator in such a manner that the identity of the human subject **cannot** readily be ascertained, directly or through identifiers linked to the subjects;
☐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 subject's financial standing, employability, education advancement, or reputation; or
☐The information obtained is recorded by the investigator in such a manner that the identity of the humans 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 45 CFR §46.111(a)(7).

NOTE: Document Limited Review below.

(ii) For the purpose of this provision, **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 not reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include have the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) 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.

☐ 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:

☐The identifiable private information or identifiable biospecimens are publicly available;
☐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;
☐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 [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR §164.501 or the "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 nonresearch activities. If the research generated 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, 44U.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 or benefits or services under those programs.

Such projects include, but are not limited to, internal studies by federal employees, and studies under contracts or consulting arrangements, cooperative agreements or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

☐ Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website 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 conduct or support under this provision. The research or demonstration project must be published on this list prior to commencing the research

☐ 6. Taste and food quality evaluation and consumer studies, if: Wholesome foods without additives are consumed, **or** 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 contaminate 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 Agriculture.

☐ 7. **This Category is not available. The CHS CIRB has chosen not to implement Broad Consent.** 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 IRB review** and makes the determinations required by 45 CFR §46.111(a)(8)

☐ 8. **This Category is not available. The CHS CIRB has chosen not to implement Broad Consent.** Secondary research for which **broad consent** is required; Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45CFR §46.116(a)(1) through (4), (a)(6), and (d);
b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR §46.117
c. An IRB conducts a **limited IRB review** and makes the determination required by 45CFR §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section ; and
d. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Method for Limited IRB Review: (check one if applicable)

☐ Limited IRB review, for research as a condition of exemption, conducted via expedited review
☐ Limited IRB review, for research as a condition of exemption, performed by the convened IRB.

The research fall into one or more of the following exempt categories for Limited Review:

☐ Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures or observation of public behavior, (including visual or auditory recording) where 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. The following must be true: (Check if "Yes")

☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

☐ Category 3: Research involving benign behavioral interventions in conjuction 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 The information obtained is recorded by the investigator in such a manner that the identity of the humans subjects can readily be ascertained, directly or through identifiers linked to

the subjects. The following must be true: (Check if “Yes”)

☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

Criteria for approval of exempt research (Check if “Yes”)

☐ The research involves no more than MINIMAL RISK to subjects (Must be checked)
☐ Selection of subjects Is equitable. That is, the research is appropriate for the population being studied. (Must be checked)
☐ There are interactions with subjects: (if checked the following must be checked also)
- ☐ There is a consent process
- ☐ The consent process will disclose that the activities involve research
- ☐ The consent proeces will disclose that participation is voluntary.
- ☐ The consent process will disclose the name and contact nformaiton for the investigator.
- ☐ There are adequate provisions to maintain the privacy interests of subjects.

_____ Exempt Status
_____ Review for Expedited Status
_____ Refer to CHS CIRB Chair
_____ Refer for full CHS CIRB Review

_____ _____
Signature of Reviewer Date

_____ _____
Signature of Chair Date
(If applicable)