TITLE: Exempt Review		POLICY/PROCEDURE NUMBER: IRB 7.3	
Author:	Jana L. Lacera, RN, MSA,CDM	Applicable To:	CHS CIRB
Supersedes:		Issued By:	CHS CIRB
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	CFNI		Community Hospital		St. Catherine Hospital		St. Mary Medical Center
X	Munster, Indiana	X	Munster, Indiana	X	East Chicago, Indiana	X	Hobart, Indiana

POLICY/PROCEDURE STATEMENT/PURPOSE:
It is the policy of the CHS CIRB that all human subjects' research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the exemption categories described in the federal regulations and complies with the Institution's ethical standards.

According to DHHD regulations 45 CFR §46, research involving the following are not appropriate for exemption:

1. FDA-regulated research;
2. Research involving prisoners;
3. Surveying or interviewing of children;
4. Observations of public behavior of children when the investigator(s) participates in the activities being observed.

Only the CHS CIRB may determine which activities qualify for an exempt review. The CHS CIRB does not "approve" an exempt study but instead makes a determination that the project meets at least one of the federal exempt categories criteria. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must contact the CHS CIRB office concerning the status of proposed research or changes in ongoing research.

Under an exempt review procedure, the review may be carried out by the CHS CIRB Chair or a qualified designee. The person (s) conducting the exempt review may either approve, require modifications (to secure approval) or refer the research to the convened CHS CIRB for review in accordance with the non-exempt review procedures. In conducting exempt review, the CHS CIRB reviewers may exercise all of the authorities of the CHS CIRB except that they may not disapprove the research.

Exempt reviews take place independently of the scheduled meetings. Research may be initiated as soon as the Principle Investigator (PI) has received a written determination by the CHS CIRB.

The CHS CIRB will request an annual update for exempt research to be able to track all projects conducted within the system. The CHS CIRB may, at its discretion, request periodic status reports.

DEFINITIONS

Broad Consent: The subject is asked to provide consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Broad consent is only required for Exempt Categories 7 and 8. ***The CHS CIRB chooses not to implement the use of Broad Consent as of the effective date of this policy.***

Benign Behavioral Interventions are:

1. Brief in duration;
2. Harmless,
3. Painless,
4. Not physically invasive,
5. Not likely to have a significant adverse lasting impact on the subjects, and
6. The investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

Human Subject: a living individual about whom an investigator conducting research; 1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Limited IRB Review: process to ensure that the security, privacy, and confidentiality of identifiable private information or identifiable biospecimens are adequately protected.
The IRB (a designee of the chair) must determine that the research procedures meet the criteria for exempt category 2 and 3 and, where appropriate, that there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data.

Minimal Risk: means that the probability and 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.

Activities that are deemed not to be research

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducts, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in research, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crises that threatens public health (including natural or man-made disasters).
3. Collection and analysis of information, biospecimens or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operation activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

CATEGORIES OF EXEMPT RESEARCH:

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:
    a. Most research on regular or special educational instructional strategies,
    b. 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:
    a. 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;
    b. 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**

c. 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)

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:

a. 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;
b. 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
c. 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).

(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:

a. The identifiable private information or identifiable biospecimens are publicly available;
b. 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;
c. 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 §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**
d. 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

a. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site 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 conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer studies, if:
   a. Wholesome foods without additives are consumed, **or**
   b. Food is consumed that contains a food ingredient at or below the level and for a use found to be safe, **or**
   c. 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 of Agriculture.

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 IRB review** and makes the determinations required by 45 CFR §46.111(a)(8)

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 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.

Investigator Responsibilities

1 May request an exempt review of materials when submitting a *Protocol Submission Form.* The form must be entirely completed even when exempt review is requested.
2 Investigators conducting exempt research are bound to adhere to the ethical obligations outlined in the Belmont Report and 45 CFR 46.
3 The PI should submit any consent documents with the Protocol Submission Form.

NOTE: Consent Requirements. If the study is found to be exempt from the requirements of 45 CFR 46, then there is no specific consent requirement for that study stemming from those regulations. Therefore there is no consent requirement that the CHS CIRB has the authority to waive. However, the CHS CIRB may request that informed consent be obtained and documented as part of the conditions of approval received in the original exemption.

4 Notify the CHS CIRB of:
   a. changes in the research plan that may affect the committee's initial determination of exempt status, i.e., a change in the risk/benefit ratio, changes that could affect the participant's willingness to participate;
   b. personnel changes that might affect the confidentiality of the records;
   c. changes to the study design or tools used to conduct the study;
   d. a proposal to continue the study to the CHS CIRB after one year if the investigator continues to collect data or enroll subjects requesting a reassessment;
   e. when the study is concluded.

   NOTE: Failure to submit appropriate documentation will result in termination of an exempt status and will be placed on the agenda of the next scheduled meeting of the CHS CIRB for a determination as to whether or not to terminate oversight for the study.

IRB Department Responsibilities

1. The CHS CIRB Chair, Co-Chair or designee will review the Submission Form and supporting documents to make a preliminary determination for an exempt review within one (1) week of receipt.
2. Any questions regarding an exempt status will be referred to the Chair or Co-Chair of the CHS CIRB.
3. The determination and any supporting statements will be documented on the Exempt Review Checklist. The Checklist will be filed in the study binder with the original submission letter.
4. A notice will be sent to the PI annually requesting an update on the current status of the study and if any changes may have occurred. The CHS CIRB Chair, Co-Chair or designee will review the update to verify that the project status remains exempt.
5. Any submissions that do not qualify for exempt review will be then assessed for potential expedited review. If the project is not eligible for either exempt or expedited review, it will be placed on the agenda of the next scheduled CHS CIRB meeting for Full Board Review.
6. Notification of approval for any submissions that do qualify for exempt review will be sent to the PI within ten (10) working days of receipt.
7. The CHS CIRB will be notified of the Exempt Review at the next regularly scheduled meeting.
8. The CHS CIRB will send a *Request for Annual Update for Exempt Research form* on a yearly basis.

REFERENCE:
Code of Federal Regulations 45, Part 46.101
Code of Federal Regulations 21, Part 50
Human Subject Regulations Decision Charts published by the Office for Human Research Protections

CROSS REFERENCE:
Exempt Category Guidance Addendum I
Exempt Review Checklist
Request for Annual Update for Exempt Research form

ACCEPTED BY:

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DATE REVISED: 12/05/2006, 5/2010, 4/2011, 3/2014, 2/2018, 1/2019

REVIEWED BY: CHS CIRB 4/12/2005, 1/10/2007, 5/11/2010, 4/12/2011, 6/14, 2016, 1/2019 , 1/2021

Date	Initials
1/2007	JL
5/2010	JL
4/2011	JL
2/2014	JL
6/2016	JL
2/2018	JL
1/2019	JL
1/2021	JL