The Christ Hospital IRB
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STANDARD OPERATING PROCEDURE

Exempt Research: Determination of Human Subjects Research and Research Exempt from Federal Human Subjects Protection Regulations

1.0 POLICY

All research involving human subjects must be approved or receive exemption by the IRB before the research is conducted. Exempt research is a specific sub-set of human subjects research that does not require ongoing IRB oversight. Research activities may qualify for exemption if it is no more than minimal risk and all of the research procedures fit within one or more of the categories listed in the federal regulations 45 CFR 46.104(d).

Investigators do not have the authority to make an independent determination that research involving human subjects qualifies for an exemption. Studies that qualify for exemption must be submitted to the IRB for review before starting the research. The IRB must determine that the study is in compliance with applicable laws and regulations, including the HIPAA Privacy Rule, state law, and institutional policy as applicable to research. Studies that qualify for exemption must adhere to principles of sound research design and ethics. Participant rights and welfare must also be protected in a manner appropriate for research that poses minimal risk.

Submissions of research which may qualify for exemption will be reviewed by the IRB chair or designee to determine whether the study is exempt from further IRB review and from applicable federal regulations governing human research. The reviewer may request the assistance of other individuals in consideration of exempt status. The IRB chair or designee may determine that the research qualifies as exempt only if it falls into one or more of the exempt categories and meets the additional requirements as described below.

2.0 OVERVIEW

2.1 Exempt Review Categories

Eight exemption categories are outlined by federal regulations (ref. 45 CFR 46.104(d)).

2.1.1 Category 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. Ref. 45 CFR 46.104(d)(1)

2.1.2 Category 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 (45 CFR 46.104(d)(2)):

2.1.2.1 The information obtained is recorded by the investigator in such a manner that the identity of the human participant's cannot readily be ascertained, directly or through identifiers linked to the participants;

2.1.2.2 Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation;

2.1.2.3 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 IRB review to make the determination required by 45 CFR 46.111(a)(8)(iii)

2.1.3 Category 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 (ref. 45 CFR 46.104(d)(3)).

2.1.3.1 The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the subjects;

2.1.3.2 Any disclosure of the human participants' responses outside the research would not reasonably place the subjects at risk of

criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; or

2.1.3.3 The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(8)(iii).

For the purposes of this provision, benign behavioral interventions are brief, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no 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 having 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.

If the research involves deceiving the subjects regarding the nature or purpose 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.

2.1.4 Category 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 are met (45 CFR 46.104(d)(4)):

2.1.4.1 The identifiable private information or identifiable biospecimens are publicly available; or

2.1.4.2 Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants; or

2.1.4.3 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, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for

"public health activities and purposes" as described under 45 CFR 164.512(b); or

2.1.4.4 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 generates 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, 44 U.S.C. 3501 *et seq.*

2.1.5 Category 5

Research and demonstration projects that are conducted by or subject to the approval of (Federal) department or agency heads and which are designed to study, evaluate or otherwise examine (45 CFR 46.104(d)(5)):

2.1.5.1 Public benefit or service programs;
2.1.5.2 Procedures for obtaining benefits or services under those programs;
2.1.5.3 Possible changes in or alternatives to those programs or procedures; or
2.1.5.4 Possible changes in methods or levels of payment for benefits or services under those programs.

2.1.6 Category 6

Taste and food quality evaluation and consumer acceptance studies (45 CFR 46.104(d)(6))

2.1.7 Category 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 § 46.111(a)(8).

NOTE: The Christ Hospital (TCH) has made an Institutional decision that broad consent will not be permitted at this time. As a result, TCH IRB will not consider applications under exempt Category 7 which require broad consent.

2.1.8 Category 8

Secondary research involving use of identifiable private information or identifiable biospecimens for which broad consent was required (45 CFR 46.104(d)(8)(i)).

NOTE: The Christ Hospital has made an Institutional decision that broad consent will not be permitted at this time. As a result, the TCH IRB will not consider applications under exempt Category 8 which require broad consent.

2.2 **Additional Requirements**

Research qualifies as exempt only if it falls into one or more of the Exempt Categories described above, and meets these additional requirements:

2.2.1 The research must present no more than minimal risk to subjects;
2.2.2 The research is consistent with the ethical principles established by the Belmont Report to ensure the ethical conduct of research including autonomy/respect for persons, beneficence, and justice;
2.2.3 If there is recording of identifiable information, there are adequate provisions to maintain the privacy interests of participants and the confidentiality of data;
2.2.4 The research does not involve a test article regulated by the FDA, unless the research meets the criteria for exemption described in 45 CFR 46.104(d)(6) and 21 CFR 56.104(d); and
2.2.5 The research does not involve prisoners.

2.3 **Limited IRB Review**

Limited IRB Review is a process that is required for projects qualifying for Exempt Categories 2 (c.), 3(c.), 7, and 8 above, and does not require consideration of all the approval criteria described in 45 CFR 46.111.

3.0 PROCEDURE

3.1 **Application**

If a research study meets the federal regulations and institutional and ethical criteria to qualify for exemption, the investigator must complete an e-application for exemption through the web-based IRB submission system, Mentor IRB.

3.2 **HIPAA Compliance**

3.2.1 The reviewer will determine whether the proposed research involves the use and/or disclosure of Protected Health Information (PHI).
3.2.2 If PHI is to be used/disclosed in the research, the investigator may request that a HIPAA waiver or alteration of authorization to be approved by the IRB. Alternatively, the investigator may obtain authorization from each subject.

3.2.3 Any time the IRB grants a waiver or alteration of Authorization, the IRB office will indicate that a waiver or alteration has been granted to the investigator in the approval letter.

3.2.4 Investigators must account for any disclosures under a waiver of authorization.

3.3 Obtaining Informed Consent in Exempt Research

Informed consent is a practice that helps to ensure that the rights and welfare of participants are protected. TCH IRB requires that informed consent from participants be obtained when it is reasonable and practicable to do so, and the process of informed consent must still be upheld in research exempt from Federal Human Subjects Protection Regulations. Consent documents processed for exempt research are marked with an IRB approval stamp in the header; however, because the project does not expire or require continuing review, no expiration date will appear with the stamp.

3.4 Changes to Exempt Research

3.4.1 Investigators should consult with the IRB or submit an amendment if they wish to make changes to an exempt study.

3.4.2 Investigators shall submit document revisions accompanied by an Amendment Description through Mentor IRB.

3.4.3 The IRB will evaluate revisions according to 45 CFR 46.104(d) to determine if the revised research meets the exempt criteria.

3.4.4 The IRB Office will notify investigators of the determination.

3.4.4.1 If the revisions alter the research such that the study is no longer exempt from IRB review, the investigator shall re-submit the study through Mentor IRB requesting expedited review and IRB approval must be secured prior to implementation of the changes.

3.4.4.2 If the revised research study continues to meet the exempt from IRB review criteria, the IRB Office will document the exempt category on the IRB Approval Letter.

3.5 Limited IRB Review

Limited IRB review may be completed by the IRB Chair or designee IRB member. The individual performing the limited review may not disapprove the research and may refer the limited IRB review to the full board for consideration. The Christ Hospital retains the authority to suspend or terminate IRB approval of research approved with a limited review.

Exempt Categories Providing for Limited IRB Review

Exempt categories 2, 3, 7, and 8 include a provision for limited IRB review.

3.5.1 Categories 2 and 3

For exempt categories 2 and 3, the requirement for limited IRB review is triggered when:

3.5.1.1 The information obtained is recorded by the investigator in such a manner that the identity of the human subject can readily be ascertained, directly or through identifiers linked to the subjects, AND

3.5.1.2 Any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, education advancement, or reputation.

3.5.2 Categories 7 and 8

For exempt categories 7 and 8, limited review is always required. It is also important to remember that exempt categories 7 and 8 are only available for use when broad consent will be (or has been) obtained. The Christ Hospital has made an Institutional decision that broad consent will not be permitted at this time. As a result, the TCH IRB will not consider applications under exempt categories 7 and 8.

4.0 RESPONSIBLITIES

4.1 Review of Exempt Application

4.1.1 IRB Chair Review

The IRB Chair or designated member of the IRB reviews exempt application and submission:

4.1.1.1 Conducts the review by completing the New Protocol Reviewer Checklist;

4.1.1.2 Makes determination:

4.1.1.3 Exemption Approved;

4.1.1.4 Additional Information Requested;

4.1.1.5 Deferral for review by either the expedited or convened IRB process;

4.1.2.3 Reports the action to the IRB.

4.1.3 IRB Office

4.1.3.1 Documents and relays the reviewer's determination;

4.1.3.2 Issues approval letter in Mentor IRB; and

4.1.3.3 Assigns the research protocol to the Exempt/Expedited Report agenda for review at the next convened IRB meeting.

4.1.4 Investigator

4.1.4.1 Submits e-application for exemption of the proposed research through the web-based IRB submission system, Mentor IRB;

4.1.4.2 Ensures that the study is conducted in compliance with applicable laws and regulations including the HIPAA Privacy Rule, state law, and institutional policy;

4.1.4.3 Ensures that the study conforms to the principles of sound research ethics, in accordance with principles of the Belmont Report;
4.1.4.4 Begins research activities after documentation of IRB approval or exemption is received;
4.1.4.5 Conducts the research in compliance with the protocol as submitted to and exempted by the IRB;
4.1.4.6 Obtains approval for all changes to the protocol prior to implementing the changes; and
4.1.4.7 Adheres to IRB policy for reporting unanticipated problems.

4.2 **Limited IRB Review**

In limited IRB review, the IRB must determine that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of subject data (45 CFR 46.111(a)(7)).

4.2.1 IRB Chair Review

The IRB Chair or designated member of the IRB reviewing exempt applications requiring limited review:

4.2.1.1 Identifies the necessity for limited review;
4.2.1.2 Conducts the review by completing the Limited Review questions on the New Protocol Reviewer Checklist;
4.2.1.3 Makes determination:
4.2.1.3.1 Exemption Approved with Modifications, or
4.2.1.3.2 Exemption Approved, or
4.2.1.3.3 Deferral for review by either the expedited or convened IRB process.
4.2.1.4 Reports the action to the IRB.

4.2.2 IRB Office

The IRB Office documents and relays the reviewer's determination:

4.2.2.1 Issues approval letter in Mentor IRB, and
4.2.2.2 Assigns the research protocol to the Exempt/Expedited Report agenda for review at the next convened IRB meeting.

5.0 REFERENCES

5.1 Code of Federal Regulations
5.1.1 U.S. Department of Health and Human Services
5.1.1.1 45 CFR 46.104(d)
5.1.1.2 45 CFR 46.104(d)(1)
5.1.1.3 45 CFR 46.104(d)(2)
5.1.1.4 45 CFR 46.104(d)(3)
5.1.1.5 45 CFR 46.104(d)(4)

5.1.1.6 45 CFR 46.104(d)(5)
5.1.1.7 45 CFR 46.104(d)(6)
5.1.1.8 45 CFR 46.104(d)(8)(i)
5.1.1.9 45 CFR 46.111
5.1.1.10 45 CFR 46.111(a)(7)
5.1.1.11 45 CFR 46.111(a)(8)
5.1.1.12 45 CFR part 160
5.1.1.13 45 CFR part 164, subparts A and E
5.1.1.14 45 CFR 164.501
5.1.1.15 45 CFR 164.512(b)
5.1.1.16 45 CFR 46.104(d)
5.1.1.17 45 CFR 46.111(a)(8)

5.1.2 U.S. Food and Drug Administration: 21 CFR 56.104(d)

5.2 U.S. Congress, Privacy Act of 1974, 5 U.S.C. 552a

5.3 U.S. Department of the Interior - Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

5.4 U.S. Department of Justice - Section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note

5.5 AAHRPP Domains and Elements
5.5.1 II.2.A
5.5.2 II.2.B
5.5.3 II.2.C