Complete this form if you believe that your activity may meet the criteria for a determination of exempt status. The determination of exempt status must be made by a disinterested person knowledgeable in the interpretation of Human Subjects Research regulation and guidance. At Western Michigan University Homer Stryker M.D. School of Medicine (WMed), this responsibility is delegated by policy to the IRB Chair and Vice Chair who also have the authority to require modifications to exempt research in order to ensure protections of human subjects.

A determination of exempt status does not in any way absolve the investigator from his or her responsibilities in protecting the rights and welfare of the subjects participating in the research. Exempt research is subject to the policies and oversight of the Human Research Protection Program. All principles of the Belmont Report and WMed policies on the protection of patient(s) privacy and confidentiality also apply.

Investigators must submit any proposed modifications to the research for a determination of whether or not the modified activity still qualifies for exemption and must notify the IRB office when an exempt research project is complete so that an accurate database of active research can be maintained.

**In addition to this form, include the following with your submission:**

1. The protocol
2. Any subject materials such as recruitment materials, information sheets, consents, scripts, and questionnaires or surveys
3. The grant application (if the project is federally-funded and WMed is the prime awardee or is serving as the IRB of record for the prime awardee)
4. Evidence of departmental and institutional approval
5. The Conflict of Interest form (Supplement N)
6. Provide the CITI training certificate for the PI and all study team members.

**I. Basic Information**

1. Protocol Title:
2. Funding Support:

NA, this project is unfunded

Grant. Describe:

Contract. Sponsor:

Other. Describe:

1. Principal Investigator

|  |  |
| --- | --- |
| **PI Name:** | **Date:** |
| Degrees/Credentials (e.g., licenses, certifications): | |

|  |  |
| --- | --- |
| Department/Division/Unit: | |
| Address: | |
| Email: | Phone Number: |
| Human Subjects Training (i.e. CITI) Certificate Date: | |

1. Additional Personnel NA

**NOTE:** *Other study personnel include all individuals responsible for the design, conduct, or reporting of the study, including Sub-Investigators. All personnel must have current (within 4 years) human subjects training certification.*

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Study Role | Department/Division/  Unit (if applicable) | Human Subjects Training (CITI) Date |
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**II. Basic Criteria for Eligibility for Exemption**

1. Does the intended subject population include prisoners?

Yes. The research is not eligible for exemption. Apply to the IRB using the Initial Study Application.

No. Go on to the next question.

1. Is the research subject to FDA regulations (i.e., clinical investigation of drugs, devices, biologics, and other FDA-regulated products)?

Yes. Category 6 (certain taste & food quality studies) is the only allowable category that is exempt from the requirements of FDA regulations for IRB review. If your research does not fit the criteria for Category 6 you must apply to the IRB for either expedited or convened board review.

No. Go on to the next question.

**III. Exempt Categories**

In order to be exempt, the only involvement of human subjects must be in one or more of the following categories.

1. Indicate all of the categories which you believe are applicable to this research:

**Category 1:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**Category 2:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.

If the research involves any of the following, then this exemption does not apply:

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.

The research involves surveys or interviews with children.

The research involves observations of children’s public behavior; **and,** the investigator(s) plan to participate in the activities being observed.

**Category 3:** 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 Category 2, if:

The 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.

**Category 4:** Research involving the collection or study of EXISTING data, documents, records, pathological specimens, or diagnostic specimens, if:

The sources are publicly available; or

The information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects

1. Do all of the data and/or specimens exist today?

Yes. This exemption applies. The date range from which the data or specimens will be drawn must be clearly delineated in the protocol.

No. This exemption does not apply.

1. Will you be maintaining a temporary list of identifiers (e.g., so that you know which records need to be accessed)?

Yes. All of the following must be true (‘Yes’) in order for the research to qualify for exemption:

* 1. The information that will be accessed for the research comes from one source, for example, outpatient clinic records.  Yes  No
  2. A list of identifiers, for example, medical record numbers, without any associated information, will be used for the purpose of identifying records or specimens that might be necessary to conduct the research analysis.  Yes  No
  3. A separate document or dataset, without identifiable information, will be created and used for analysis. This dataset or document will be stored separately from the list of identifiers.  Yes  No
  4. The list of identifiers will be destroyed immediately after data collection is complete (i.e., prior to analysis).  Yes  No

No. A temporary list of identifiers will not be maintained.

**Category 5:** Research and demonstration projects which are designed to study, evaluate, or otherwise examine (i) Federal public benefit or service programs, (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; if:

The projects are conducted by or subject to the approval of Federal Department or Agency heads, and

The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act), and

There is no statutory requirements for IRB review, and

The research does not involve significant physical invasions or intrusions upon the privacy of subjects, and

The exemption is invoked with authorization or concurrence by the funding agency

NOTE: **ALL** of these criteria must be met for this exemption to apply.

**Category 6:** Taste and food quality evaluation and consumer acceptance studies, if:

Wholesome foods without additives are consumed; or

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

1. Are there any research activities that are not encompassed within one of the above categories?

Yes. Describe:

No

**IV. Protection of Human Subjects**

1. How do you plan to identify subjects or records for inclusion in the study?

1. Describe any inclusion and exclusion criteria or reference where this information can be located in the protocol.

1. Describe the provisions that will be taken to protect the confidentiality of subjects’ information and research data (e.g., storage of research data in a locked file cabinet, separate storage of key to code that allows re-linking of data, encrypted files, etc.).

1. If the research involves interaction with or observation of subjects, please answer the following. If not applicable to your study, write N/A.
   1. Describe how subjects will be recruited to participate in the research. Include any materials that will be used to recruit subjects in your submission package.

* 1. Describe any provisions that will be taken to protect the privacy of potential and actual subjects. Privacy is about having control over the extent, timing, and circumstances of sharing oneself with others. Consider the settings where recruitment, observation, interaction, procedures, and/or interventions will occur.

* 1. Although the regulations do not require consent for exempt research, researchers have an ethical obligation under the Belmont Report to ensure that subjects are properly informed and voluntarily agree to participate in research whenever possible (e.g., the research involves interactions with subjects in person or through surveys or interviews). A formal consent form is not required, but consent scripts, survey cover letters, or information sheets for exempt studies should include all of the following elements:
* A statement that the activities involve research
* A description of the procedures to be performed
* A statement that participation is voluntary
* The investigator's name and contact information

Will potential subjects be asked to provide informed consent?  Yes  No

If yes, describe the consent process and include with the submission any materials that will be used to explain the research and/or document consent.

* 1. Describe any measures that will be taken to ensure that subjects don’t feel obligated or pressured to participate in the research.

1. Will Protected Health Information (PHI) *(See Appendix 1)* be accessed, used, or disclosed for the purposes of the research?

Yes  No

*If yes, please answer the following:*

* 1. Provide a comprehensive description of the PHI needed for the study or provide a data sheet as an attachment.

* 1. Describe the sources of the PHI, including whether PHI is being obtained from any non-WMed sources

* 1. If the sources of the PHI include any external (non-WMed) entities, explain the steps you are taking to ensure compliance with the entities’ HIPAA and data use requirements.

* 1. Will you be disclosing WMed PHI to any external parties such as a collaborator, sponsor, or other organization?

Yes  No

If yes, is the data to be disclosed:

Stripped of all elements considered to be identifiers under HIPAA (See Appendix 1)

A Limited Data Set (See Appendix 2). Include a copy of the DUA with your submission. If not yet executed or you need more information contact the Assistant Dean, Research Compliance.

Identifiable (contains PHI and is not restricted to a Limited Data Set).

* 1. Will you obtain written HIPAA authorization from subjects for use of their data or are you requesting a waiver of HIPAA authorization? Note: The requirement to obtain authorization, or a waiver of authorization, does not apply if your only use or exposure to PHI will be a Limited Data Set (See Appendix 2).

NA. Limited Data Set

If there is more than one subject group (e.g., prospective subjects and historical control), indicate all that apply.

Written authorization. *Include a copy of the authorization form with your submission.*

All Subjects  Some Subjects. Explain:

Waiver of Authorization.

All Subjects  Some Subjects. Explain:

If you are requesting a waiver for some or all subjects, please provide responses to the following so that the IRB can determine whether or not the project qualifies for a waiver.

* + 1. Describe your plan to protect PHI from improper use and disclosure

* + 1. Describe your plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so). *Note: In many cases, identifiers will need to be retained after the research is completed (e.g., for publication or data verification purposes or because of contractual requirements or grant terms).*

* + 1. Describe why the research could not practicably be conducted without the waiver

* + 1. Describe why the research could not practicably be conducted without access to and use of the PHI

**V. Principal Investigator Certification**

I certify that the information provided in this application is complete and correct.

If a waiver of authorization is being requested, my signature below also certifies that:

(1) The PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule

(2) The PHI that will be accessed, used, or disclosed for the purposes of the research is the minimum necessary to achieve the objectives of the research

**Signature of Principal Investigator Date**

**HRPP/IRB Use Only**

**Reviewer:** If you have a conflict of interest, please do not complete this review. Instead, contact the IRB office at 269-337-4345 so that the review may be reassigned.

**Basic Ethical Evaluation:**

Selection of subjects is equitable and appropriate

Provisions for the protection of confidentiality are appropriate

Recruitment process and materials, if applicable, are appropriate  NA

Provisions for the protection of privacy are appropriate  NA

Provisions for the consent of subjects are appropriate  NA

**HIPAA:**

This research does not involve the access or use of PHI

Or:

The PHI accessed or used for the research is a Limited Data Set  NA

Provisions for HIPAA authorization are appropriate  NA

Criteria for waiver of HIPAA authorization are satisfied  NA

**Determination:**

Exempt, Category(ies):

Additional information is needed:

Modifications are needed:

Refer to IRB:

**Appendix 1: Protected Health Information**

*Protected health information means, generally,* health information that is individually identifiable (i.e., patient-specific) and that is created, maintained, used or disclosed by or for by a covered entity. More specifically, the term refers to information that:

1. identifies or could reasonably be used to identify the individual; and
2. relates to:
3. an individual’s physical or mental health or condition;
4. the provision of health care to an individual, or
5. Payment for health care provided to an individual.

Health Information that includes or is combined with any of the following elements is considered identifiable under HIPAA.

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
   1. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
   2. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web universal resource locators (URLs).
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

**Appendix 2: Limited Data Sets**

*Limited Data Set*refers to PHI that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual’s Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement.

*Data Use Agreement*refers to an agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.

Direct Identifiers that **must be excluded** for PHI to be considered a Limited Data Set:

1. Names.
2. Postal address information, other than town or city, state, and ZIP Code.
3. Telephone numbers.
4. Fax numbers.
5. Electronic mail addresses.
6. Social security numbers.
7. Medical record numbers.
8. Health plan beneficiary numbers.
9. Account numbers.
10. Certificate/license numbers.
11. Vehicle identifiers and serial numbers, including license plate numbers.
12. Device identifiers and serial numbers.
13. Web universal resource locators (URLs).
14. Internet protocol (IP) address numbers.
15. Biometric identifiers, including fingerprints and voiceprints.
16. Full-face photographic images and any comparable images.

A Limited Data Set **may include**: city; state; ZIP Code; elements of date; and other numbers, characteristics, or codes not listed as direct identifiers.