## 9C20844B-9BFB-4AB9-A757-14007340F01B@local

## IRB – Exemption from IRB Review

## Principal Investigator for the project:       Routing Location:

## Full Title of the Study:

## SP Code:

**List MC/MCRF Departments/Centers associated with this study:**

**Additional Investigators:**

## Person completing the form:

**While ORIP and/or the IRB is ultimately responsible for deciding if research qualifies for exemption, investigators are asked to make an initial determination of the appropriate exemption category(ies) 1-6 below. All research activities must qualify for exemption under one or more allowable categories.**

**Please select the exemption category(ies) below that you believe apply (1-6):**

**Category #1:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

* Research on regular and special education instructional strategies, or
* Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

\*\* This exemption is not applicable to FDA-regulated research. The research may also not involve prisoners as participants.

 [ ]  Applies - explain how your proposed activity meets this category:

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

* Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
* Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

\*\* This exemption is not applicable to FDA-regulated research, or survey or interview research involving children. It also does not apply to observations of public behavior involving children, except when the researchers do not participate in the activities being observed.

 [ ]  Applies - explain how your proposed activity meets this category:

**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 Exemption Category #2, if:

* The human participants 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.

\*\* This exemption is not applicable to FDA-regulated research. The research may not involve prisoners as participants.

 [ ]  Applies - explain how your proposed activity meets this category:

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

* these sources are publicly available; or
* if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

\*\* This exemption is not applicable to FDA-regulated research. The research may not involve prisoners as participants.

 [ ]  Applies - explain how your proposed activity meets this category:

**Category #5:** Research and demonstration projects which are conducted by or participant to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine one or more of the following:

* Public benefit or service programs.
* Procedures for obtaining benefits or services under those programs
* Possible changes in or alternatives to those programs or procedures
* Possible changes in methods or levels of payment for benefits or services under those programs.

\*\* This Category is rarely applicable to individual investigators. Please first contact ORIP if you believe your research falls into this category.

 [ ]  Applies - explain how your proposed activity meets this category:

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

* If wholesome foods without additives are consumed; or
* If 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.

\*\* The research may not involve prisoners as participants.

 [ ]  Applies - explain how your proposed activity meets this category:

**Note: If none of the categories (1-6) above apply an IRB New Research Application for convened/expedited review is required.**

**Complete the following questions**

1. Does this project involve interaction, intervention or collection of data from or about any of the following protected populations: Prisoners; pregnant women; fetuses; or institutionally mentally disabled (individuals residing as patients in an institution who are mentally ill or decisionally impaired; emotionally disturbed; psychotic or senile)?

 [ ]  No

 [ ]  Yes, you may not apply for exempt review and must submit for expedited or full Board review

1. Are the data you propose to collect from or about minors?

[ ]  No

[ ]  Yes,

If yes, will the research involve a survey, an interview, or observation in which the investigator participates in the activity being observed?

 [ ]  No

 [ ]  Yes,

 If yes then exempt category #2 does not apply for exempt review and project must be submitted

 for expedited or full Board

1. Provide the anticipated number of participants/data/specimens to be involved in the project.
2. Does this study involve interaction with participants?

 [ ]  No

 [ ]  Yes - describe the steps you will take to ensure the following:

* Participants understand that the activity is research, and that taking part is voluntary:
* The research is free of coercion or undue influence (include a description of any planned incentives or reimbursement):
* Participants are able to contact you with questions or concerns:
1. Provide scientific and ethical justification if you plan to exclude from enrollment any class of persons who might benefit from the research:

 [ ]  Not applicable

1. How will you identify potential participants?
2. How are participants being approached and informed about this research project?
3. Please provide anticipated start and completion dates of research project
4. How will participant privacy be protected?
5. How will confidentiality of data be maintained?
6. Will you use or disclose Protected Health Information (PHI) in conducting this activity?

 [ ]  No – **Skip to question #22**

 [ ]  Yes

1. Will you or study staff be accessing PHI prior to obtaining written authorization from participants, such as for screening or recruitment?

 [ ]  No

 [ ]  Yes – By signing this form, the PI makes the following representations that he/she will:

1. Request only the minimum necessary PHI
2. Use PHI only to identify potential participants or prepare a research protocol
3. Ensure that no PHI used for this purpose leaves Marshfield Clinic and
4. Request only PHI that is necessary for screening, recruitment or protocol preparation
5. Will you be obtaining written HIPAA authorization containing all required elements from participants?

[ ]  No - I am requesting a waiver of the authorization requirement – ***Skip to question #15***

[ ]  No - I am seeking an alteration of HIPAA authorization to request that core element(s) or required

 statement(s) be waived

[ ]  Yes – ***Skip to question #22***

1. What core elements of authorization are you requesting to waive?

[ ]  Description of PHI to be used or disclosed

[ ]  Name or class of person to use or disclose PHI

[ ]  Name or class of person to whom you will disclose of PHI

[ ]  Description of each purpose of the use or disclosure of PHI

[ ]  Expiration date

[ ]  Dated signature of the research participant

[ ]  Subject has the right to revoke the authorization in writing

[ ]  Either: the covered entity may not condition payment, treatment, enrollment or eligibility for

 enrollment on whether the subject signs the authorization; or the consequences to the subject of a

 refusal to sign the authorization when the covered entity can invoke such conditions

 [ ]  That PHI disclosed pursuant to the authorization may be re- disclosed by the recipient and no longer

 protected by the Privacy Rule

1. Do you believe the use or disclosure presents greater than minimal risk to the privacy of participants?

 [ ]  No

 [ ]  Yes - *Do not complete remaining questions; waiver or alteration is not allowed. You must obtain*

 *signed authorizations from research participants or otherwise satisfy the Privacy Rule (contact*

 *ORIP with questions)*

1. How do you plan to protect the identifiers from improper use or disclosure, and how will you ensure the PHI will not be re-used or shared improperly?
2. Describe your plan to destroy identifiers at the earliest opportunity or justify why you plan to retain identifiers:
3. Explain why this specific research could not be conducted without the waiver, or if you are requesting an alteration, provide information that is specific to your request:
4. Describe the specific PHI to be used:
5. Describe the specific PHI to be disclosed:
6. Why is the use or disclosure of PHI necessary for this research?
7. Will you be sharing biological material, with or without accompanying data, with external individuals or entities?

[ ]  No [ ]  Yes – Material only - **Complete Appendix A**

**APPENDIX A**

**Sharing of Biological Material**

1. **In general terms, describe the data/material to be shared.**

1. **Indicate who will have access to data/material and for what purpose.**

1. **For each group of data or material to be shared, discuss the degree to which data/material will be de-identified by noting whether any of the following will be included:**
2. **Indirect subject codes** (not derived from or related to information about the subject)
3. **Indirect identifiers** (city, state, county, precinct, zip code, dates [except year] directly related to a subject, ages over 89 and all elements of dates [including year] indicative of such age)
4. **Direct identifiers** (name, address, phone#, fax, email, SSN, MHN, health plan #, account #’s, certificate / license #’s, vehicle ID #’s, device ID #’s and serial #’s, URL, IP address, biometric ID’s, facial photos or comparable images, any unique identifying number, characteristic or code)

1. **If data/material to be shared will contain direct or indirect identifiers, explain why identifiers are needed, and how the information will be secured both during the transfer of data/material and once at the recipient’s site.**

**[ ]** Not Applicable

1. **Are the material(s) accompanied by data discussed in a HIPAA authorization signed by research subjects as described, or in a waiver of authorization as described?**

[ ]  Yes

[ ]  No (Also submit the form, “IRB Waiver - Consent and Authorization”)

1. **Explain why coded information is not sufficient.**

1. **Describe specifically how each organization plans to secure the data.**

1. **State whether the organization will release data with identifiers to others.**

If so, for what purpose?

**SIGNATURE AND CERTIFICATION**

**Principal Investigator Attestation**

I certify that the information provided herein and attached is true and complete to the best of my knowledge, and that research staff are qualified (e.g., credentials and when relevant, privileges) to perform procedures assigned to them during the study.

**Comments:**

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Signature of Principal Investigator Date

Printed Name of Principal Investigator Routing Location

**[ ]**

***Please submit along with this Request form:***

[ ]  *Protocol (if available);*

[ ]  *Information Sheet for participants (if applicable)*

[ ]  *Survey*

[ ]  *Interview questions/script*

[ ]  *Educational test*

[ ]  Other pertinent documents

**Submit completed paperwork to: Office of Research Integrity & Protections – 1R4**