

Principal Investigator: (name of person submitting application)

Study Title:

PI Address:

PI Telephone / Email:

Research ethics training source: NIH/NCI CITI Other:

Date Research Ethics Training Completed:

Does this study involve a contractual agreement between PPMH, a study sponsor, and/or the PI?

Yes – Has the contractual agreement been finalized? Yes No
No

If Request is being submitted by a student, please complete the following:

- Type of Student Research: Thesis Dissertation N/A
- Name of School/College:
- Department:

Projected Data Collection Dates: From To

Note: Data Collection cannot begin before IRB approval is received.

Research Staff: Please list names of all personnel involved in the research
(If you require additional space for Research Staff, please submit Supplemental Form J)

Name	Primary Department (use abbreviation)	Role in the research (e.g. co-investigator, research coordinator, statistician, etc.) **	interpersonal contact communication with subjects, or access to private identifiable	Involved in consent process?	Research Ethics Training Source (NIH/NCI, CTI, Other)?	Date Research Ethics Training Completed	Any potential or actual financial interest related to this research?	
							Yes	No
<i>Ex: Sally Smith, MD</i>	<i>PS</i>	<i>Co-Investigator</i>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>NIH</i>	<i>March 2014</i>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<i>Ex: John Doe</i>	<i>OB</i>	<i>Research Coordinator</i>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>CITI</i>	<i>December 2015</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

****Faculty Advisor information required for Students or Post-Doctoral Research Projects**

For all Research Staff involved and listed above, please submit signed and dated Curriculum Vitae, Medical License, and Ethics Training Certification.

Research Description

To determine if the project falls within one or more of the specified categories of exempt research per the federal regulations, the following information is needed.

- Abstract.** Provide an abstract of the proposed research or teaching in language that can be understood by a non-scientist. The abstract should summarize the objectives of this project and the procedures to be used, with an emphasis on what will happen to the participants.

2. **Risk Classification.** What is the overall risk classification of this research?

Minimal

Greater than minimal (if the research involves greater than minimal risk, then it is not eligible for exemption).

If the classification is minimal risk, please justify why that category is appropriate:

3. **Participants.** Describe the participants who will be included in this research. Identify the location(s) in which participants will be recruited.

Indicate if any of the following will be included in this research:

Children

Prisoners

Pregnant women/fetuses/neonates

Cognitively Impaired

Students

Handicapped

Institutionalized persons

Senior citizens

Non-English speaking

Employees

4. **Instruments.** Describe the instruments, if any, to be used to collect data in this study:

Attach copies of all questionnaires, surveys, interview questions, etc. If the research involves interviews that could evolve as the research progresses, include a list of discussion topics and any "starter" questions for each topic that can reasonably be expected to be covered. If a draft of a written questionnaire or survey is attached, it should be clearly labeled as such and a final version must be submitted before data collection begins.

5. **Confidentiality.** Describe what identifiers will be collected on the participants. If participants will be identified, describe the procedures in place to protect their confidentiality.
6. **Privacy.** Explain provisions to protect privacy interests of participants. This refers to how investigators will contact participants and/or access private information from or about participants during and after their involvement in the research (e.g., time, place, etc. of research procedures).
7. **Consent**
- a. Will consent be obtained from participants?
- Yes
- No
- If yes, describe how consent will be obtained and documented.
- If no, explain why this is justified.
- b. If consent will be obtained, will consent be documented?
- Yes
- No

If yes, describe how consent will be documented.

If no, explain why this is justified.

Exemption Determination

In order for a study to be exempt, at least ONE of the six categories listed below must apply. Please select the one that is appropriate and indicate why this category is justified based on the nature of the research. (NOTE: Use of prisoners as participants is prohibited under ALL exempt categories. Contact the IRB office for information involving the use of prisoners as participants.)

Exempt 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.

Justification:

Exempt Category 2:

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

Note: This exemption does not apply to the following types of research; 1) research involving children that includes surveys, interviews, and observations of public behavior when the investigator is a participant in the activities being observed; and 2) research in which information could reasonably place the participants at risk.

Justification:

Exempt Category 3:

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

- 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.

Justification:

Exempt 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.

Note: All of the data or materials must exist prior to proposing the research.

Justification:

Exempt Category 5:

Research and demonstration projects that are conducted by or subject to the approval of department or agency heads and that are designed to study, evaluate, or otherwise examine:

- public benefit or service programs;
- 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 for benefits or services under those programs.

Note: In order to be eligible for this exemption, all of the following must apply:

- * The research is conducted pursuant to specific federal statutory authority.
- * The research has no statutory requirements for IRB review.
- * The research involves no significant physical invasions or intrusions upon the privacy interests of the participant.
- * The research has authorization or concurrence by the funding agency.

Justification:

Exempt 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 (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the US Department of Agriculture (USDA).

Justification:

Principal Investigator Acknowledgement

I will conduct the study identified above in the manner described narrative. If I decide to make any changes in the procedure, or if a participant is injured, or if any problems occur which involve risk or the possibility of risk to participants or others, I will immediately report such occurrences or contemplated changes to the PPMH Institutional Review Board.

P.I.'s Name: _____ Date: _____

Electronic Signature:

Faculty Advisor Acknowledgement

(If the Investigator is a student, a Faculty Advisor must sign below)

I have read and approved this protocol. I believe this is research as defined by the Department of Health and Human Services (i.e., a systematic investigation designed to develop or contribute to generalizable knowledge) and that the study is competent to conduct the activity as described herein.

Faculty Advisor's Name: _____ Date: _____

Electronic Signature:

Please save a copy of the form for your records and submit the final form electronically by clicking the "Submit Form" to the left or at top of page.

**IRB Review of Request for Exemption
(Completed by IRB Office Only)**

Date of Receipt:

Is the Form Complete with Required Documents?

Yes

No

Exemption Approved: Yes

No