



**Type of Review Requested****Full Board Review****Exempt Review (attach *Request for Exemption* form)**

Studies may be Exempt from review if they fall into one of the following categories:

- Normal education practices and settings
- Anonymous educational tests, surveys, interviews or observations
- Identifiable subjects in special circumstances (i.e., public officials)
- Collection or study of existing data
- Public benefit or service programs
- Taste and food evaluation and acceptance studies

**Expedited Review**

Studies may qualify for Expedited Review if it meets any of the following categories:

- Studies of minimal risk (Risk as experienced no more than in daily activities)
- Collection of blood samples from healthy, non-pregnant adults who weigh at least 110 lbs and from whom blood collection does not exceed 550 mL in an 8-week period
- Prospective collection of biological specimens through non-invasive means
- Collection of data through non-invasive means routinely employed in clinical practice
- Research involving materials that have been collected, or will be collected solely for non-research purposes
- Research on group characteristics or behavior
- Continuing review of research previously approved by a convened IRB where the research is permanently closed to new enrollment; all subjects have completed research related interventions; and the research remains active only for the long-term follow-up of subjects; OR for studies where no subjects have been enrolled and no additional risks have been identified; OR for studies where the remaining research activities are limited to data analysis
- Continuing review of research not conducted under an IND or IDE where the categories above do not apply but the IRB has determined and documented at a convened meeting that the research involves no more than minimal risk and no additional risks have been identified

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

**IRB Full Board Review Fees**

All Initial Review requests are assessed a fee of \$2,000 for Full IRB Board Review (\$1,000 for Expedited Review) which includes a review of the protocol, informed consent form, investigator's brochure, FDA Form 1572, Principal Investigator credentials, and advertisement (if any). Fees are subject to change without notice and are non-refundable. Exceptions to these fees may be approved by the IRB Administrator with proper justification. To apply for a waiver of IRB review charges, please mark a category:

Study Funding: (select from drop down box)

Name of funding source:

Explain why the Principle Investigator is unable to pay the IRB fee:

IRB Office Action

Fee Waiver Approved

Fee Waiver Denied

**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

1. Please describe the major research questions of the proposed study in language that can be understood by an individual who is not a specialist in the field.

2. What are the major procedures you will use to collect data? How will you carry them out and how will participants be involved? Please include separate information for each different procedure that you plan to use.

3. Check ALL the different procedures planned for this study.

Records review – retrospective

Use of Internet in Human Participants Research  
*Supplement D must be completed*

Records review – prospective

Questionnaires / surveys

Interviews

Research Involving Stored Data for Future Use  
*Supplement E must be completed*

Audiotaping / videotaping

Social or behavioral intervention

Behavioral observation

Other

4. Data Collection

NOTE: Please attach data collection information separately for each major phase, research strategy, tool, involved population, etc. that you plan to use. It will help the review committee if you present the materials in the same order that you present them in this application and if you label each clearly in terms of the research activity so the committee knows which questions, scales, etc. go with which research activity.

- Attach copies of all questionnaires, surveys, interview questions, etc. If a draft of one of these documents is attached, it should be clearly labeled as such and a final version must be submitted before data collection begins.
- 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.

5. Outline the planned timing and sequence of the research activities:

6. If there is more than one researcher involved, explain the division of tasks among research staff. What will be the roles and responsibilities?

### Research Setting

1. Describe the settings in which research will be carried out (e.g., clinic, lab, etc.):

2. List all PPMH sites where the research will be carried out. For each site, explain how the Investigator has access to a population that would allow recruitment of participants.

3. List all non-PPMH sites where the research will be carried out, including contact information where applicable. For each site, explain how the Investigator has access to a population that would allow recruitment of participants. What kind of permission is necessary to carry out research at this site? Has the researcher received permission? If so, please attach a copy of the permission.

4. Do any of the other sites have an IRB? If so, describe the communication with the relevant IRB(s). What date was permission given?

**Participant Population**

1. The research involves the following (check all that apply):

Adults (no impairments)

Children

Prisoners

Children who are wards of the state

Pregnant Women, Fetuses, or Neonates

Students – specify school:

Cognitively Impaired

Non-English Speakers

2. Will any groups or categories of participants be excluded from this research?

Yes

If “Yes”, please specify  
and provide the rationale for  
excluding these subjects.

No

**Participant Recruitment**

1. Describe how participants will be recruited for participation in this study.

**Attach copies of any proposed flyers, posters, pamphlets, print advertisements, etc. and any scripts for on air advertisements or phone calls. All recruitment material must be approved by the IRB prior to use.**

**2. Recruitment Information**

Which of the following recruitment methods will be used?

<b>Recruitment Activity</b>	<b>Yes/No</b>		<b>Explanation</b>
Paper files (e.g., school or medical records)	No	Yes (indicate where paper files are located)	
Electronic files (e.g., school or medical records)	No	Yes (indicate who maintains electronic files)	
Other records	No	Yes (indicate what they are)	
Databases	No	Yes (specify type and location)	
Flyers / Brochures	No	Yes (include a copy in application)	
Web Postings	No	Yes (specify website address)	
Advertising Company	No	Yes (specify company and service they will provide)	
Letters	No	Yes (include a copy with application)	
Any other method	Please specify in detail below:		

**3. Will participants be offered compensation for participating in the research?**

Yes

No

If Yes, describe the nature of the compensation. Provide amounts and schedule of payments.



How did you make the determination that this level of compensation is appropriate?

Are the terms of the participation agreement and the amount of payment specified in the informed consent form?

Yes

No

### **Description of Risks and Plans to Mitigate/Address**

1a. Describe any physical risks that may be faced by participants in this research. If there will be physical risks, answer 1b. Otherwise, go on to question 2a.

1b. Describe how you will inform participants of the physical risks and what you will do to mitigate these risks or their effects. Describe availability of medical services that may be required as a consequence of research participation. If none are available, what provisions are made when necessary?

2a. Describe any psychological risks that may be faced by participants in this research. If there will be psychological risks, answer 2b. Otherwise, go on to question 3a.

2b. Describe how you will inform participants of the psychological risks and what you will do to mitigate these risks or their effects. Describe availability of any psychological services, including counseling, which may be required as a consequence of research participation. If none are available, what provisions are made when necessary?

3a. Describe any social risks that may be faced by participants in this research. If there will be social risks, answer 3b.

3b. Describe how you will inform participants of the social risks and what you will do to mitigate these risks. Describe availability of social services, including support services that may be required as a consequence of research participation. If none are available, what provisions are made when necessary?

4. Explain provisions to protect privacy interests of subjects. This refers to how investigators will contact subjects and/or access private information from or about subjects during and after their involvement in the research (e.g., time, place, etc. of research procedures) and the subjects' expectations of privacy in the situation.

### Privacy of Protected Health Information

***If PHI is being accessed in the course of the study, and you are seeking a waiver of HIPAA Authorization, also complete IRB Supplemental Form H – Request for Waiver of HIPAA Authorization.***

1. Is PHI being accessed in the course of this study? This question is answered YES if any information that can potentially identify an individual is accessed during any phase of the study, even if such data is not collected as a component of the study. Consent of study subjects is needed and must be submitted to the IRB, unless a waiver of HIPAA consent is granted.

Yes

No

2. What are your sources of PHI? (select from drop down box)

Other:

3. Will individuals other than the IMMEDIATE STUDY TEAM or employees of PPMH who may have some study involvement have access to PHI?

Yes

No

If yes, provide reason why such access is needed: (select from drop down box)

Other:

4. Why is access to PHI required? (select from drop down box)

5. Provide additional justification why use of PHI is needed for this study:

6. The following HIPAA identifiers will be utilized: (select from drop down box)

7. Describe how the confidentiality of the PHI will be maintained.

8. The investigator feels that the use of PHI in the study presents no more than minimal risk due to one or more of the following: (select from drop down box)

Other:

9. Will access to EMR be required?

Yes (If YES, contact the Compliance Department for access procedures)

No

10. How will electronic data be secured: (select from drop down box)

Other:

11. Will data that identifies individual subjects be published or in any way be disclosed to third parties other than project personnel?

Yes

No

If yes, please explain here and be sure to incorporate in consent form.

12. Will the data collected in the course of the study be considered sensitive data (e.g. mental health, HIV status, social security number, etc.)?

Yes

No

If yes, provide the rationale for why this data is needed.

If yes, could any of this data, if disclosed, have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation?

Yes

No

***If yes, make sure that answers to VI 1b, 2b, and 3b discuss clearly how you will disclose this information and what you will do to mitigate the possibility of adverse consequences.***

13. Describe any other resources needed for the protection of subjects in the conduct of this research (e.g., participant communication needs, language translation services).

14. Do you believe that this research is minimal risk?

***NOTE – According to DHHS Regulations minimal risk means “The probability and magnitude of harm or discomfort anticipated in the research are not greater in and out of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”***

Yes

No

If yes, please provide justification.

**Precautions in Projects of More than Minimal Risk**

1. If the classification is greater than minimal risk, describe all possible harms (including non-physical harms) in detail, assess their seriousness and estimate the probability of the harms occurring.
  
2. Describe other alternative and accepted procedures, if any, which were considered that might involve less risk and why they will not be used.
  
3. For all research involving more than minimal risk, describe the data and safety monitoring plan (DSMP). The DSMP should address the following statements:
  - A description of the plan to monitor research progress and subject reactions, including who will do the monitoring and how monitoring will be accomplished.
  - A plan for dealing with adverse events and unanticipated problems involving risk to subjects or others.
  - A description of the plan to assure compliance with reporting of adverse events and/or unanticipated problems involving risks to participants or others.
  - A description of the plan to assure data accuracy and protocol compliance.

***Please attach this document as an appendix.***

**Benefits**

1. Assess the potential benefits to science and/or society which may accrue as a result of this research.
  
2. Are there any benefits (other than the compensation described in VI. 3. above) which may accrue to the individual participants in this research?

Yes

No

If yes, please explain:

3. If the risk in this study is more than minimal, explain how the risks are reasonable in relation to the benefits.

### **Informed Consent**

Unless waived by the IRB, informed consent is necessary for all research involving human participants and must be documented in some manner. The investigator may determine which method would best serve the interest of the participant population, but the IRB reserves the right to require alternative or more stringent means of securing consent.

If this project has different phases, activities, or participant populations, you may want to use several different forms of consent. If so, describe clearly which forms of consent will be used for which phases, activities, or participant populations.

1. Which of the following apply to this research?

Informed consent will be obtained from all subjects and documented with a signed, written consent form. If so, answer questions in part 2 below.

Informed consent will be obtained from subjects, but no signed consent form will be used. This includes oral consent and implied consent (e.g., completing a survey). If so, answer the questions in part 2 and complete Supplement A Request for Waiver of Written Documentation of Consent.

Fully informed consent will not be obtained from all subjects because it is impossible logistically to obtain consent (for example, participant observation research). If so, complete Supplement B Request for Waiver of Informed Consent.

Fully informed consent will not be obtained from all participants, because some deception, withholding information, etc., will be involved. If so, complete Supplement C Request for Approval of Deception in Research.

2. Informed Consent.

Please see the Informed Consent Checklist for the basic required elements of informed consent that should be included in informed consent.

- a. How will the participants' informed consent be documented? Please indicate all the ways in which consent is documented.

b. Describe how the required information is being presented to subjects (consent form, orally, information sheets, etc.). You must provide copies of all written consent forms. If you will be presenting information orally, present a “script” of the information being presented to participants.

c. Describe the circumstances under which consent will be obtained, including where the process will take place.

d. Who will obtain consent? Describe their experience in obtaining consent from subjects.

e. How will it be determined that the subjects or the subjects’ authorized representatives understand the information presented

f. If non-English speaking subjects will be included, describe how translation of consent forms will be provided. All translated consent forms must be submitted to the IRB.

g. If subjects cannot read the consent form, due to literacy or language problems, how will the consent be documented?

h. Will any subjects be cognitively impaired so that they may not have the capacity to give consent?

Yes (complete Supplement F Research Involving Cognitively Impaired Individuals)

No

### Conflict of Interest

1. Do any members of the research team or any of their immediate family members have any financial interest in the sponsor of this research and/or in the results of this research?

Yes (complete Supplement G Financial Conflict of Interest Form)

No

### Checklist

Please check all the categories that apply to this research. For those checked, please complete the supplements indicated. You do not need to complete any supplements which do not apply.

Supplemental Forms may be found on the PPMH Institutional Review Board website: [www.phoebehealth.com/IRB](http://www.phoebehealth.com/IRB)

List of Forms:

IRB Supplemental Form A Request for Waiver of Written Documentation of Consent

IRB Supplemental Form B Request for Waiver of Informed Consent

IRB Supplemental Form C Request for Approval of Deception in Research

IRB Supplemental Form D Use of Internet in Human Participants Research (DO NOT complete if only using internet to recruit participants)



IRB Supplemental Form E Research Involving Stored Data for Future Use

IRB Supplemental Form F Research Involving Cognitively Impaired Individuals

IRB Supplemental Form G Financial Conflict of Interest Form

IRB Supplemental Form H Request for Waiver of HIPAA Authorization

IRB Supplemental Form I Multiple Adverse Events Reporting Form

IRB Supplemental Form J Additional Members Team Research

IRB Informed Consent Checklist

### **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 Application for Approval of Research Involving Human Participants  
(Completed by IRB Office Only)**

Date of Receipt:

Is the Application Complete with Required Documents?      Yes

No

Has supporting documentation been submitted, if applicable?      N/A

Yes

No

Report returned to Investigator (indicate reason):

Type of Review:      Full Board Review      Expedited Review

Expedited Review Category:

Study Approval Date: