

IRB APPLICATION NUMBER:

DATE OIC RECEIVED:

## UMD IRB APPLICATION

Instructions: Questions are in bold. Required items are specified with an asterisk. Question specific instructions are provided in parenthesis () and italic. Please indicate your responses following each question. Prior to approval of this application, every person listed must complete ethics/compliance training using [citiprogram.org](http://citiprogram.org). The Principal Investigator accepts responsibility for the training of all personnel associated with this study. PIs must complete this application and the document titled *IRB Research Proposal*. Completed applications and documents should be sent to Andrew Karberg, Office of Institutional Compliance – 217F ATMC.

**\* 1. IRB Project Title:**

**Grant Title:**

*(List the IRB project title. For funded research: If project is funded and the grant title is different from the project title, please list both titles here).*

**\* 2. Please Indicate the Level of Review your Application Requires**

\_\_\_ Full Board

\_\_\_ Expedited (see expedited category numbers) [45 CFR 46.110](#)

\_\_\_ Exempt (see exempt category numbers) [45 CFR 46.101 \(b\)](#)

*(Studies that involve the audio or video recording of subjects CANNOT be submitted as Exempt).*

**3. Prior IRB Review:** *(If this Study has had prior IRB review, outside of UMD, please describe by listing each approval/review and the institutions. Do not confuse this with Continuing Review at UMD. Please submit approval letters for IRB review from institutions other than UMD).*

**4. Student Research:** *(Please indicate if this is STUDENT research. Student research requires IRB approval unless it is a project designed to train students in the conduct of research without being designed to develop or contribute to generalizable knowledge. If the student research is for training purposes please use the Class Project Review Form (Coming Soon). If the PI is a student, a Faculty Sponsor must be listed. The faculty sponsor agrees to supervise and mentor the student PI.)*

**\* 5. Principal Investigator's (PI) Information:** *(Name, Address, Telephone, Email - All correspondence about the study will be sent to the PI's official address or email address on file with the University).*

**\* 6. Principal Investigator's Department/Research Unit:**

**7. Key Researchers/Investigators:** *(Name, Dept. (or address if not UMD employee), email. As a guide, list people who will "contribute in a substantive way to the scientific development or execution of the project" (co-investigators, consultants, projects managers, etc.).)*

**8. Research Assistant/Project Coordinator:** *(If needed, use this space to list the names for other people who either are involved in or have a need to know about this study and that a*

*protocol is being submitted for IRB approval. Examples of types of people to list here are research assistant or project coordinator. Individuals listed here do not have signatory responsibility; they are additional contacts for communication regarding the study).*

**\* 9. Conflict of Interest:**

*(An investigator is said to have a conflict of interest whenever the PI or IRB member, his or her spouse, or dependent child falls under any of the following conditions (indicate any that apply)):*

- Is an investigator or sub-investigator on the protocol (*IRB members only, not applicable to PI's*);
- If the IRB member, the member's spouse, or dependent children are involved in the conduct of research;
- Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest;
- Acts and officer, director, or agent of the sponsor;
- Has any equity interest in the sponsor or agent of the sponsor that when aggregated for the investigator or member and the investigator's or member's spouse and dependent children of \$10,000 or greater as determined through reference to public prices (e.g., NYSE or NASDAQ), any amount if the value cannot be determined through references to public prices, or 5% of the equity of the sponsor;
- Has received payments or other considerations from the sponsor that when aggregated for the investigator or member and the investigator's or member's spouse and dependent children of \$10,000 or greater;
- Has identified him or her self for any other reason as having a conflict of interest.

Do you or does UMD hold a patent or license for any material, object, invention, or process used in the study or do you intend to file a patent application at a later date?

No  Yes

If there is a sponsor for the study, do you own equity or financial interest in the sponsor, give presentations for the sponsor, serve as a consultant to the sponsor, or work in any capacity for the sponsor (such as board member, officer, etc.)?

No  Yes

To the best of your knowledge, do any of the Key Personnel listed on this study have a conflict of interest associated with this study?

No  Yes

Please list any other possible conflicts of interest:

*(The following section requests brief answers on topics that you must cover in detail in your research Proposal, consent forms, and other supporting documents. Completing this section does NOT relieve you of the responsibility to cover these issues in detail in your Research Proposal or any other supporting documents.)*

**\*10. Types of participants involved in this study:**

- |   |   |
|---|---|
| <input type="checkbox"/> UMD FACULTY/STAFF                  | <input type="checkbox"/> MINOR CHILDREN (UNDER AGE 18)                    |
| <input type="checkbox"/> MENTALLY/PSYCHOLOGICALLY IMPAIRED  | <input type="checkbox"/> PREGNANT WOMEN OR FETUSES                        |
| <input type="checkbox"/> PHYSICAL ILLNESS/INJURY/DISABILITY | <input type="checkbox"/> PRISONERS  |
| <input type="checkbox"/> UMD STUDENT                        | <input type="checkbox"/> OTHER - If selected, list all participant types: |

**11. If the participants are students, is the investigator/researcher their instructor or advisor?**  No  Yes  Some may be but not selected on that basis

**12. If the participants are employees of UMD, are they directly supervised by the investigator?**  No  Yes

**\* 13. Subject Age Range:** *(If the study subjects will be just one age, fill in the same age for both minimum and maximum. Estimate to the best of your knowledge.)*  
minimum age:  
maximum age:

**\*14. Gender of subjects:**  Male  Female  Both  Transgender  
If you are using only one gender population, please mark one of the following:  
 Only the gender selected has the condition (gender specific)  
 Other, please describe:

**\* 15. Does the study require that the subjects be recruited from one or more specific races/ethnicities?**  No  Yes, please specify:  White  Black  Hispanic  Asian  Native American  Other:  
Reason for specific race/ethnicity:  
 The condition being studied occurs only in the selected group(s);  
 Other, please specify:

**\*16. How many subjects do you plan to enroll in your study? If using an existing dataset, list the number of subjects in the dataset.** *(If there is more than one group, please indicate number of groups and number of individuals per group. Your study will need to be amended PRIOR to INCREASING enrollment size from number given here).*

**\* 17. Time required of each subject:** (*ESTIMATE and round up to the nearest unit. Ex: record 1 hr a week for 5 years as 260 hours and describe as necessary*).

**18. Check any of the following items YOU will be ASKING THE SUBJECTS TO PROVIDE on research forms or in response to research questions (this question pertains to data YOU are collecting):**  Name  Phone number  Address  Social Security #  
Please specify any other information you're collecting that may identify the subjects:

**\* 19. HIPAA Regulations: Use of Protected Health Information (PHI):**

(*PHI is defined under HIPAA as health information transmitted or maintained in any form or medium that:*

- *Identifies or could be used to identify an individual;*
- *Is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and*
- *Relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of healthcare to an individual.*

*Health-related information is considered PHI if any of the following are true:*

- *The researcher obtains it directly from a provider, health plan, health clearinghouse or employer (other than records relating solely to employment status);*
- *The records were created by any of the entities listed above and the researcher obtains the records from an intermediate source which is NOT a school record or an employer record related solely to employment status; OR*
- *The researcher obtains it directly from the study subject in the course of providing treatment to the subject.*

*Health-related information is not considered PHI if the researcher obtains it from:*

- *Student records maintained by a school;*
- *Employee records maintained by an employer related to employment status; OR*
- *The research subject directly, if the research does NOT involve treatment.)*

**As part of this study, do you:**

**Collect PHI from subjects in the course of providing treatment/experimental care?**

No  Yes

**Have access to PHI in the subjects' records?**

No  Yes

***If yes to A or B above, complete and attach the HIPAA FORM (email OIC to request form).***

**\* 20. Will the subjects be recorded with audio or video equipment?**  No  Yes

(*Federal regulations stipulate that studies involving the use of audio or video equipment may be reviewed at the expedited level or higher*).

**21. Will students from a class or set of classes, who are to be research subjects, receive class credit or bonus points for participation?**  No  Yes

If yes, will the alternative options for getting class credit be explained in full to the students in the consent form or in other material given to the students such as the course syllabus?  
 No  Yes

**\* 22. Are you using controlled substance(s) in this study?**  No  Yes - please list the DEA number and expiration date (mm-dd-yyyy):

**23. If individuals with diseases or conditions are to be specifically included, is there a potential for direct benefit to these subjects?**

No  Yes - please explain:

**24. If individuals with diseases or conditions are to be specifically included AND if the study involves a treatment for their disease or condition, please explain how that treatment will differ from standard care that they would ordinarily receive, or already receiving, i.e., procedures already being performed for diagnostic or treatment purposes.**

**\* 25. Will any medical procedures (such as lab tests, biopsies, or x-rays, etc.) be performed for the subjects?**  No  Yes - briefly describe:

**26. Are there specific medications that MUST be used to meet the requirements of this protocol?**  No  Yes, please list them:

**27. If the study uses medical devices not approved by the FDA, you must describe measures taken to ensure they are used only by qualified personnel and only on participants:**

**\* 28. Do you agree that sufficient resources, staff, necessary equipment, and time necessary to conduct the research exist?**  No  Yes

**29. Are women of childbearing potential to be included in this study?**  No  Yes

If so, is a pregnancy test required?  No  Yes - please state who will pay for the test:

**\* 30. This item is divided into three sections (A, B, and C) all pertaining to subject CONSENT. You must fill out either Part A, B, or C.**

If the study consent plans are for . . .

- **WRITTEN, SIGNED, INFORMED CONSENT, answer item A**
- **WAIVER OF DOCUMENTATION OF CONSENT - NO SIGNED CONSENT, BUT A WRITTEN COVER LETTER THAT DESCRIBES THE STUDY OR FULL VERBAL INFORMED CONSENT, answer item B**
- **A COMPLETE WAIVER OF INFORMED CONSENT - NO DESCRIPTION, OR ONLY BRIEF ORAL DESCRIPTION OF RESEARCH PROVIDED TO PARTICIPANTS, answer item C**

**A. WRITTEN, SIGNED, INFORMED CONSENT:**

Is the language in the document appropriately matched to the comprehension level of your intended subjects?  No  Yes

Will the document be provided in language(s) other than English?  No  Yes  
If yes, please describe:

Will you be providing subjects a copy of their consent document?  No  Yes

Does your document in any way ask or imply that subjects are waiving any right or releasing you from any liability?  No  Yes

Who will PROVIDE informed consent?

- the subject
- the subject's parent or guardian
- Other, please explain:

Who will OBTAIN informed consent?

- the Principal Investigator/Researcher
- key personnel/co-investigator
- Other, please explain:

Is the language in the document appropriately matched to the comprehension level of your intended subjects?  No  Yes

Will the document be provided in language(s) other than English?  No  Yes  
If yes, please describe:

#### B. WAIVER OF DOCUMENTATION OF CONSENT NO SIGNED CONSENT, BUT A WRITTEN COVER LETTER THAT DESCRIBES THE STUDY OR FULL VERBAL INFORMED CONSENT.

(An IRB may waive the requirement for the investigator to obtain a SIGNED consent form for some or all subjects if it finds all statements in ONE category to be true. Read each set of items carefully and check one of the sets (verifying that this study meets each requirement in one of the sets) - then check the statement requesting a waiver of SIGNED consent. (Please note that the IRB must formally approve this waiver)).

- The research presents no more than minimal risk; **AND**
- The research involves procedures that do not require written consent when performed outside of a research setting (45 CFR 46.117; 21 CFR 56.109(c)(1)).

#### **OR**

- The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research; **AND**
- The consent document is the only record linking the subject with the research; **AND**
- This study is not FDA regulated (45 CFR 46.117).

**request for waiver of signed documentation of consent (waiver of signed consent)**

Please describe the rationale for your waiver request:

Please provide a written script of the information provided orally, if any. (You should submit a document containing this information with your application and research protocol).

**C. A COMPLETE WAIVER OF INFORMED CONSENT NO DESCRIPTION, OR ONLY BRIEF ORAL DESCRIPTION, OF RESEARCH PROVIDED TO PARTICIPANTS.**

*(According to 45 CFR 46.116(d), an IRB may waive or alter some or all of the requirements for informed consent if all conditions (below) are met. Read each item carefully and check (verifying that this study meets each requirement) - then check the statement requesting a COMPLETE waiver of consent. (Please note that the IRB must formally approve this waiver)).*

- The research presents no more than minimal risk to subjects;
- The waiver will not adversely affect the rights and welfare of subjects;
- The research could not practicably be carried out without the waiver;
- Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study; **AND**
- This study is not FDA regulated (45 CFR 46.117).

Request for COMPLETE waiver of Informed Consent

Please describe the rationale for your waiver request:

**\* 31. Is there a person (other than the Principal Investigator) or a group that will be responsible for reviewing unanticipated problems and other issues related to the safety of the study?**  No  Yes

**\* 32. Is this a multi-site study where you are the lead investigator or the University is the coordinating center?**  No  Yes - *If yes, please describe how you will manage information that may be relevant to the protection of research participants, such as reporting of unspecified problems, protocol modifications, and interim results:*

**\* 33. Is there financial or material support for this study?**  No  Yes

(If this grant is NIH, [submit a Certificate of Consistency.](#))

If yes, please indicate the type of sponsorship and whether it has been obtained or is pending:

**\* 34. Will the study provide reimbursement of the subjects' expenses?**  No  Yes

Please state amount:

**\* 35. Will compensation be provided?**  No  Yes

Additional Documentation:

Remember to submit additional documentation with your application. At a minimum, you must provide the research proposal and the consent form.

Examples of Additional Documentation include:

- 1) Research Proposal (required) \*
- 2) Questionnaire
- 3) Cover Letter
- 8) Consent Form (req'd unless waived)
- 9) Survey
- 10) Recruitment Flyer

- 4) Email Recruitment Message
- 5) Site Letter (if off campus)
- 6) Grant Proposal (DHHS)
- 7) Prior IRB Review Letter
- 11) Telephone Script
- 12) HIPPA Form
- 13) Certificate of Consistency (DHHS)
- 14) Other Documentation

**SIGNATURES:**

\_\_\_\_\_  
\*PI Signature

\_\_\_\_\_  
\*Date

\_\_\_\_\_  
Faculty Sponsor / CO-PI Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Student / CO-PI Signature

\_\_\_\_\_  
Date