UMD EXEMPT HUMAN PARTICIPANTS 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. Answers may be entered directly into the application or responses may be listed on a separate document with corresponding numbering. Prior to approval of this application, every person listed must complete ethics/compliance training using citiprogram.org. The Principal Investigator accepts responsibility for the training of all personnel associated with this study. Faculty sponsors / mentors are considered the PI of record for their students’ projects. Completed applications and documents should be sent to irb.research@umassd.edu.

* 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 applicable exemption category (see 45 CFR 46.104(d)(1) – (8)):
  1. ___  2. ___  3. ___  4. ___  5. ___  6. ___  7. ___  8. ___

3. Student Research: (If this is STUDENT research please list the student’s name, address, phone number, and email. 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. If this is a student project, a Faculty Sponsor must be listed. The faculty sponsor agrees to supervise and mentor the student. Faculty sponsors on student research projects should be listed under #5 below as PIs).

* 4. Principal Investigator's / Faculty Sponsor (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).

* 5. Principal Investigator's Department/Research Unit:

6. CO-PI/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.)).

7. 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).

* 8. Conflict of Interest:
  (Key personnel are said to have a conflict of interest whenever the key personnel, 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;

__ 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:

*9. Types of participants involved in this study: (Identify the sources of potential participants, derived materials, or data. Describe the characteristics of the subject population such as their anticipated number, age, sex, ethnic background, and state of health. Please describe whether some or all of the participants are likely to be vulnerable to coercion or undue influence, and if so, what additional safeguards are included to protect their rights and welfare. Identify the criteria for inclusion and/or exclusion. Explain the rationale for the use of special classes of participants whose ability to give voluntary informed consent may be in question. Such participants include students in one’s class, people currently undergoing treatment for an illness or problem that is the topic of the research study, people who are mentally retarded, people with a mental illness, people who are institutionalized, children, prisoners, pregnant women, etc. Explain how you will have access to a population that will allow recruitment of the required number of participants within the proposed recruitment period).

*10. 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).

*11. Describe the procedures for the recruitment of the participants. (Append copies of fliers and the content of newspaper or radio advertisements. Explain here any incentive (financial, gifts or other items of value) that will be given to persons who identify or refer subjects for enrollment. If potential participants will be screened by an interview (either telephone or face-to-face) provide a script of the screening interview.

*12. 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:

13. 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

If yes, how will the alternative options be explained to the students?

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

* 15. 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
If not, why?

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
B. WAIVER OF DOCUMENTATION OF CONSENT NO SIGNED CONSENT, BUT A WRITTEN COVER LETTER THAT DESCRIBES THE STUDY OR FULL VERBAL INFORMED CONSENT.
(The OIC 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 OIC 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
OR
__ The principal risks are those associated with a breech 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

__ 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.
Please provide a copy of the cover letter accompanying the survey or interview.

C. A COMPLETE WAIVER OF INFORMED CONSENT - NO DESCRIPTION, OR ONLY BRIEF ORAL DESCRIPTION, OF RESEARCH PROVIDED TO PARTICIPANTS.
(The OIC 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 OIC 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

__ Request for COMPLETE waiver of Informed Consent

Please describe the rationale for your waiver request:
*16. Describe the procedure for obtaining informed consent: *(Where will consent be obtained? Who will obtain consent? How will signed consent forms be collected? Be very specific and detailed about the procedure for obtaining informed consent).*

*17. Please state your research protocol: *(What will you ask your participants to do? When and where will they do it? How long will it take them to do it? Describe the type of research information that you will be gathering from your subjects, i.e., the data that you will collect. Append copies of all surveys, testing materials, questionnaires, and assessment devices. Append copies of topics and sample questions for non-structured interviews and focus group discussions).*

*18. How will you protect the privacy and confidentiality of participants? *(Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Confidentiality pertains to the treatment of information or data that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Note that ensuring privacy of participants is different from confidentiality of data).*

*19. Discuss the procedures that will be used to maintain the confidentiality of the research data. *(Specifically, how will data be stored to ensure that it is secure and remains confidential? How will the investigator handle that data? If the subject’s responses are taped and the tape can be linked to a participant because his or her name is on an audiotape or because the tape is a videotape, precautions must be taken. These safeguards include storing the tape in a secure place (file cabinet in a locked office), limiting access to the tape to the researcher and his or her associates, and destroying the tape, if it is reasonable to do so, after it has been transcribed or the information on it has been coded. Describe the disposition of the tapes in the consent form. If the tapes are to be retained after the study is completed and they have been analyzed, explain the rationale for doing so in the proposal and state that they will be retained in the consent form).*

*20. 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:

*21. Will the study provide reimbursement of the subjects' expenses? __ No __ Yes Please state amount:

*22. Will compensation be provided? __ No __ Yes

*23. Will compensation be prorated? __No __Yes

*24. Research Method, Design, and Proposed Statistical Analysis: *(Provide a brief overview of your research methodology and design and your proposed analysis of the research data).*

*25. Describe any potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. *(Most studies pose some degree of risk, even though the risk may be minimal. For example, one common risk is the loss of the confidentiality of the participants’ responses. Describe the procedures for protecting against (or minimizing) any potential risks and include an assessment of their effectiveness).*

*26. Indicate the specific sites or agencies involved in the research project. *(Will the data collection for this study take place at UMD? Please list department, building, or site below. Please list location(s) such as agencies or school districts below and indicate the number of subjects per site. If data collection takes place at any site off campus, please include: contact information for the site; whether the site has an IRB (if the site’s IRB has approved the research, please attach their approval letter; Indicate whether the site
granted permission to conduct the research there. Demonstrate that PI has the resources and facilities necessary to conduct proposed research. These agencies may include school districts, day care centers, nursing homes, etc. Include, as an attachment, approval letters from these institutions or agencies on their letterhead. The letter should grant you permission to use the agency’s facilities or resources; it should indicate knowledge of the study that will be conducted at the site. If these letters are not available at the time of IRB review, approval will be contingent upon their receipt.)

27. If the project has had or will receive review by another IRB, indicate this. Attach a copy of this approval to this application or submit it to the IRB secretary of the IRB when you receive it. The UMD IRB will usually accept the versions of consent forms that have been approved by IRBs affiliated with hospitals or medical schools, or by the site where the research will be conducted.

*28. When do you expect human subject involvement in this project to begin and when do you expect it to end?

SIGNATURES:

*PI Signature / Faculty Sponsor

___________________________  ____________________________
  Pi Signature                  *Date

___________________________  ____________________________
Student / CO-PI Signature       Date

___________________________  ____________________________
Student / CO-PI Signature       Date

***If necessary, please attach your informed consent form***