

UNIVERSITY OF MASSACHUSETTS DARTMOUTH

Institutional Review Board

APPLICATION FOR REVIEW

Topics to Address in the Research Proposal

Use this template to provide a description of your research proposal. All applications for review should contain the following information, presented in paragraphs prefaced by the number of the item and the underlined descriptive phrase. When not applicable, DO list the heading and then indicate N/A. This form and the UMD IRB application should be completed and submitted to Andrew Karberg, Office of Institutional Compliance – ATMC 217F.

Please note that if this study is part of an NIH funded grant proposal, you will need to attach ONE copy of the complete grant proposal, in addition to the information requested below.

I. Title

II. Investigators (co-investigators)

III. Hypothesis, Research Questions, or Goals of the Project

IV. Background and Significance:

Describe relevant background literature to support the rationale for doing this study. This rationale should provide sufficient information to justify the study. It should be limited to no more than two to three pages. Cite appropriate references.

V. 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.

VI. Human Subject Interactions

- A.** 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. When do you expect human subject involvement in this project to begin and when do you expect it to end? Explain how you will have access to a population that will allow recruitment of the required number of participants within the proposed recruitment period.

If the participants are prisoners or residents of correction facilities, the composition of the IRB must be augmented by a prisoner's advocate. Please inform the IRB if this applies to your project.

If some of the potential participants or the parents of child participants are likely to be more fluent in a language other than English, the consent forms should be translated into that language. Both English and the other language versions of the form should be provided, with one language on one side of a page and the other on the other side of the page. Specify here your intentions with respect to the languages of the consent forms.

- B.** 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.

If the potential participants are members of a group that may be construed as stigmatized (e.g., spousal abusers, members of support groups, people with AIDS, etc.) your initial contact with the potential participants should be through advertisements or fliers or through people who interact with the potential participants because of their job duties. These people may describe your study to the potential participants and ask them to contact you if they are interested in talking to you about the study.

- C.** Describe the **procedure for obtaining informed consent**. If you do not plan to obtain active written consent, specifically point this out and explain why not. Include the consent form(s) for review. Children (people under 18) need parental consent to participate in studies. Participants between 7 and 17 should be given an opportunity to assent to their participation. (See Sample Assent Forms for Children).

- D.** **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.*

- E.** 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.

- F.** 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.

- G.** Please describe your research resources. Discuss the staff, space, equipment, and time necessary to conduct research and how these needs are met. Explain how you will adequately inform all persons assisting with the research about the protocol and their research-related duties and functions. Please include a description of the proximity of any resources such as emergency facilities, emergency care or medical / psychological care, and any support services. If the study necessitates Environmental Health & Safety (EHS) or Institutional Biosafety Committee (IBC) oversight and approval please describe here.
- H. Study-specific costs and compensation:** If providing compensation to participants, will it be prorated? If so, describe the prorated amounts and schedule. If compensation is provided but will NOT be prorated, explain WHY. If you are providing any type of treatment to the subjects, will the treatment be provided free of charge? Explain. If an agency/3rd party is paying for ADDITIONAL treatment for the subjects (such as lab tests, biopsies, or x-rays) briefly describe by listing the agency/party responsible for payment. Who (or which agency) will pay for the specific medications used as part of this study for treating participants?
- VII.** Describe any potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Describe alternative and potentially less risky methods, if any, that were considered as possible methods and why they were not used. If the research methods impose risks on the subjects, include evidence that may justify their use (such as previous experience with the procedures). 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.

One risk that may arise in studies with children or interviews with parents about their children is the risk that you may acquire information about familial child abuse. If you acquire this information, you are required to report it to the Department of Children and Families, 1-800-792-5200. If your study is likely to result in responses that may suggest child abuse and you do not provide anonymity to the respondents, you must inform the parents in the consent form (and the child in the assent form) that you are legally required to report this information. Research data can be subpoenaed by a court of law, so questions about illegal activities such as drug use place respondents at risk unless the participants' responses are anonymous. A Certificate of Confidentiality can eliminate the risk of having one's data subpoenaed.

Describe the procedures for protecting against (or minimizing) any potential risks and include an assessment of their effectiveness. For all research involving human subjects research, you should understand what is meant by an "unanticipated problem" in relation to your study. Note that you are required to complete an Unanticipated Problem Form and promptly submit to the IRB office in the event that such an incidence occurs. In some cases, studies that are greater than minimal risk, involve greater than minimal risk interventions or devices, include vulnerable populations, your sponsor and/or the IRB will require inclusion of a data safety monitoring plan (DSMP).

If the study involves a procedure that introduces a physical risk, specify arrangements for providing medical treatment if it should be needed. If the study involves a procedure that introduces a psychological risk, such as the recall of a traumatic event, specify arrangements for providing psychological treatment if it should be needed. If participants need ancillary resources as a consequence of taking part in the research (e.g., psychological counseling, or emergency treatment), explain how these will be made available. Please state whether or not you will provide payment for physical or psychological harm if it is incurred.

- If your study involves deception, describe the procedures for debriefing the participants.
- VIII.** Describe and assess the **potential benefits** to be gained by participants (if any) and the benefits that may accrue to society in general as a result of the planned work. Discuss the risks in relation to the anticipated benefits to the participants and to society.
- IX.** 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.
- X.** 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.