

**College of Notre Dame of Maryland
Institutional Review Board**

Initial Application for Research Involving Human Subjects

Please complete this cover page AND provide all information requested in the attached instructions.

Name of Principal Investigator (PI) or Project Faculty Advisor _____ Tel. No. _____

Name of Co-Investigator (Co-PI) _____ Tel. No. _____

Department or Unit Administering the Project _____

E-Mail Address _____ E-Mail Address of Co- _____

Where should the IRB send the approval letter? _____

Name of Student Investigator _____ Tel. No. _____

E-Mail Address of Student Investigator _____ @ _____

Check here if this is an undergraduate project master's thesis or a dissertation research project

Project Duration (mo/yr – mo/yr) _____ -- _____

Project Title _____

Sponsored Project Data	Funding Agency _____
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Vulnerable Populations: The proposed research will involve the following (Check all that apply):
minors/children , prisoners , students , individuals with mental disabilities ,
individuals with physical disabilities

Exempt or Nonexempt (Optional): You may recommend your research for exemption or nonexemption by completing the appropriate box below.

Exempt---List Exemption Category _____ Or Non-Exempt

If exempt, briefly describe the reason(s) for exemption. Your notation is a suggestion to the IRB Chair.

Date _____ Signature of Principal Investigator or Faculty Advisor (PLEASE NOTE: Person signing above accepts responsibility for the research even when data collection is performed by other)

Date _____ Signature of Co-Principal Investigator

Date _____ Signature of Student Investigator

Date _____ REQUIRED Departmental Signature
Name _____, Title _____
(Please also print name of person signing above)

(PLEASE NOTE: The Departmental signature block should not be signed by the investigator or the student investigator's advisor.)

***PLEASE ATTACH THIS COVER PAGE TO EACH SET OF COPIES**

Instructions for Completing the Application

The Departmental Signature block should be signed by the Department Head.

Please provide the following information in a way that will be intelligible to non-specialists in your specific subject area.

1. **Abstract:** Provide an abstract (no more than 200 words) that describes the purpose of this research and summarizes the strategies used to protect human subjects.
2. **Subject selection:**
 - a. Who will be the subjects? How will you recruit them? If you plan to advertise for subjects, please include a copy of the advertisement.
 - b. Will the subjects be selected for any specific characteristics (e.g., age, sex, race, ethnic origin, religion, or any social or economic qualifications)?
 - c. State why the selection will be made on the basis or bases given in 2(b).
 - d. How many subjects will you recruit?
3. **Procedures:** What precisely will be done to the subjects? Describe in detail your methods and procedures in terms of what will be done to subjects. How many subjects are being recruited? What is the total investment of time of the subjects? If subjects will complete surveys and/or other instruments on more than one occasion, state this in the procedures section. If you are using a questionnaire or handout, please include a copy within each set of application documents. If you are conducting a focus group, include a list of the questions for the focus group. If you plan to collect or study existing data, documents, records, pathological specimens or diagnostic specimens, state whether the sources are publicly available and if the information will be recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects. If you are collecting or studying existing data, describe the dataset and the information that you will extract from the dataset.
4. **Risks and Benefits:** Are there any risks to the subjects? If so, what are these risks including physical, psychological, social, legal and financial risks? Please do not describe the risk(s) as minimal. If there are known risks, please list them. What are the benefits? If there are known risks associated with the subject's participation in the research, what potential benefits will accrue to justify taking these risks?

5. **Confidentiality:** Adequate provisions must be made to protect the privacy of subjects and to maintain the confidentiality of identifiable information. Explain how your procedures accomplish this objective, including such information as the means of data storage, data location and duration, description of persons with access to the data, and the method of destroying the data when completed. If the research involves audio taping, videotaping or digital recordings, state who will have access to the tapes or recordings, where the tapes or recordings will be kept, and state the final disposition of the tapes or recordings (i.e. Will the tapes or recordings be destroyed? If so, when will the tapes or recordings be destroyed?).
6. **Information and Consent Forms:** State specifically what information will be provided to the subjects about the investigation. Is any of this information deceptive? State how the subjects' informed consent will be obtained. Will you obtain informed consent in a language other than English? If so, list the language(s) in which you will obtain informed consent. Provide consent forms in all languages that will be used. Refer to the attached consent form template, sample consent form and additional consent form guidance on pages 7 to 13. If a consent form has more than one page, please add a signature and date line and the number of pages (e.g., "1 of 2," "2 of 2") to each page. Please allow a 2-inch bottom margin to accommodate the IRB approval stamp. If you plan to obtain consent over the telephone (e.g. consent for a telephone survey), include a copy of the consent script.
7. **Conflict of Interest:** Describe the potential conflict of interest, including how such a conflict would affect the level of risk to the study participants.
8. **HIPAA Compliance:** State whether you are using HIPAA protected health information or "PHI".

9. **Research Outside of the United States:** Provide responses to the following questions. Separate responses are required for each country where the research will be conducted. If you are not conducting research outside the U.S., please state “Not Applicable”
- a) Did the investigator(s) previously conduct research in the country where the research will take place? Briefly describe the investigator’s knowledge and experience working with the study population.
 - b) Are there any regulations, rules or policies for human subjects research in the country where the research will take place? If so, please describe and explain how you will comply with the local human subject protection requirements. The United States Department of Health and Human Services, Office for Human Research Protections (OHRP) has an International Compilation of Human Subject Research Protections with a listing of the laws, regulations and guidelines of over 50 countries. This compilation can be accessed on the OHRP website:
<http://www.hhs.gov/ohrp/international/>
 - c) Do you anticipate any risks to the research participants in the country where the research will take place, taking into account the population involved, the geographic location, and the culture? If so, please describe, including any physical, psychological, social, legal and financial risks. Do you anticipate that subjects who participate in this research will be placed at risk of criminal or civil liability? If so, please describe
10. **Research Involving Prisoners:** Provide responses to the following additional IRB criteria for research involving prisoners. If you are not conducting research involving prisoners, please state “Not Applicable”
- a) the research under review represents one of the categories of research permissible described below;
 - i. study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - ii. study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - iii. research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or
 - iv. research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
 - b) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the

- limited choice environment of the prison is impaired;
- c) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
 - d) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
 - e) the information is presented in language which is understandable to the subject population;
 - f) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
 - g) if there is a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

SUPPORTING DOCUMENTS

Each copy of the application should include the IRB application cover form, the information required in items 1-10 above, and all relevant supporting documents **including: consent forms, letters sent to recruit participants, questionnaires completed by participants, and any other material germane to human subjects review.** Please also include a mailing label for the IRB to send the approval notification.

NUMBER OF COPIES

Please submit 1 original application with signatures and 1 copy of the signed, original application to the Chair of the IRB. Also submit an electronic copy to irbndm@ndm.edu.

EXEMPTION CATEGORIES

(PLEASE NOTE: Exempt research must be approved by the IRB Chair before data collection may begin.)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods. **Research involving surveys or interviews with children does not qualify for exemption. Also, this exemption does not apply to research involving the collection of person identifiable data in which any disclosure of the data outside of the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.**
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. **Exemption category #2 does not apply to research with children, except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed. Also, this exemption does not apply to research involving the collection of person identifiable data in which any disclosure of the data outside of the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.**
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. **E.g.the research is conducted for the Department of Justice under Federal statute 42 U.S.C. 3789g and the research conducted for the National Center for Education Statistics under Federal statute 20 U.S.C. 12213-1, which provide certain legal protections and requirements for confidentiality.**
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 subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects **which are conducted by or subject to the approval of Department or Agency heads**, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

If the research is funded by the United States Department of Health and Human Services, the following criteria must be met:

- a) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).**
- b) The research or demonstration project must be conducted pursuant to specific federal statutory authority.**
- c) There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).**

The project must not involve significant physical invasions or intrusions upon the privacy of participants.

- 6.** Taste and food quality evaluation and consumer acceptance studies, if (a) wholesome foods without additives are consumed or (b) 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 or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

NOTE: The 6 exemption categories do not apply to research involving prisoners.

CONSENT FORM

[Instructions: Please use this template to prepare your consent form. Bolded, italicized text found throughout this Document offers guidance and suggestions. Replace this text with the appropriate wording for your project.]

Project Title	<i>[This title should be the same as the project title used in the IRB application.]</i>
Why is this research being done?	<i>This is a research project being conducted by _____ at the College of Notre Dame of Maryland. We are inviting you to participate in this research project because you _____. [describe why the person reading the consent form is a possible research subject for your project] The purpose of this research project is _____. [describe the knowledge or information that is being sought and explain why you are seeking the knowledge or information]</i>
What will I be asked to do?	<i>The procedures involve __. [Describe the procedure(s) chronologically using lay language and short sentences. State the location where the study will be conducted. Explain educational, medical and other technical terminology using simple language. State the overall duration for the subject's participation and, if appropriate, how long each procedure will take. If the research involves surveys or interviews, include a detailed description of the questions. Identify experimental procedures. Describe alternative procedures or courses of treatment, if any that might be advantageous to the subject.]</i>

Project Title	<i>[This title should be the same as the project title used in the IRB application.]</i>
What about confidentiality?	<p><i>We will keep your personal information confidential. To help protect your confidentiality, _____ [Include a description of the procedures to maintain the confidentiality of the data, e.g. having locked filing cabinets and storage areas, using identification codes only on data forms, and using password-protected computer files. For anonymous surveys, state that "the surveys are anonymous and will not contain information that may personally identify you". For coded identifiable information, state the following, if applicable (1) your name will not be included on the surveys and other collected data; (2) a code will be placed on the survey and other collected data; (3) through the use of an identification key, the researcher will be able to link your survey to your identity; and (4) only the researcher will have access to the identification key.</i></p> <p><i>[If there is a possibility that you will collect information on child abuse or neglect, abuse or neglect of the developmentally disabled or other vulnerable adults, danger to the subject or others, or similar types of information that may need to be disclosed to comply with legal requirements, professional standards, etc., the possibility of such disclosure must be included in the consent form. See the following example, and modify it to include all applicable types of information.</i></p>

	<i>If there is a possibility that you will collect such information, but you do not intend to disclose it, you must provide an explanation and any justification for non-disclosure in your IRB Application. If you have a Certificate of Confidentiality, refer to the Appendix.]</i>
What are the risks of this research?	<i>Describe any known risks including physical, psychological, social, emotional, legal and financial risks that may result from participating in the research. Some studies include risks that may be better described as things that could make the subject feel uncomfortable such as fear, embarrassment or fatigue. These are also examples of risks that should be included. Do not describe risks as minimal and do not state that there are no risks beyond everyday life. There are no known risks with participating in this research project.</i>

Project Title	<i>[This title should be the same as the project title used in the IRB application.]</i>
What are the benefits of this research?	<i>The benefits to you include [only list the direct and reasonably expected benefits to the subject. Monetary compensation and extra credit for courses are not benefits and should be described in the procedures section] _____ We hope that, in the future, other people might benefit from this study through improved understanding of _____. Describe the anticipated benefits to science or society expected from the research, if any.</i>
Do I have to be in this research? May I stop participating at any time?	<i>Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify. [If applicable, include an explanation of any circumstances under which a subject's participation may be terminated by the investigator without regard to the subject's consent. If applicable, include an explanation of the consequences of a subject's decision to withdraw from the research and any procedures for orderly termination of a subject's participation.]</i>
What if I have questions?	<i>This research is being conducted by [principal investigator's name and department] at the College of Notre Dame of Maryland. If you have any questions about the research study itself, please contact _____ [principal investigator's name] at: _____ [Address, telephone number, and (if appropriate) e-mail address of principal investigator.]</i>

Project Title	<i>[This title should be the same as the project title used in the IRB application.]</i>	
Statement of Age of Subject and Consent <i>[Please note: Parental consent always needed for minors.]</i>	<i>Your signature indicates that: you are at least 18 years of age; the research has been explained to you; your questions have been fully answered; and you freely and voluntarily choose to participate in this research project.</i>	
Signature and Date <i>[Please add name, signature, and date lines to the final page of your consent form]</i>	NAME OF SUBJECT	
	SIGNATURE OF SUBJECT	
	DATE	

******Please note: When the consent form requires more than one page, please include a space for the subject to initial and date at the top right-hand corner of each page. The corner should appear as: Initials _____ Date _____**

Also, each page must display a page range such as: Page 1 of 2, then Page 2 of 2. This additional information would confirm that the subject agreed to the entire contents of the consent form. ****

APPENDIX
COLLEGE OF NOTRE DAME OF MARYLAND
CONSENT FORM TEMPLATE
ADDITIONAL GUIDANCE FOR SPECIFIC ISSUES

Informed Consent

Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. Therefore, informed consent language and its documentation must be written in language that is understandable to the people being asked to participate. The College of Notre Dame of Maryland Consent Form Template and Sample Consent Form contain the basic elements of informed consent as identified in and required by the Federal Policy for the Protection of Human Subjects, 45 CFR 46.

Research Involving Minors

For research involving individuals under the age of 18, include a Parental Permission Form to ask parents for consent to the participation of their child and an Assent Form to ask the minors if they agree to participate in the research, depending on whether the children are capable of assenting. The Parental Permission form should contain all of the elements of the sample consent form and the consent form template provided with the IRB application. However, the parental permission form should be written in language appropriate for parents granting permission for their child's involvement rather than as though they themselves will be participating (e.g. we are inviting your child to participate the risks to your child's participation include). When determining whether the children are capable of assenting, take into account the ages, maturity, and psychological state of the children involved. Assent forms should be written in age-appropriate language.

Research Involving Individuals with Impaired Decision-making Capacity

Using the Informed Consent Form Template, prepare a consent form to ask the research subject's authorized representative for consent to the participation of the research subject. Prepare an assent form to ask the research subjects if they agree to participate in the research, depending on whether the subjects are capable of assenting. When determining whether the subjects are capable of assenting, take into account the decision-making capacity of the research subjects.

SUGGESTED WORDING

Instructions: You should cut and paste these paragraphs, where applicable, into the appropriate area of the Informed Consent Form. However, the suggested wording below should be modified appropriately for the specifics of your study.

Audio taping/Videotaping/Photographs/Digital Recordings

[Include the following information in the What about confidentiality? section]

This research project involves making *[audiotapes/videotapes/photographs]* of you.

[Then explain why the tapes/photos are being made, who will have access to them, where they will be stored, and when (or if) they will be destroyed]

- ___ I agree to be [videotaped/audio taped/photographed] during my participation in this study.
- ___ I do not agree to be [videotaped/audio taped/photographed] during my participation in this study.

Research Projects Involving Data Collection in a Classroom

[Include the following information in the Do I have to be in this research? Can I stop participating at any time? Section]

Participation is not a course requirement. You and your class members have other options for earning the same amount of credit **[describe the options for earning the same amount of credit. The options must not be more difficult than participating in the research.]**

Research Projects Involving Prisoners

[Include the following information in the Do I have to be in this research? Can I stop participating at any time? Section]

Your decision to participate or not participate in this research project will not affect or influence the length of your sentence, your parole, or any other aspect of your incarceration. Also, if you decide to participate and then leave the study before it is over, that will not affect or influence the length of your sentence, your parole, or any other aspect of your incarceration.

Certificate of Confidentiality

[Replace the What about confidentiality? section with the following information.]

We will do our best to keep your personal information confidential. To help protect your confidentiality, _____ *[Include a description of the procedures to maintain the confidentiality of the data, e.g. having locked filing cabinets and storage areas, using identification codes only on data forms, and using password-protected computer files.*

For anonymous records, state those names and other identifiers will not be placed on surveys or other research data. For coded identifiable information, state the following, if applicable (1) your name will not be included on the surveys and Other collected data; (2) a code will be placed on the survey and other collected data; (3) through the use of an identification key, the researcher will be able to link your survey to your identity; and (4) only the researcher will have access to the identification key.] If we write a report or article about this research project, your identity will be protected to the maximum extent possible.

To help us further protect your privacy, we have obtained a Certificate of Confidentiality from _____ **[Name of agency issuing the Certificate of Confidentiality]**. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding.

We may, however, release identifying information in some circumstances. For example, the Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should also understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality also does not prevent the researchers from voluntarily disclosing identifying information, and the researchers may notify appropriate individuals and/or authorities if information comes to their attention concerning child abuse or neglect or potential harm to you or others. **[Modify as needed to include any other conditions under which disclosure would be made (e.g., abuse or neglect of the developmentally disabled or vulnerable adults, reportable communicable diseases, etc.). If no such disclosures will be made, the researchers should provide an explanation in the IRB Application.]**