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| **Research Exempt from IRB Committee Review**Category 2: Surveys/Interviews, Standard Education Tests & Observations of Public BehaviorVersion 2.1Updated October 2, 2006This application form is based on the University of Minnesota IRB's *Research Exempt from Committee Review Application Form Category 2* and has been adapted with their permission. | IRB Use Only |
| Date received: \_\_\_\_\_\_\_\_\_\_\_Project Number: \_\_\_\_\_\_\_\_\_IRB Review Date: \_\_\_\_\_\_\_\_[ ] Approved as submitted[ ] Approved with minor suggestions for changes[ ] Approved with stipulations[ ] Deferred[ ] Not approved |

## Reminders for Exemption Category 2 Research:

1. Surveys on sensitive or personal topics that may cause stress to study participants are not exempt from IRB review.
2. Exemptions in category 2 may be applied to research involving children for standardized educational tests or when the investigator observes public behavior but does not participate in that behavior or activity.
3. Research with surveys or interviews involving children is not exempt under category 2.
4. If you are using a private list for recruitment you must have permissible access to make initial contact yourself. If you do not have permissible access to the list you must ask the custodian of the record to make initial contact for you (you will need to provide a description of how they will do this) and let the potential subjects contact you if they are interested.
5. If you are mailing a survey to subjects and asking them to return it to you, or doing a phone interview, you must send or read a consent statement that includes the same information as the consent form but is not signed.
6. No personal or sensitive information can be sought under this exempt category (doing so is not exempt research).
7. Exempt research must not include direct identifiers or a link to identification of the subject.

1. Project Identification and Signatures

* 1. Project Title (Project title must match grant title. If different, also provide grant title):

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* 1. Person preparing this document

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| Name:       | Phone number:       |
| Email:       |

* 1. Principal Investigator (PI)

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| **Name** (Last name, First name MI)**:**       |
| **Mailing Address:**      | **Phone Number:**       | **Fax:**       |
| **Email:**       |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **University Department** (if applicable):      | **Highest Earned Degree:**       |
| **As Principal Investigator of this study, I assure the IRB that the following statements are true:**The information provided in this form is correct. I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc. I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study. I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation. I will not begin my research until I have received written notification of final IRB approval. I will comply with all IRB requests to report on the status of the study. I will maintain records of this research according to IRB guidelines. The grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application. If these conditions are not met, I understand that approval of this research could be suspended or terminated. |
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| Typed Name of PI |
|  |       |  |
| Original Signature of PI | Title of PI | Date |

***If PI is faculty, staff or student, a Department head signature is required.***

***If PI is also the Department head, provide the signature of the Dean or Division head.***

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| **As Department head or Dean/Division head,** I acknowledge that this research is in keeping with the standards set by my department and I assure that the Principal Investigator has met all departmental requirements for review and approval of this research. |
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| Typed Name of Department head, or Dean/Division head |
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| Original Signature of Department head or Dean/Division head | Date |

* 1. Co-Investigator(s)

Co-Investigators responsible for, or working on this project should be listed below. Include any individual who will have responsibility for the consent process, direct data collection from subjects, or follow-up.

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| **Name** (Last name, First name MI)**:**       |
| **Mailing Address:**      | **Phone Number:**       | **Fax:**       |
| **Email:**       |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **University Department** (if applicable):      | **Highest Earned Degree:**       |
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| Original Signature of Co-Investigator | Title of Co-Investigator | Date |

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| **Name** (Last name, First name MI)**:**       |
| **Mailing Address:**      | **Phone Number:**       | **Fax:**       |
| **Email:**       |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **University Department** (if applicable):      | **Highest Earned Degree:**       |
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| Original Signature of Co-Investigator | Title of Co-Investigator | Date |

* 1. Research Staff

Personnel you wish to be included in correspondence related to this study e.g. project managers/study coordinators

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| **Name** (Last name, First name MI)**:**       | **University Department** (if applicable): |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **Mailing Address:**      | **Phone Number:**       | **Fax:**       |
| **Email:**       |

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| **Name** (Last name, First name MI)**:**       | **University Department** (if applicable): |
| **Occupational Position:** [ ] Faculty [ ] Staff [ ] Student [ ] Other:       |
| **Mailing Address:**      | **Phone Number:**       | **Fax:**       |
| **Email:**       |

* 1. Student Research

**If the PI of this research is a student**, include **Appendix J** filled out by the advisor with this application form and include the advisor’s signature below.

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| Student Research requires the approval of an Academic Advisor. As Academic Advisor to the Student Investigator, I assume responsibility for ensuring that the student complies with University Policies and Federal Regulations regarding the use of Human Subjects in research. |
| Advisor’s Name (Last name, First name MI):      | Department:       |
| Mailing Address:       | Phone Number:       |
| Email:       |
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| Original Signature of Academic Advisor | Date |

* 1. For each researcher involved with human subjects on this study, describe the training and education completed in the protection of human subjects:

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2. Funding

2.1 Is this research funded by an internal or external agency?

[ ]  Yes. Include Appendix A

[ ]  No. Explain how costs of research will be covered:

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3. Institutional Oversight

3.1 Is this research proposal being reviewed by any other institution or peer review committee?

[ ]  Yes. *Attach copy of materials submitted for peer review.*

[ ]  No.

4. Conflict of Interest

Federal Guidelines have been revised to require IRBs to assure that there are no conflicts of interest in research projects that could affect human subject participation. If this study involves or presents a potential conflict of interest, additional information may need to be provided to the IRB. Examples of potential conflicts of interest may include, but are not limited to:

1. A researcher or family member participating in research on a technology owned by a business in which the faculty member holds a financial interest
2. A researcher participating in research on a technology developed by that researcher
3. A researcher or family member assuming an executive position in a business engaged in commercial or research activities
4. A researcher or family member serving on the Board of Directors of a business from which that member receives University-supervised sponsored research support

4.1 Do any of the Investigators or personnel listed on this research have a potential conflict of interest associated with this study?

[ ]  Yes.

[ ]  No.

If yes, has this potential conflict of interest been disclosed as per the relevant policy?

[ ]  Yes. *Include a copy of the plan for IRB review.*

[ ]  No. *The IRB cannot review a study before a potential conflict has been disclosed.*

5. Summary of Activities

*Use lay language, do not refer to grant or abstract.*

5.1 Describe the objective(s) of the proposed research including purpose, research question, hypothesis, and relevant background information etc.

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5.2 Which methods will this study include?

Check all that apply:

[ ]  Descriptive

[ ]  Ethnographic

[ ]  Experimental/Control Design

[ ]  Field work

[ ]  Formative

[ ]  Longitudinal

[ ]  Oral history

[ ]  Phenomenological

[ ]  Qualitative

[ ]  Quantitative

[ ]  Other, specify :

5.3 Describe the research study design.

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5.4 Describe the tasks subjects will be asked to perform.
Describe the frequency and duration of procedures, psychological tests, educational tests, and experiments; including screening, intervention, follow-up etc. *Reminder:* No personal or sensitive information can be sought under exempt guidelines. (If you intend to pilot a process before recruiting for the main study please explain.)

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*Attach surveys, instruments, interview questions, focus group questions etc.*

5.5 Describe what non-participants will do during this period (activities and supervision):

*It is important that the study design not penalize students who will not be participating if not all students will be participating.*

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5.6 How long do you anticipate this research study will last from the time final approval is granted?
Exempt research is generally considered short-term in nature so include a thorough description of longer lasting research.

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6. Participant Population

6.1 Expected Number of Participants:

6.2 Expected Age Range

Check all that apply:

[ ]  0-7 (Include parental consent form)

[ ]  8-17 (Include child’s assent form, parental consent form)

[ ]  18-65

[ ]  65 and older

**Exact ages to be included:**

6.3 Describe the criteria for inclusion and exclusion of subjects in this research study.

Inclusion Criteria:

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Exclusion Criteria:

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6.4 Location of Subjects during Research Data Collection

Check all that apply:

[ ]  Elementary/Secondary Schools (include Appendix M)

[ ]  Community Center, specify:

[ ]  University Campus (non-clinical), specify:

[ ]  Subject’s Home, specify:

[ ]  International Location (include Appendix K):

[ ]  Other special institutions, specify:

7. Compensation

7.1 Will you give subjects gifts, payments, compensation, reimbursement, services without charge or extra credit?

[ ]  Yes.

 [ ]  No.

If yes, please explain:

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8. Recruitment

8.1 Are subjects chosen from records?

[ ]  Yes. *Complete 8.1a-c*

 [ ]  No. *Continue to 8.2*

8.1a Who controls the permissible access for the use of the records?

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If using public lists for recruitment, attach scripts for any and all forms of initial contact, i.e. email, phone, letter, advertisement.
If using private lists for recruitment, you must have permissible access to make initial contact yourself. If you do not have permissible access to the list you must ask the custodian of the record to make initial contact for you (describe how they will do this in 8.1c) and let the potential subjects contact you if they are interested.

8.1b What type of records:

[ ]  Medical

[ ]  Educational

[ ]  Employment

[ ]  Other:

8.1c Describe your permissible access to this population (or include written documentation for the cooperation/permission from the holder or custodian of the records, i.e., Schools, agencies, organizations):

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8.2 Describe the recruitment process to be used:

Attach a copy of any and all recruitment materials to be used e.g., advertisements, bulletin board notices, e-mails, letters, phone scripts, or URLs.

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8.3 Explain who will approach potential subjects to take part in the research study and what will be done to protect individuals’ privacy in this process:
Initial contact of subjects identified through records search must be made by the official holder of the record, i.e., primary physician, therapist, public school official.

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9. Confidentiality

9.1 Describe provisions taken to maintain confidentiality of data (e.g. surveys, video or audio tape, photos):

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9.2 Describe the security plan for data including where stored and for how long:

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9.3 Will there be a link to identify subjects?

[ ]  Yes.

[ ]  No.

9.4 Will data be made available to anyone other than the PI?

[ ]  Yes.

**[ ]** No.

If yes, explain who and why they will have access to the data:

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10. Informed Consent Process

Visit the [IRB website](http://www.nwhealth.edu/research/ORAC/irb/forms.html) for example consent forms.

***Reminder:*** *If you are mailing a survey to subjects and asking them to return it to you, or doing a phone interview, you must send or read a consent statement that includes the same information as the consent form but is not signed.*

10.1 Describe who will present the consent process to subjects and how they will obtain consent from subjects:

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10.2 Recognizing that consent itself is a process of communication, describe what will be said to subjects to introduce the research: Do not say “see consent form”. Write the explanation in lay language.
*If you are using telephone surveys, attach telephone scripts.*

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10.3 Prepare and attach consent forms for review. Include parental consent form, or assent form for minors when applicable.

***Under specific conditions, when justifiable, documentation of informed consent can be waived. These limited conditions are described in*** [***45 CFR 46.117***](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.117)***. If you believe that this research qualifies according to the regulations, include Appendix W.***

*You have reached the end of this form. Please make sure that you have responded to every question on this application (even if your response is “not applicable”).*