Instructions for Completing the IRB Application Form

This is NOT the application form! The application form you must use when asking IRB to approve your research is found in IRBNet. For more information, see http://grad.mnsu.edu/irb/process.html

DO NOT convert this form to a word document, fill it out and submit it to IRB for approval.

(This information is only for a new application not a Revision, Continuation, or request for Closure.)

• The hints that follow should make your job of submitting a successful IRB application easier.

• Below, you will find a replica of an MSU IRB Application, with one exception
  Written in blue are tips for filling out the selected sections

• If you read through the sections with the blue hints, you may avoid some common pitfalls.
Application for the Conduct of Human Research
Minnesota State University, Mankato

University policy requires that all research involving human participants be reviewed by the Institutional Review Board (IRB). In completing the application, be aware that the persons reviewing it may be unfamiliar with the field of study involved. Present the request in non-technical terms. Incomplete proposals will be returned without review. Data collection may not begin until approval is received from the IRB.

To facilitate a timely review, please make sure all spelling and grammar are correct. After you complete this form, please upload it on IRBNet, electronically sign it (click “Sign this Package”), and submit it (click “Submit this Package”).

NOTE: This form has pre-set fillable text boxes. Use Tab key to advance to each text box or check box. When making amendments/modifications, put changes in all CAPS so reviewers can easily see them.

1. Project Title:

2. Key Personnel

   a. MSU Faculty/Staff (not adjunct) Principal Investigator (PI) Name:

      Department:

      Campus Mail Code:

      Phone Number:

      Email:

      PI is a salaried MSU Employee (not adjunct): ☐ Yes ☐ No

   b. Co-Pi Name:

      Department:

      Campus Mail Code:

      Phone Number:

      Email:
c. Student PI Name:
   Department:
   Campus Mail Code:
   Phone Number:
   Email:

3. Project Information

a. Has this project previously been approved by the MSU IRB?
   - Yes
   - No

   If Yes, IRBNet ID#:

   If Yes and not officially closed, please submit a revision rather than a new application.

b. Has this proposal been submitted to another human subjects committee?
   - Yes
   - No

c. Has this proposal been approved by another human subjects committee?
   - Yes
   - No

   If Yes, please attach a copy of approval letter with your attachments.

d. Will results be presented beyond class presentations (e.g., submitted for presentation or publication including thesis, Alternate Paper Plan, dissertation or presentation)?
   - Yes
   - No

e. Will you need to ask anyone to use any MSU resources to recruit participants or obtain data (e.g., use an MSU e-mail distribution list, obtain registration data, etc.)?  There is a guideline regarding the use of university resources to contact potential participants and participants. IRB has added this question so; we may be able to help expedite your research. If you answer, yes, someone from IRB will likely contact you to be sure you do not need permission from the IRB administrator to use the resource. IRB wants you to be aware that approval for research from IRB does not guarantee that you will be allowed to use the university resources such as e-mail lists for all faculty, all staff, and/or all students.
   - Yes
   - No

   If Yes, briefly describe what you need:

   If Yes, please indicate whether you have access and permission to use the resources. The IRB coordinator may contact you to provide direction for how to obtain permission to use or obtain
the resources.

<table>
<thead>
<tr>
<th>f. Funding Source</th>
<th>Click applicable box on left. Type explanation on right.</th>
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<tbody>
<tr>
<td>☐ MSU Funding Source. Explain here:</td>
<td></td>
</tr>
<tr>
<td>☐ Non-MSU Funding Source. Explain here: If you are using your own money for example to pay for gift cards, explain here.</td>
<td></td>
</tr>
<tr>
<td>☐ No Funding</td>
<td></td>
</tr>
</tbody>
</table>

| g. Provide a concise statement of the purpose for the research. Two sentences maximum. We are looking for the purpose not an explanation of why you are doing the research. |

<table>
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<tr>
<th>4. Archival Data: Archival data&quot; is (1) data that is legally made available to the public, (2) data that was collected by the researcher as part of non-research activity, or (3) data that was collected for a separate project under IRB approval. Data that is collected for the proposed study before seeking IRB approval is not archival and will NOT receive IRB approval.</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Is archival data being used? ☐ Yes. Complete the remainder of section 4. Do not complete any more of the application unless you will also be actively collecting data.</td>
</tr>
<tr>
<td>☐ No. Go on to section 5. Do not complete section 4.</td>
</tr>
<tr>
<td>b. Describe the source of the data: From where will you get the data? Are you the ‘owner’ of the data? What is the data you wish to use?</td>
</tr>
<tr>
<td>c. Describe how the identity of participants will be protected: What identifying information does the data contain? Who will have access to the data?</td>
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<th>5. Potential Participants</th>
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<tr>
<td>a. Will participants be under age 18? ☐ Yes ☐ No</td>
</tr>
<tr>
<td>Please provide age range of children:</td>
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</tbody>
</table>
b. Are you specifically recruiting participants because they are pregnant women?

- [ ] Yes
- [ ] No

c. Are you specifically recruiting participants because they are people with cognitive impairments?

- [ ] Yes
- [ ] No

If you answered ‘Yes,’ explain:

d. Are you specifically recruiting participants because they are prisoners/incarcerated people?

- [ ] Yes
- [ ] No

e. Are you specifically recruiting participants because of their membership in marginalized populations (e.g., ethnic minority, low socioeconomic status, differently abled?)

- [ ] Yes
- [ ] No

f. Do any of the researchers have a pre-existing relationship (e.g., supervisor, instructor, coach, advisor) with the potential participants?

- [ ] Yes
- [ ] No

If yes, please explain the relationship and how the participants will not feel pressured to participate: Stating that you will tell participants nothing adverse will happen if they do not participate will not suffice. Many potential participants do not believe this to be true.

6. Procedures Please respond to the questions asked. Try to put only information not requested in your answers as it often confuses the reviewers when information not related to the question is included. Remember that the reviewers are not likely familiar with your area of expertise. Define terms and do not use jargon.

a. Where will the research be conducted? . If you are collecting data using an online survey tool, tell IRB that data is being collected online and provide the name of the survey tool (e.g. Qualtrics).

   If data will be collected through another organization or off campus, you should obtain a dated, signed letter indicating permission from the organization/institution (on their official letterhead) to allow the data to be collected at that location. It is best to obtain that approval after you receive IRB approval. A suggested template can be found at http://grad.mnsu.edu/irb/permission_letter_template.docx IRB suggests you upload the permission letter to IRBNet as part of your IRB documentation for your research.

b. Describe how participants will be recruited, including how researchers will first contact potential participants (including how their contact information will be obtained, if applicable), script and/or recruitment materials.

   • Note that this question is concerned with **HOW** participants are being recruited, not **who is being recruited**. Include who if you like but be sure to say how.
   • Describe how you will get access to the participants and/or mailing/email lists with participant contact information.
   • If you are accessing private email/mailing/phone lists, you will have to have a
message (letter, email) granting you access to the list.

- If you are recruiting participants online, you are responsible for abiding by the rules regarding privacy, research, recruitment rules from any webpage, social media groups, and so forth.

c. What exactly will participants be asked to do? Include participants in any control condition, a description of research procedures, data collection tools, time commitment, and anything else that might be pertinent.
   - This query needs to be addressed thoroughly and all components of the research must be included.
   - In the case of interviews and focus groups, the strategy for recording the interviews must be noted.
   - To facilitate review, please present the procedures in the order of expected occurrence.
   - If participants are expected to return surveys/questionnaire, you need to describe the procedures for return.
   - If you are administering surveys using email, please consider using a commercial vendor such as Qualtrics. Investigators who decide to use email should be prepared to describe the precautions they are taking to protect security.
      If interviewing, the instruments used to record the interview must be noted.
   - If interviewing, describe
      1. procedures for transcribing interviews and who will transcribe them,
      2. where and for how long the transcriptions (and, if appropriate recordings) will be securely stored,
      3. for how long the transcriptions (and recordings) will be stored.
      4. when the transcriptions (and recordings) will be destroyed and who will destroy them

d. If this study will involve deception, is a clinical trial, or might otherwise have an ambiguous end time, how will participants know when the study has ended?

   Click here if not applicable: ☐    If applicable, explain here:

e. What are the potential risks participants may encounter, and how will you ensure these risks are managed and minimized (risks can include but are not limited to physical or mental harm, stress, discomfort, undesirable social, economic, and/or financial consequences)?
   - Risks can be social and/or emotional as well as physical.
   - It is not accurate to claim that there are no risks. IRB recognizes two terms to describe risk: “minimal risk” or “greater than minimal risk.”
   - Minimal risk is defined as: harm not beyond that encountered in everyday life.
   - If investigators are using email or the internet, they have must address possible security risks.

f. What are the potential benefits to the participants of participating in the study? Compensation is not a benefit. Note that the question asks about benefit to the participants not you or society in general. If there are no direct benefits to the participants state, “There are no benefits for participation in this research.” This statement will also go in your consent form

g. What are the potential benefits of this research for society?
h. Will compensation be given to participants (e.g., money, extra credit, gift cards)?

☐ Yes  ☐ No  If yes, please describe:

i. How will the privacy, confidentiality, and/or anonymity of participants will be protected?  Do not just assure the IRB and/or participants that rights will be protected; the investigators must explain procedures for protection.

7. Consent

a. Will you be seeking a waiver of consent (i.e., research will be done without seeking the consent of persons whose records/tissue are analyzed)?  If you are seeking a waiver of consent it is best to check with the IRB to obtain direction before you submit your application. Send a message to irb@mnsu.edu

☐ Yes  ☐ No  If Yes, please explain why:

b. Will you be seeking a waiver of documented consent (i.e., consent obtained but there is no signed consent form)?  If you are seeking a waiver of documentation of consent it is best to check with the IRB to obtain direction before you submit your application. Send a message to irb@mnsu.edu

☐ Yes  ☐ No  If Yes, please explain why:

c. Unless you have requested a waiver of consent, explain when and how will you obtain informed consent: this question addresses the consent process not the data collection process. Be sure to explain when you will get consent. Please be very explicit about how you will obtain informed consent. Do not just say the participants will sign a consent form. Give details. Will you just hand out the consent and tell them to sign it? Will you explain the research and ask if they have questions? Will the consent form be mailed to the participants? Are you obtaining signed consent? When participants sign a consent form, we say we have documentation of informed consent. Signed consent is not always required. For online surveys, documentation of informed consent may not be required. All the elements of consent must be provided to the potential participants but the potential participant does not need to sign his/her name

d. The Principal Investigator will ensure that signed Informed consent/assent records of the participants are kept in a secure location at Minnesota State University, Mankato or satellite site for at least three years after the completion of the research. Where will they be kept?

Click here if not applicable:  ☐  If applicable, complete below:

Name of Person Responsible:

Location (Campus address or other university site):

8. Instructions for Informed Consent: The Informed Consent Check List below must be complete or submission will be returned without review. (Consent form not required if only archival data is being used.)
To expedite IRB approval, use the enclosed checklist to be sure the required elements of consent are present. Your consent form/information should be written as if you were talking to the potential participant, in a manner appropriate for the audience level (eighth-grade reading level).

Do not add limitations to any of the required components. For example, one of the required elements is that a statement be included indicating that refusal to participate will involve no penalty or loss of benefits or that the decision whether or not to participate will not affect the participant’s relationship with Minnesota State University, Mankato. If you changed the “Minnesota State University, Mankato” to ‘your professor,’ for example, that would not be correct. By making this change, you have limited those with whom the relationship will not be affected.

If there are no specific risks related to the research, state, “The risks you will encounter as a participant in this research are not more than experienced in your everyday life.” Do not say there are no risks or that the risks are less than minimal.

CONSENT ISSUES:
• If you plan to contact participants with follow-up questions or recruitment to another phase of the research, this must be listed in the consent form.
• If you are recording interviews or focus groups, be sure to describe how the interviews will be transcribed and who will transcribe them, where/how/how long they will be stored and who will store them, who will destroy them, and how they will accomplish the destruction.
• At http://grad.mnsu.edu/irb/, examples of consents and assents as well as a consent checklist also can be accessed. The same examples of consent and assent forms can be used as templates and they are also available in the IRBNet site. Feel free to adapt the examples to your needs.

<table>
<thead>
<tr>
<th>Informed Consent Check List</th>
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<tr>
<td>Is this information reflected in your consent form/consent information?</td>
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**Required Components**

Does the consent form/information...

Click each box to select.

- [ ] ... state that the study involves research, with the term research prominently featured in the first lines?
- [ ] ... use clearly written language appropriate to the participants’ comprehension level?
- [ ] ... explain the purpose(s) of the research?
- [ ] ... indicate the time commitment for participants?
- [ ] ... describe what the participants will be asked to do?
- [ ] ... describe any reasonably foreseeable risks or discomforts participants may encounter? Risks may be social and/or emotional as well as physical.
- [ ] ... describe any benefits to the participants or to others that may reasonably be expected from the research? If there are no direct benefits to the participants, state that there are no benefits to the participants.
- [ ] ... describe measures taken to ensure confidentiality of participant information (if applicable)?
... Include this statement in your consent form: “If you have any questions about this research study, contact (researcher’s name) at (phone & email). If you have any questions about participants' rights and for research-related injuries, please contact Dr. Barry Ries, Administrator of the Institutional Review Board, at (507) 389-1242 or barry.ries@mnsu.edu.”

... If collecting data online or storing identifiable information (e.g. consent forms) electronically, add the following statement to your consent form: “If you would like more information about the specific privacy and anonymity risks posed by online surveys, please contact the Minnesota State University, Mankato Information and Technology Services Help Desk (507-389-6654) and ask to speak to the Information Security Manager.”

... state that participation is voluntary?

... Include this statement in your consent form: “Your decision whether or not to participate will not affect your relationship with Minnesota State University, Mankato, and refusal to participate will involve no penalty or loss of benefits.” Do not modify this statement.

... state that individuals may discontinue participation at any time before the data collection is complete without penalty or loss of benefits? Explain how they may discontinue.

... indicate that participants have a right to a copy of the consent form and how it may be obtained?

... list the IRBNet id number. When documented informed consent is required, the number must appear on the signature page. The IRB needs this number to find the electronic files related to the submission. The number is six or seven digits and does not have a dash with a number following the dash. For example, 436121-3 is not correct. The number that is needed is 436121.

... for multi-page consent forms that are signed by the participants, supply a line for initialing each page to signify the participant has read each page?

... include a statement in which the participant agrees that they are at least 18 years of age.

... if recording audio and/or video, describe the type of recording used and how participants' privacy and confidentiality will be protected? (Additional instructions can be found following the checklists below.)

If relevant
Does the consent form/information ...

Click each box to select.

... describe any compensation for participation?

... list additional costs to the participant that may result from participation in the research?

... explain whether any medical treatments are available if injury occurs, what they consist of, and who will pay for them and/or where further information may be obtained?

... list any procedures that are experimental?
... identify research interventions or alternative treatments that might be advantageous to the subject?

... state that significant new findings developed during the course of the research that may influence a participant’s willingness to continue will be provided to the participant?

... list the approximate number of participants involved in the study?

... state that a particular treatment or procedure may involve risks to participants (or the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable?

... describe anticipated circumstances under which the participant’s involvement may be terminated by the investigator without any prior notice?

... describe procedures the participant is to use to terminate participation in the research?

If you are using electronic recording, audio and/or video:

A. If signed Consent Forms are used, participants must be advised in the Consent Form that their participation includes the use of audio/video recording. Participants must be advised when recordings will be erased or destroyed.

B. If signed Consent Forms are not used, an appropriate signed release must be obtained from the participants or guardian (if applicable) before recording or photographing of the interview. This release statement may be included on the recording if results of the interview would otherwise be anonymous.

C. In studies that do not include signed written consent (i.e. recorded interviews in person or over the telephone), the elements of consent as they are explained to the participants should be included as a preamble to the recorded procedure.

D. Before consenting to being recorded (audio or video) or photographed, participants should be informed of the current and planned use of the materials, including storage and access by persons other than the researcher. Normally, this information will be contained in the consent or release form.

E. The researcher must make proper arrangements for secure storage of all recordings and assure that their use complies with the guidelines outlined in the informed consent/release form. Plans must include storage, erasing, or destroying after a given time period.

9. Attachments

Click each box to select what documents you will be attaching.

☐ Approval from another IRB
☐ Consent Form/Statement
☐ Assent Form/Statement
☐ Cover letters, recruitment scripts, flyers or other information that will be given to participant prior to participation in the study
☐ Any other relevant or supporting documentation, including questionnaires:
☐ Permission Letter from Cooperating Agency (after approval from IRB)

The electronic signature of the PI is required before the IRB can review the submission. On the left side of the page in IRBNet you will find the link “Sign this Package.” Click the link, “Sign this Package,” answer the questions that appear, and submit it. By electronically signing the IRBNet proposal, you are agreeing to the following:
“In making this application, I certify that I have read and understand the Minnesota State University, Mankato IRB Manual, and that I intend to comply with the letter and spirit of the University Policy. Changes in the protocol will be submitted to the IRB for approval prior to these changes being put into practice. Informed consent/assent records of the participants will be kept by the Principal Investigator in a secure location at Minnesota State University, Mankato for at least three years after the completion of the research.”