I. **Research Protocol**

Provide a summary by answering each of the following points, A-E. This summary should not exceed two pages.

*Please type your answers to the following questions in a contrasting font.*

**A. Background of and rationale for this activity.**

This section should provide a brief description of why (aside from a degree requirement!) you are undertaking this study. Briefly explain how your proposed study builds on existing research and how your study findings might be used.

**B. Objectives of this specific research.**

Clearly state your research purpose and the specific research questions or objectives that are guiding your study.

**C. Describe how subjects will be involved, specify what they will do.** Attach (Attachment B) any cover letters, information statements, questionnaires or other formal instruments to be used in the research, describe procedures and/or protocol(s) for unstructured interviews, etc.

*In many ways, this is the “guts” of your IRB proposal. The information in this section determines the type of IRB review that your proposal needs to undergo. It is in this section that you also will be demonstrating that you are protecting your subjects’ rights. Be certain to address the following issues:*

**Subjects**

*Remember that the IRB considers records of individual information to be a human subject.*

Who will participants be?

Why are you using this particular group?

How will subjects be recruited and selected? If records are being used, how will they be selected and by whom?

**Study procedures**

What is going to be done to subjects – or what will they be doing as study participants?

*If participants will be completing a questionnaire – how many items does it have, what type of information are they being asked to provide and in what form (e.g., checklist, open-ended questions), how long should it take to complete? Be sure to specifically identify if subjects are being asked to provide sensitive information (e.g., drug use, sexual practices). Also describe how and where the questionnaire will be administered. If it is to be administered in a group setting (e.g., classroom), who will be present and what will those who do not want to participate be doing? The actual questionnaire or interview guide must be attached as an appendix.*
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If participation involves an interview – under what conditions and in what setting will the interview take place, nature of questions, estimated time for interview, whether interview will be audio- or videotaped, and transcription process (who, how, confidentiality pledges). The interview guide must be attached as an appendix.

If your study involves an intervention of any kind, this must described in a step-by-step manner.

D. Explain how data obtained will answer the research problem.

Briefly describe data analysis plans and how they will lead you to be able to answer your research questions. If you are hiring someone to complete any part of your data analysis (e.g., transcription, data entry, statistical consultation), describe this person’s qualifications.

E. Identify alternative procedures if any, that might be advantageous to the subject.

This usually does not apply. However, sometimes it is appropriate to discuss, for example, why you are choosing to collect data by face-to-face interview rather than by anonymous questionnaire. If your study has an intervention, you should describe why you have chosen this particular intervention over another one that might have similar results.

II. Human Subjects

A. Number of subjects, including individuals who serve as "controls:"

<table>
<thead>
<tr>
<th>Approximate number and ages of participants:</th>
<th>Number</th>
<th>Age Range</th>
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<tbody>
<tr>
<td>Normal</td>
<td></td>
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<tr>
<td>Vulnerable</td>
<td></td>
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<tr>
<td>Control</td>
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<tr>
<td>Total</td>
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</table>

A “normal” subject would be 18 years of age or older and not in a vulnerable group. The following would be considered “vulnerable” subjects: children, any hospitalized or otherwise institutional individual, students, individuals suffering from a medical or mental illness, individuals who are being questioned about a traumatic event (e.g., rape).

B. Source(s) and type(s) of subjects:

You may have already discussed, but describe this information again – from where are subjects being drawn/recruited and what will be their defining characteristics.

C. Criteria for selection/exclusion of subjects:

Yes, this does get a bit repetitive, but please describe specific inclusion and exclusion criteria for your subjects.

D. How subjects will be approached and by whom:

This should be self-explanatory. This item is particularly important in qualitative studies and in studies involving vulnerable subjects – will potential subjects be approached by you, the
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researcher, or by another party? If you are approaching them, how will you insure that they do not feel coerced to participate?

E. Location where procedures are to be carried out:

This also should be self-explanatory – we are particularly concerned about privacy issues. If data are being collected in a classroom setting, who will be present? If a teacher is present, do students feel coerced to participate and does it compromise privacy issues?

Voluntary Participation

A. Describe the method for ensuring that subjects understand that their participation is voluntary and that they do not feel coerced.

This should be addressed in your consent form and you can refer to those statements. Your comments here also should be supported by your description of how you are recruiting subjects and how data are being collected.

B. Will subjects receive an inducement, e.g., payment, services without charge, extra course credit? Specify details. What is the rationale for offering the inducement?

An inducement should never be so great that it might be considered coercion. It is OK to give study participants a small token of appreciation (e.g., a Power Bar after they participate in a physical fitness test, refreshments during a focus group interview). It also is acceptable to reimburse participants for expenses they incur as a result of study participation – e.g., parking fees, babysitting, etc. If data are being collected in a group setting, both participants and nonparticipants must be given the same “payment.” If students will receive extra credit for participating in a study, then those students who do not want to participate must be given an alternative way of earning the same extra credit.

C. If subjects are children and they are capable of assent, describe provisions for soliciting their assent as well as the provisions of soliciting permission of their parent(s) or authorized representative. If there is an assent form or standard briefing statement for children, provide a copy as an attachment (Attachment C).

Parents must provide signed informed consent for a minor to participate in a study. “Negative permission” – returning a form only if they do not want their child to participate – is not OK, unless that is the policy of the participating setting AND an in-house IRB has approved this.

D. Attach a copy of the consent form to be signed by the subject and/or any explanations of the research to be given orally to the subject (Attachment D). If no consent form is to be used, explain the procedures to be used to ensure that participation is voluntary.

(See instructions for contents of consent forms and safeguards for vulnerable populations.)

This is self-explanatory!
E. If any deception (withholding of complete information) is required for the validity of this activity, explain why this is necessary, and describe a debriefing plan and/or attach a debriefing statement (Attachment E).
   Again, this is self-explanatory.

III. Confidentiality and Anonymity

A. Will participation be anonymous, that is, the investigator will have no way to identify subjects by appearance, name or data?
   Remember that anonymity is different from confidentiality! Anonymity means that there is no way to identify responses with who gave them....You can “anonymize” participants or a research setting by giving them pseudonyms. Confidentiality has to do with keeping data secure once they are collected – e.g., by storing data in a locked file, etc.

B. If data are collected that could be associated with individual subjects, describe the methods to be used to ensure the confidentiality of data obtained. (Confidentiality for data is required unless subjects give express written permission that their data may be identified.).
   Here is where you can talk (again) about using pseudonyms. Also, talk about how data will be secured – locked cupboards, etc.

C. Who specifically will have access to some or all of the data? What provisions are there for control over access to documents and data?
   If you are using a transcriptionist or statistical consultant, say so here. You should also mention confidentiality assurances and how they will be instructed to keep data secure and private.

D. How long will data be held? How will they be ultimately disposed of?
   Per federal guidelines, raw study data must be held for three years in a secure place. Paper documents should then be shredded, tapes erased and destroyed, etc.

IV. Risks/Benefits

A. Will subjects in the proposed research be placed at more than minimal risk, as defined by federal policy?
   “Minimal” risk is what is experienced in daily life.

B. Nature and amount of risk (including side effects), substantial stress, discomfort, or invasion of privacy:
   Be sure to consider immediate as well as delayed risks, and psycho/social/emotional, as well as physical risks. Also, consider risks that could be incurred by losing privacy.
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C. What steps are being taken to reduce the level of risk, including any follow-up planned as part of the risk mitigation procedures?
   Describe the safety nets that you have put in place – e.g., when you would stopping study procedures or data collection.

D. Plan for handling adverse effects:
   Describe the conditions that would lead you to stop data collection processes or study procedures. Identify resources that you would use to assist with handling any adverse effects.

E. Arrangement for financial responsibility for adverse effects:
   Usually you will want to clarify that these expenses would be incurred by the participant. Of course, this needs to be clearly stated in your consent form, too.

F. Describe the benefits to the subject and/or society of the proposed research. Why do the benefits outweigh any risks that may be involved?
   Talk about how study findings might be useful. What you want to do here is demonstrate that potential benefits are greater than the risks to which you are exposing study participants. Consider long-term, as well as immediate effects. Consider potential psychological, social, material, financial, and physical benefits.
<table>
<thead>
<tr>
<th>Checklist to be completed by investigator</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>A. Will any group, agency, or organization other than G.U. be involved? If yes, please specify. If yes, attach a letter of permission to conduct your study. This letter should indicate that all study procedures and materials have been reviewed and approved. If your study proposal has been approved by an IRB at another institution, attach the letter or correspondence that indicates this approval.</td>
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<td>B. Will materials with potential radiation risk be used, e.g., x-rays, radio- -- isotopes? If yes, please indicate: 1. Status of annual review by Radiation Safety Officer (RSO). If approved, attach one copy of approval (Attachment F). 2. Title of application submitted to Radiation Safety Committee (RSC).</td>
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<td>C. Will any other hazardous materials come in contact with research subjects? -- If yes, indicate nature of hazard and steps taken to mitigate risk to subjects.</td>
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<td>D. Will an investigational new drug (IND) be used? -- If yes, give name, proposed dosage, how administered, status with FDA, and IND number. Enclose one copy (Attachment G) of: (1) available toxicity data; (2) reports of animal studies; (3) description of human studies done in other countries; (4) a concise review of the literature prepared by the investigator.</td>
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<tr>
<td>E. Will other drugs be used (including over the counter drugs)? -- If yes, give names, dosages, how administered, and side effects.</td>
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<td>F. Will medical, academic or other records be used?</td>
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<td>G. Will audio-visual or tape recordings, or photographs be made?</td>
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<td>H. Should this activity be covered by adverse effects insurance? -- If yes, explain why</td>
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Be sure to provide sufficient information about any “yes” answers above. If any items are checked “yes,” the study probably does not qualify as exempt.
ATTACHMENT A