FULL IRB REVIEW PROTOCOL SUMMARY FORM

Title of Research Project

<table>
<thead>
<tr>
<th>Principal Investigator/Project Director</th>
<th>Department</th>
<th>Phone Extension</th>
<th>Email address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Co-investigator/Student Investigator</th>
<th>Department</th>
<th>Phone Extension</th>
<th>Email address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Co-investigator/Student Investigator</th>
<th>Department</th>
<th>Phone Extension</th>
<th>Email address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Anticipated Funding Source: ____________________________________________________________

Projected Duration of Research: _________ months  Projected Starting Date: ______________

Other organizations and/or agencies, if any, involved in the study: ____________________________________________________________

Please answer the questions below and return this form with:
- ♦ A memo that briefly describes the intent of the project
- ♦ A completed copy of the Consent Form Checklist
- ♦ A copy of the Consent Form that will be provided to the participants

I. Project Information:

A. Project Activity Status:
   - ☐ New Project
   - ☐ Periodic Review of Continuing Project
   - ☐ Revision to Previously Approved Project

B. This project involves Kettering University students
   - ☐ Yes  ☐ No

C. Human Subjects from the following populations will be involved in this study
   - ☐ Minors  ☐ High School Students
   - ☐ Mentally Disabled  ☐ Prisoners
   - ☐ Elderly  ☐ None of the above

D. Total number of subjects to be studied: ____________________________________________

II. Abstract Describing Project and Purpose (Include a description of all experimental methods to be used and design and program activities; what measures or observations will be
taken in the study? If any questionnaires, tests or other instruments are to be used include a brief description and a copy of such instrument.

III. Protocol (Who will be the research subjects? How will they be solicited or contacted? Include any recruitment letters or other recruitment materials with this document; How much time will be required of each subject? Describe procedures to which humans will be subjected – use additional pages if necessary)

IV. Precautions (What steps will be taken to insure that each subject’s participation is voluntary? What, if any, inducements will be offered to the subjects for their participation?)

V. Confidentiality of data (Describe the methods to be used to ensure the confidentiality of data obtained, including plans for publication, disposition or destruction of data, etc)

VII. Consent (Attach a copy of all consent forms to be signed by the subjects and/or any statements to be read to the subject)

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

- Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented
- Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair
- The principal investigator is responsible for retaining informed consent documents for a period of three years after the project.
- The principal investigator should include with the IRB submission a confirmation that the research has been approved; i.e. the Project Approval Form.
- The principal investigator shall notify the Kettering IRB chairperson when the research proposal has been approved or modified by another institution’s IRB.
- The principal investigator will provide a copy of the final research results to the chairperson of Kettering’s IRB.
<table>
<thead>
<tr>
<th>Signature of IRB Committee Chair:</th>
<th>Date: / /</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Chair: Check 1 box:</td>
<td>□ Approved</td>
</tr>
</tbody>
</table>
### Consent Form Checklist

<table>
<thead>
<tr>
<th>N/A</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>f.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>g.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>h.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If there was a “NO” response to any of the above questions, the consent form must be revised accordingly unless the investigator can satisfactorily justify why it is appropriate as submitted.
ELEMENTS OF INFORMED CONSENT

Researchers must obtain the informed consent of participants. For those less than 18 years of age, the researcher must obtain the informed consent of parents or legal guardian and all reasonable attempts must be made to obtain each participant’s assent, which is defined as the participant’s agreement to participate in the study.

The informed consent must include the following in sequential order and in language which the participants can understand:

1. Statement of purpose of the study.

2. Short description of methodology and duration of participant involvement.

3. Statement of risks/benefits to the participants.

4. Statement of data confidentiality.

5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.

6. An offer to answer any questions the participant may have.

7. Contact information of all Principal Investigators, and also contact information for Kettering’s Institutional Review Board (Associate Provost of Sponsored Research, 810-762-9616).

8. Line for signature of participants and/or parents or legal guardian except for questionnaire research in which return of questionnaire gives implied consent.

9. Statement that participant is 18 years of age or older unless parent or legal guardian has given consent.

In situations where participants will be deceived, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, after the study is complete, each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" in order to guarantee informed consent.
Kettering University

SAMPLE INFORMED CONSENT

The following suggestions are offered as guidelines. The exact language is the decision of the researcher. Keep in mind, however, that the Institutional Review Board must determine if the participants will be giving informed consent. (Note: that in the case of children, it is assent).

Dear (student, parent, sir, madam, etc.):

We are conducting a study to determine ___________________. In this study, you (your child/ward) will be asked to ___________________________. Your participation should take about ______ minutes.

There are no risks to you (your child/ward).

or

The only risks to you (your child/ward) include ________________________________.

All information will be handled in a strictly confidential manner, so that no one will be able to identify you (your child/ward) when the results are recorded/reported.

Your (your child's/ward's) participation in this study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply ____________________________________.

Please feel free to contact __________________________ (names(s), title(s) of principal researchers) at _______ phone) if you have any questions about the study. Or, for other questions, contact Kettering’s Associate Provost for Sponsored Research (810-762-9616).

________________________________________________________________________

If the participant is of age (18 years old or older), use:

I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

________________________________  Signature of Participant  Date

If the participant is not of age, use:

I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible.

________________________________  Signature of Parent/Guardian  Date

ASSENT format:

I understand what I must do in this study and I want to take part in the study.

________________________________  Signature of Child/Ward  Date

Attach Consent Form that will be provided to the participants