Illinois State University Institutional Review Board
Protocol Review Form to be completed by the
Department/Unit Representative

After completing this review form, please attach it to the original protocol and forward to Research Ethics & Compliance, Campus Box 3330. Please note that the sections on this form generally correspond to those on the IRB Protocol Submission Form. For more information, please refer to rsp.illinoisstate.edu/research/, or contact REC at (309) 438-2529 or via email to rec@IllinoisState.edu.

I. GENERAL INFORMATION and II. PRINCIPAL INVESTIGATOR ASSURANCE

<table>
<thead>
<tr>
<th>Project Title</th>
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</tr>
</thead>
<tbody>
<tr>
<td>PI Name</td>
<td></td>
</tr>
<tr>
<td>Co-PI Last Names</td>
<td></td>
</tr>
</tbody>
</table>

Have all investigators completed the required CITI Training? Yes | No

Is all required information complete including original PI signature? Yes | No

III. PROJECT DESCRIPTION

A. RESEARCH DESIGN — The proposed design must be scientifically sound and not unnecessarily expose subjects to risk.

1. Briefly describe the proposed research in layperson’s terms:

B. METHODOLOGY

1. Subject Selection/Recruitment — Subject selection must be equitable. Rationale for inclusion/exclusion must be addressed.

<table>
<thead>
<tr>
<th>Who is to be enrolled?</th>
<th>Adults (18 and Over)</th>
<th>Children (under 18, Appendix B required)</th>
<th>Males</th>
<th>Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the research specifically targeting?</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will participants be recruited from any of the following vulnerable populations?</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Required appendices should be attached.</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please specify):</td>
<td></td>
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</table>

| Is the identification of subjects appropriate? | Yes | No |
| Will permission be obtained to access restricted information? | Yes | No |
| Is the recruitment process appropriate? | Yes | No |

2. Informed Consent — Consent documents must be understandable to subjects.

<table>
<thead>
<tr>
<th>Informed Consent for Participants 18 and over</th>
<th>If no waiver or alteration is requested, does the study include an informed consent process that includes the eight required elements?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the informed consent form included?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Permission and assent for children or subjects requiring a guardian or legally authorized representative</th>
<th>If no waiver or alteration is requested, does the parent/guardian/representative permission process include the eight required elements?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the parent/guardian/representative permission form included?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Are appropriate assent forms or scripts included?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

3. Compensation — If offered, is compensation appropriate? Yes | No | N/A
### C. PROCEDURES and D. INSTRUMENTS/APPARATUS

1. Which techniques will be used to collect data?
   - Questionnaire
   - Files/Records
   - Task(s)
   - Interview
   - Physical Exercise
   - Specimens
   - Treatment
   - Observation
   - Tests
   - Other (please specify):
     - Recording (Appendix I required):
     - Audio
     - Video
     - Still Image

2. Are the individuals collecting the data appropriately trained to handle foreseeable adverse events?
   - Yes
   - No
   - Not enough information to make a determination

3. Will the study involve any of these? If so, the appropriate appendix must be attached.
   - Psychological intervention? (Appendix F required)
   - Deception? (Appendix G required)
   - Biomedical Procedures? (Appendix H required)

### E. DATA — Data may be either anonymous, confidential, or neither.

1. If data will be confidential, does the study adequately state a plan for...
   - Storing the data securely?
   - Access to the data?
   - Use of the data?
   - Disposition of the data?

### F. RISKS

1. Is the probability and magnitude of harm or discomfort greater than that encountered in daily life or during the performance of routine physical or psychological examinations or tests?

   - Physical
   - Psychological
   - Social
   - Coercion of Children/Prisoners
   - Special Risks to Mother and Fetus or Neonate
   - Special Risks from Breach of confidentiality
   - Special Risks regarding Genetic Information

2. Does the protocol adequately identify risks and describe how they will be minimized? If the study involves risks in the shaded area, additional safeguards must be provided.

### G. BENEFITS

1. Does the protocol adequately describe anticipated benefits?

2. Do the benefits justify the risks?

### IV. CHECKLIST

1. Does the protocol include all required appendices?

2. Are all the appendices complete and satisfactory?
V. DEPARTMENT/UNIT REPRESENTATIVE RECOMMENDED LEVEL OF REVIEW

<table>
<thead>
<tr>
<th>Name (please print):</th>
<th>Date:</th>
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Please review your responses above carefully! All shaded areas above indicate an expedited or full level of review. In the space below, please check either Exempt, Expedited Review, or Full Board Review. For Exempt and Expedited, please indicate the category number(s). Please note the category descriptions below are just summaries. Refer to the regulations or your departmental representative handbook for complete descriptions and limits on applicability.

**EXEMPT FROM FURTHER REVIEW**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices...
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless the information is obtained in such a manner that human subjects can be directly or indirectly identified AND any disclosure of the human subjects' 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.
3. Research involving the use of educational tests, surveys, interviews, or observation of public behavior that is not exempt under the above criterion, if the subjects are elected or appointed officials or candidates for public office...
4. Research involving the collection of existing data, documents, records, pathological 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 public benefit or service programs...
6. Taste and food quality evaluation and consumer acceptance studies...

**EXPEDITED REVIEW**

1. Research on drugs or medical devices for which an investigational new drug application or an investigational device exemption is not required.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture...
3. Prospective collection of biological specimens for research purposes by noninvasive means...
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects.)
8. Continuing review of research previously approved by the convened IRB where (a) no new subjects will be enrolled, all subjects have completed all research-related interventions and the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**FULL BOARD REVIEW**

- All other studies, including those involving deception of subjects in ways that may lead to their distress or the collection of data in ways that may identify individual subjects.

Comments: