This form assists TUC Public Health IRB members to assess whether projects or studies require formal IRB review. It also provides documentation that the IRB has reviewed the project or study. If you believe that your project requires IRB review, please attach a full IRB proposal to this form [http://research.tu.edu/irb/](http://research.tu.edu/irb/)

Please allow up to ten (10) business days for review and response. Please email completed forms to sahai.burrowes@tu.edu & annette.aalborg@tu.edu

<table>
<thead>
<tr>
<th>IRB Use Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Exempt from formal IRB Review</td>
</tr>
<tr>
<td>☐ Review status unclear; more information needed</td>
</tr>
<tr>
<td>Requires TUC IRB Review</td>
</tr>
<tr>
<td>☐ Expedited Review</td>
</tr>
<tr>
<td>☐ Full Board Review Recommended</td>
</tr>
</tbody>
</table>

**Project Title**

**Anticipated Project Start Date:**

**Anticipated Project End Date:**

**Section 1: Study Investigators & Contact Information**

- **TUC Project PI:** (Last name, First name, MI)
- **TUC PI email address:**
- **TUC PI phone number:**
- **Co-PIs:** (Last name, First name, MI)

**Study/Project Type**

- ☐ Student Capstone Project
- ☐ Student Independent research
- ☐ Touro Faculty Project

For student led projects, please fill out Section 2

**Section 2: Student Information**

2.1 Academic Program

- ☐ MPH
- ☐ PAS/MPH
- ☐ DO/MPH
- ☐ COP/MPH

2.2 Student Name (Last name, First name, MI)

2.3 Anticipated Graduation Date:
### Section 3: Is this Project Human Subjects Research as Defined by Federal Regulations?

Research is defined in the Code of Federal Regulations, 45CFR46.102(d), as a systematic investigation designed to develop or contribute to generalizable knowledge.

The Belmont report states “...the term ‘research’ designates an activity designed to test a hypothesis or answer a research question(s) [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”

Research generally does not include operational activities such as routine outbreak investigations and disease monitoring and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services.

Generalizable knowledge is information where the intended use of the research findings can be applied to populations or situations beyond that studied. Note that publishing the results of a project does not automatically meet the definition of generalizable knowledge.

<table>
<thead>
<tr>
<th>3.1 Do you have a specific research question or hypothesis?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

If you have research questions please include them here.

<table>
<thead>
<tr>
<th>3.2 Is your primary intent to generate knowledge that can be applied broadly to the group/condition under study?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

### Section 4: Project Abstract

4.1 Provide a brief description of your project.

- Include specific study aims or project goals. Describe the major study method and/or design.
- Include a description of the data accessed and/or collected and a description of any activities, interactions, or interventions that involve human subjects: this includes observation and qualitative data collection.
- For student Capstone projects, approved project proposals may be attached to this document in lieu of providing a written summary. (1,000 character limit).

4.2 Study Type

<table>
<thead>
<tr>
<th>Policy Analysis</th>
<th>Systematic Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Evaluation (internal management purposes only)</td>
<td>Research Study</td>
</tr>
<tr>
<td>Program Evaluation (general)</td>
<td>Other</td>
</tr>
</tbody>
</table>

4.3 Are all of the data used in this project publicly available, e.g. blog, aggregate data, etc.?

| [ ] Yes  [ ] No |

Human subject is defined in the Code of Federal Regulations, 45CFR46.102(f)(1or2), as a living individual about whom an
investigator obtains data through intervention or interaction or identifiable private information.
The specimen(s)/data/information must be collected from or be about live subjects. Research on cadavers, autopsy specimens or specimens/information from subjects now deceased is not human subjects research.

4.4 Does this project involve the participation with living individuals? (e.g. conducting surveys, interviews, interventions, observations, medical or educational testing)
  Yes  No

4.5 Does this project involve access to identifiable private or personal data or specimens from living individuals (e.g. names, birth date, addresses, etc.)?
  Yes  No

4.6 If yes to questions 4.4 and/or 4.5: Please indicate if the study or project includes participants any of the populations below (check all that apply)
  - Children or youth under 21 years outside an educational setting
  - Neonates/Fetuses
  - Prisoners
  - Pregnant women
  - Decisionally impaired
  - HIV/AIDS patients
  - Non-English speaking
  - Terminally ill
  - Student or employee under the supervisory or evaluative authority of the researcher
  - Institutionalized individuals
  - Individuals engaged in illegal or quasi-legal activity
  - Crime victims
  - Substance abusers
  - Other vulnerable group (e.g. disabled, mentally ill)

4.7 Does this project consist exclusively of interviewing or surveying subjects about their area of expertise, with a focus on policies, practices, and/or procedures (e.g., the collected data does not focus on personal opinion, reported behavior, or private information)?
  Yes  No

Flowchart Outlining the Questions Addressed in this Screening Form:
Abstracted from the HHS Human Subjects Regulations Decision Flowchart (http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html)