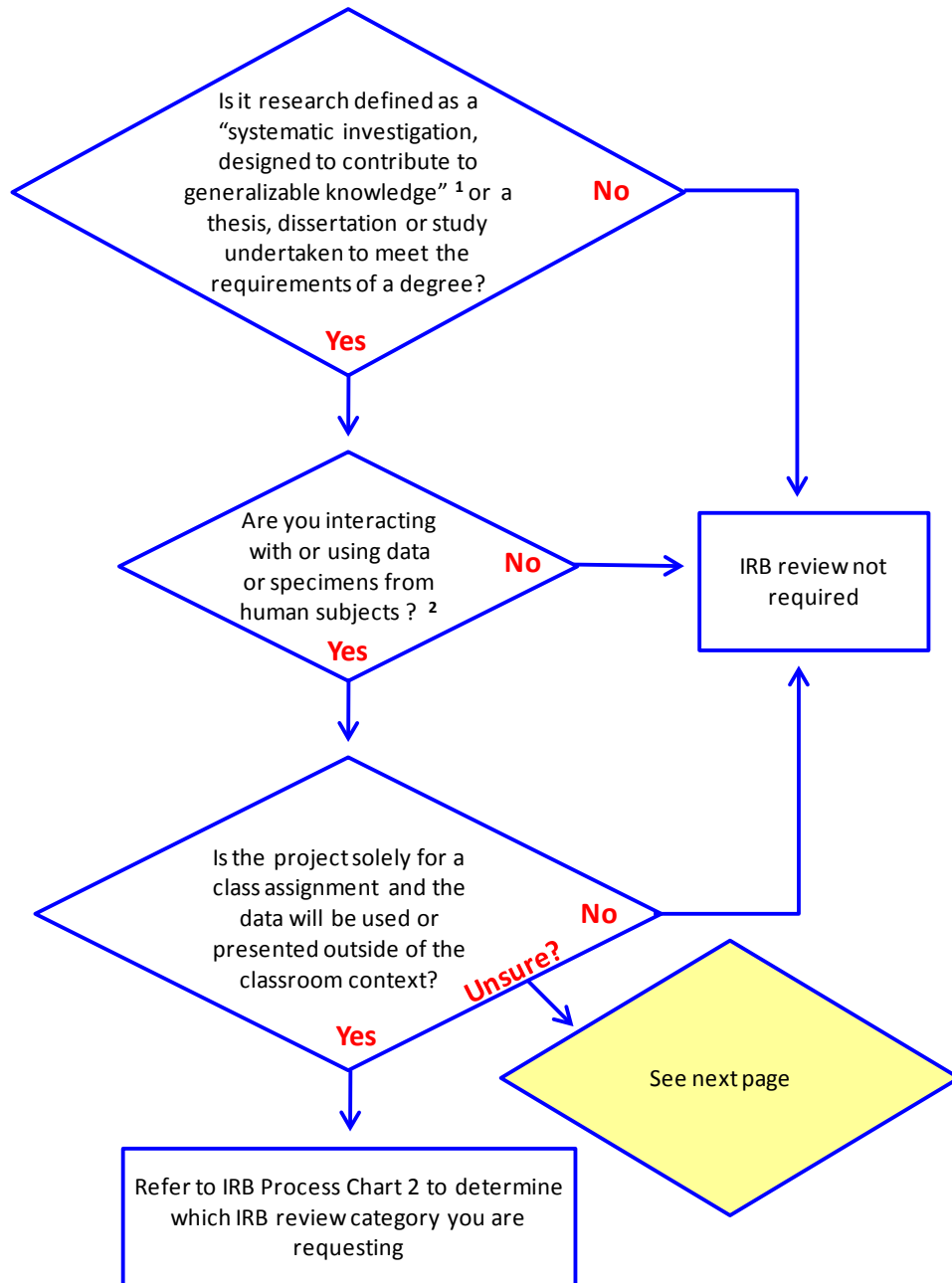


## Determining if IRB Approval is Required



<sup>1</sup> Examples of **systematic investigation** include: surveys and questionnaires, interviews and focus groups, analyses of existing data or biological specimens, epidemiological studies, evaluation of social or educational programs, cognitive and perceptual experiments. Code 45 CFR 46.102 (d)

Contributing to **generalizable knowledge** means that your research activities are intended to lead to published results, such as publication in a journal or presenting your findings at a professional meeting

<sup>2</sup> **Human subject** is defined a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Code 45 CFR 46.102 (f)

## Questionnaire to Determine if Research is Human Subject Research

Federal regulations require IRB review of research involving human subjects. The IRB recognizes it may be difficult at times to distinguish between research projects that require IRB review and those which are designed to provide an experience in research methodology and learning course materials. *Use this form to determine if your research constitutes human subject research.*

	YES	NO		
<p>1. Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?  <i>A "systematic" approach involves a plan to study a specific topic, answer a specific question, test a specific hypothesis, or develop a theory. It incorporates the collection of quantitative or qualitative data, or specimens, and analysis.</i></p> <p><i>Generalized knowledge is knowledge gained from a study may be applied to populations beyond the specific study population, inform policy, or generalize findings.</i></p>	<p><b>STOP</b> Submit IRB application</p>	<p>continue to #2</p>		
<p>2. Do any of the following categories apply to the primary participants in your project?</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> <p>Children Elderly FGCU students/trainees Pregnant women Prisoners (Individuals residing in court mandated treatment facilities are considered prisoners)</p> </td> <td style="width: 50%; border: none;"> <p>Fetuses Persons with acute/severe <b>mental</b> illness Persons with acute/severe <b>physical</b> illness Persons who are cognitively disabled Non-English speaking persons Persons in a specific/formal program</p> </td> </tr> </table>	<p>Children Elderly FGCU students/trainees Pregnant women Prisoners (Individuals residing in court mandated treatment facilities are considered prisoners)</p>	<p>Fetuses Persons with acute/severe <b>mental</b> illness Persons with acute/severe <b>physical</b> illness Persons who are cognitively disabled Non-English speaking persons Persons in a specific/formal program</p>	<p><b>STOP</b> Submit IRB application</p>	<p>continue to #3</p>
<p>Children Elderly FGCU students/trainees Pregnant women Prisoners (Individuals residing in court mandated treatment facilities are considered prisoners)</p>	<p>Fetuses Persons with acute/severe <b>mental</b> illness Persons with acute/severe <b>physical</b> illness Persons who are cognitively disabled Non-English speaking persons Persons in a specific/formal program</p>			
<p>3. Is the project a thesis, dissertation or study undertaken to meet the requirements of a degree?</p>	<p><b>STOP</b> Submit IRB application</p>	<p>continue to #4</p>		
<p>4. Do you anticipate that the results of the research be presented at a meeting or conference, or submitted for publication in a journal or an internet posting?</p>	<p><b>STOP</b> Submit IRB application</p>	<p>continue to #5</p>		
<p>5. Do you anticipate the activity be listed as a scholarly or scientific activity on your professional vita or resume?</p>	<p><b>STOP</b> Submit IRB application</p>	<p>continue to #6</p>		
<p>6. Will the research be conducted in an educational setting and involve quality assessment (QA) or quality improvement (QI) of instructional techniques, curricula, or classroom management methods AND NOT contribute to generalizable knowledge?</p>	<p>Application not needed</p>	<p>continue to #7</p>		
<p>7. Is the research limited to searching existing literature and news articles?</p>	<p>Application not needed</p>	<p>continue to #8</p>		
<p>8. Will the research involve the use of surveys, interviews, or observation of public behavior of senior elected or appointed public officials or candidates for public office?</p>	<p>Application not needed</p>	<p>continue to #9</p>		

	YES	NO
9. Will the research focus on collecting information on things such as policies or business procedures and not people?	Application not needed	continue to #10
10. Does the study involve analyzing/collecting data from a living individual through any of the following? <ul style="list-style-type: none"> <li>procedures such as collection of blood, urine or hair clippings</li> <li>manipulations of the individual or his/her environment</li> <li>communication or interpersonal contact with the individual</li> <li>educational test, survey, or interview</li> <li>observation of public behavior</li> </ul>	Continue to # 10a	continue to summary below
a. Will the data or specimens contain individually identifiable private information? (i.e., the identity of the individual may be determined or associated with the information.)	<b>STOP</b> Submit IRB application	continue to #10b
b. Will the data or specimens be coded with a link that could allow it/them to be re-identified <b>AND</b> , will the Principal Investigator have access to the link?	<b>STOP</b> Submit IRB application	continue to #10c
c. Will the data or specimens be originally collected for this project? <b>If NO</b> , <ul style="list-style-type: none"> <li>i. is/are the existing data or specimens publically available?</li> <li>ii. will the information be recorded in such a manner that it can be associated with the individuals?</li> </ul>	continue to #10d  Application not needed  <b>STOP</b> Submit IRB application	Answer 10c.i.  continue to #10c.ii.  continue to #10d
d. Will the data be collected from oral histories to create a historical record of specific personal events and experiences and <b>NOT</b> to draw conclusions, inform policy or generalize findings?	Application not needed	Submit IRB application

**Summary, the study**

- **IS NOT** a systematic investigation designed to develop or contribute to generalizable knowledge
- **DOES NOT** involve intervention or interaction with human subjects
- **DOES NOT** collect private information
- **DOES NOT** include individually identifiable private information or include identifiable information that can be associated with the human subjects, and
- **DOES NOT** require an IRB application

**Still unsure? Complete the IRB application and submit it to the FGCU IRB for an official determination.**