

# Determination of Human Subjects Research Checklist

This is a guide for researchers to determine whether their activities involve HUMAN SUBJECTS RESEARCH and require IRB approval.

**Instructions:**

If **ALL** questions in Section A are NO, IRB review is NOT required.

If **ANY** question in Section A is YES, and **ALL** questions in Section B are YES, IRB review is required.

If you are unsure how to answer any of the questions in Sections A or B, consider section C.

		YES	NO
<b>Section A:</b> Does your activity involve <b>human subjects</b> ?	Is the data being obtained about living individuals?  <b>If no, stop.</b> This activity does <b>NOT</b> involve human subjects and no IRB review is required.	<input type="checkbox"/>	<input type="checkbox"/>
	Is the data collected through physical procedures or manipulations of individuals or their environments (intervention)?	<input type="checkbox"/>	<input type="checkbox"/>
	Is the data being collected through communication or interpersonal contact with individuals (interaction)?	<input type="checkbox"/>	<input type="checkbox"/>
	Will you gather data about behavior that occurs in a context in which individuals can reasonably assume that no observation or recording is taking place (private information)?	<input type="checkbox"/>	<input type="checkbox"/>
	Will you gather data that is provided for specific purposes in which the individuals can reasonably expect that it will not be made public, such as a medical or educational record (private information)?	<input type="checkbox"/>	<input type="checkbox"/>
If ALL questions in Section A are NO, IRB review is <u>not</u> required. If ANY question in Section A is YES, continue to Section B to determine if your activities are research under the federal regulations.			
<b>Section B:</b> Is it <b>Research</b> ?	Is the activity a <b>systematic</b> investigation, including research development, testing, and evaluation?	<input type="checkbox"/>	<input type="checkbox"/>
	Is the project designed to develop or contribute to generalizable knowledge?	<input type="checkbox"/>	<input type="checkbox"/>
If ANY question in Section A is YES and all questions in Section B are YES, IRB review is <u>required</u> . If any question in Section B is NO, IRB review is <u>not</u> required.  If you are unsure how to answer any of the questions in Sections A or B, consider section C below for some research types.			
<b>Section C:</b> Is IRB review required?	Does the activity involve <b>secondary data sets</b> with identifiable private information?	<input type="checkbox"/>	<input type="checkbox"/>
	Does the activity involve the use of <b>publicly available data</b> that contains sensitive, personal, or identifiable data of living individuals?	<input type="checkbox"/>	<input type="checkbox"/>
	Does the <b>interview or survey</b> focus on experiences, opinions, and sensitive information about people?	<input type="checkbox"/>	<input type="checkbox"/>

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	Is the activity an <b>oral history</b> that may be generalizable?	<input type="checkbox"/>	<input type="checkbox"/>
	Does the activity involve <b>case histories</b> of multiple individuals?	<input type="checkbox"/>	<input type="checkbox"/>
	Is the activity a <b>genetic study</b> providing private information about living relatives?	<input type="checkbox"/>	<input type="checkbox"/>
	Is the activity a <b>class related project</b> that will lead to publication or poster presentations outside of classroom requirements?	<input type="checkbox"/>	<input type="checkbox"/>

If ANY question in Section A is YES and If ANY question in Section C is YES, IRB review is likely required.  
If ANY question in Section B is NO, and ALL questions in Section C are NO, no IRB review is required.