



**IRB Research Determination Tool**

As mandated by [Federal Regulation 45 CFR 46](#), the Alvernia Institutional Review Board (IRB) is required to review and approve all research involving human subjects. This form is intended to assist researchers in determining if a project requires IRB approval. Novice researchers are encouraged to fill out the form with one or more seasoned research investigators and as part of a peer review prior to submitting an application to the IRB. [Revised 2022]

YES NO NOT SURE

<b>Section A:</b> Does your activity/project involve human subjects?	Is the data for the activity/project being collected about living individuals?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Is the data collected via intervention or interaction with individuals?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Does the data contain identifiable private information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If any question in Section A is “YES,” go to Section B.  
 If any question in Section A is “NOT SURE,” go to Section B & C.  
 If all questions in Section A are “NO,” IRB review is not required.

<b>Section B:</b> Is the activity/project research?	Is the activity/project a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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If any question in Section A is “YES” and Section B is “YES,” submit an IRB Application form.  
 If Section B is “NO,” go to Section D If Section B is “NOT SURE,” go to Section C.

<b>Section C:</b> Is IRB review required for approval?	Does the activity/project involve secondary data sets with identifiable private information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Does the activity/project use identifiable specimens or cell lines from other institutions or are they commercially available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Is the data collected for administrative purposes with the intention of publication?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Does the activity/project involve the use of publicly available data that contains sensitive, personal, or identifiable data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Does the interview or survey focus on experiences, opinions, and/or sensitive information about people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Is the activity/project a biography that is generalizable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Is the activity/project an oral history that is generalizable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Does the activity/project involve case histories of multiple individuals?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Is the activity/project a genetic study providing private information about live relatives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the activity/project a class-related assignment that may lead to publication/conference presentation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

If any question in Section C is “YES,” submit an IRB Application form. Review the categories of expedited review to determine if a study requires full or expedited review & submit an IRB Application Form. If all questions in Section C are “NO,” go to Section D. If any question in Section C is “NOT SURE,” please contact the IRB.

<b>Section D:</b> Is the focus of the activity/project on a specific population?	Does the activity/project intentionally focus on one or more specific populations listed below? If you check “YES” to any of the box(es), complete the IRB application form.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/> Children (age < 18 years) <input type="checkbox"/> Neonates/Fetuses/In vitro Fertilization Persons <input type="checkbox"/> Mentally disabled or cognitively impaired persons <input type="checkbox"/> Adults with legal guardians <input type="checkbox"/> Prisoners	<input type="checkbox"/> Pregnant or lactating women group(s)— describe: <input type="checkbox"/> Alvernia Students—name subject pool, if applicable:		

## **Human Subjects Research - Related Links**

*Office of Human Research Protections*

<https://www.hhs.gov/ohrp/>

*IRBs and Assurances*

<https://www.hhs.gov/ohrp/irbs-and-assurances.html>

*Revised Common Rule 45 CFR 46 (2018)*

<https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML>

*Exempt Research Information*

[https://www.ecfr.gov/cgi-](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104)

[bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46\\_1104](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104)

*Expedited Research Information*

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-expedited-review-procedures/index.html>

*Quality Improvement Activities*

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>

*Collaborative Institutional Training Initiative (CITI Program)*

<https://about.citiprogram.org/en/homepage/>