

**Which Application Form Should I Use?
Chaminade University IRB
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What are the differences between the forms?

Form I	Determination
Purpose:	Used to assess whether the proposed work constitutes Human Subject research or not. If not, then your work is not requiring IRB review.
Process:	Sent by email to 2 or more reviewers or the IRB Chair for evaluation.
Requires an IRB Meeting:	NO

Form II	Exemption
Purpose:	Used to assess Human Subjects Research that fall under one of the Federally-designated Exemption Categories (see Exemption Guidance Document).
Process:	Sent by email to 2 or more reviewers or the IRB Chair for evaluation.
Requires an IRB Meeting:	NO

Form III	Exemption
Purpose:	Review of non-exempt research, review of <u>any</u> application that includes a vulnerable population (e.g. minors, prisoners).
Process:	Sent by email to three reviewers, discussed at IRB meeting.
Requires an IRB Meeting:	YES

Frequently Asked Questions

I'm not sure if my research constitutes Human Subjects Research. What should I do?

Check the Guidance Document (Portal) on example of IRB-reviewable and non-reviewable research. Fill out Form I and submit it for Determination. Note that only an IRB can make this determination, Federal regulations and the CUH IRB Charter state that the individual investigator may not.

My research would be exempt but it includes minors. What should I do?

Use Form III. There are no exemptions for work that include vulnerable populations.

What does Exemption mean?

It's a common misperception that exemption refers to the project not requiring IRB approval. This is not the case. It simply refers to the project being 'exempt' from the full review process, which is more time consuming and in depth. Exempt research still cannot proceed without an IRB approval letter.

What does it mean if my research is not determined to be Human Subjects Research?

You may go ahead without IRB approval. If your protocol changes such that new activities are added that constitute research, you must fill in Form II or III and gain approval before starting.