**Full Review Information and Qualifications**

If your study does not fit the description for either an expedited or exempt review, it likely requires a full and formal review by the IRB committee. This would be especially likely if your study involves the use of a vulnerable population\* and/or involves more than minimal risk\*\*. If so, please add the [full review cover page](https://www.clarke.edu/wp-content/uploads/Cover-Sheet-full_form_2019.docx) to your application. If you are unsure as to whether a full review is needed, it is suggested that you use the full review cover page and allow the IRB committee to make the determination.

**\*Vulnerable populations in research**: Vulnerable populations may include (but are not limited to): individuals who are pregnant; prisoners; individuals who have been involuntarily committed to a medical facility; children; subordinates such as students, trainees, and employees; individuals who are economically or educationally disadvantaged; individuals who have a language barrier; individuals with a cognitive disability; and individuals with an illness for which all standard treatment options have been exhausted. (Clarke University IRB Handbook)

**\*\*Minimal risk:** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (Clarke University IRB Handbook)

Source:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/special-protections-for-children/index.html>

Research with Children FAQs:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html>