

Worksheet for consideration of Exempt Research

Does the study meet the following criteria?

YES	NO	Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: research on regular of special educational instructional strategies, or the relative effectiveness of instructional techniques, curricula, or classroom management techniques. <i>45CFR46.101(b)(1)</i>
YES	NO	Research involving the collection or study of <i>existing data</i> , documents, records. <i>Existing Data: means that all the data, documents or records are in existence prior to IRB Review.</i> And, these sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified either directly or through identifiers linked to the subjects. <i>45CFR46.101(b)(4)</i>
YES	NO	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, and information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects, <u>nor</u> place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability or reputation. <i>45CFR46.101(b)(2)</i>

If you answered yes to at least one item above, the protocol **will potentially qualify** for exempt approval. *The IRB makes the final determination of exempt status during review of applications.*

However, does this study involve?

YES	NO	Interactions, surveys or interviews involving minors?
YES	NO	Pregnant women or prisoners?
YES	NO	Any procedures that may cause a subject either physical or psychological discomfort or are perceived as harassment above and beyond what the person would experience in daily life?
YES	NO	Deception?

If you answer yes to any of these four items, the protocol **will not qualify** for exempt approval. *45CFR46.101(h)*

Please answer the following questions to the best of your ability.

YES	NO	Is the <u>probability</u> of the harm or discomfort anticipated in the proposed research greater than that encountered ordinarily in daily life or during the performance of routine physical or psychological examinations or tests?
YES	NO	Is the <u>magnitude</u> of the harm or discomfort anticipated in the proposed research greater than that encountered ordinarily in daily life, or during the performance of routine physical or psychological examinations or tests?

If you answer yes to either question above the study **will not qualify** for exempt approval. *45CFR46.102(i)*