

**EXPLORING 45 CFR 46.111,
CRITERIA FOR IRB APPROVAL OF RESEARCH**

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- ✘ 45 CFR 46, also known as the “Common Rule”, applies to “all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency...”
 - ✘ TJU’s federalwide assurance with OHRP extends application of 45 CFR 46 to all research conducted at the institution, regardless of funding source.

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- ✘ And, in fact, all reputable IRBs across the U.S. follow this model.

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- ✘ (a) In order to approve research covered by this policy [45 CFR 46] the IRB shall determine that all of the following requirements are satisfied:
 - ✘ An IRB's integrity, effectiveness, and institutional reputation depends on how well it makes these determinations.

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- ✦ (1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

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- ✘ (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- ✘ (cont'd)

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- ✘ (2) cont'd...
- ✘ In evaluating the risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research.)

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- ✘ (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems (?) of research involving vulnerable populations...

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- ✘ (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 46.116.

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- ✘ (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by 46.117.

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- ✘ (6) When appropriate, the research plan makes adequate provision for monitoring data collected to ensure the safety of subjects.

- ✘ When is “appropriate” appropriate?!

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- ✘ (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- ✘ What's the difference?

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- ✘ (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence...additional safeguards have been included in the study to protect the rights and welfare of these subjects.

- ✘ Could we get a little help here?!