

CITI – Social & Behavioral Research Questions and Answers Already Passed

What procedures must be described in an agreement called an “assurance of compliance” with OHRP? ✓✓Procedures in place that ensure that subjects will be protected in a manner commensurate with the Common Rule, including review by an independent committee comparable to an IRB.

A researcher proposes to conduct a study at a foreign site that has been determined to be exempt from the federal regulations by institutional policy. According to federal regulations, is review required at the foreign site? ✓✓If a proposed study qualifies for exemption, federal regulations do not require review at the foreign site where it will be conducted.

What are some considerations for a U.S. researcher conducting a study in a non-U.S. setting when obtaining informed consent from subjects? ✓✓In addition to the consent of the research subjects, are there other individuals or groups whose permission must be sought?

Nuremberg Code ✓✓Judged human experimentation conducted by Nazis. Voluntary consent by human subject is absolutely essential

Declaration of Helsinki ✓✓basis of good clinical practices. Addresses research protocols, informed consent, risks/benefits, et plus

Belmont Report ✓✓basic ethical principles for research involving human subjects.

- Respect for person's autonomy
- Beneficence
- Justice

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