OFFICE OF EDUCATION | POLICY BRIEF

Ethics in Research and Evaluation in the Education Sector

INTRODUCTION

USAID staff in the Education sector and our implementers are regularly involved in conducting research and evaluation to better understand what's working and what's not in education programs. In most cases, this work involves work with human subjects, which naturally comes with ethical implications. USAID's Scientific Research Policy and ADS standards were developed to comply with federal regulations around the protection of human subjects. This Policy Brief aims to clarify the roles and responsibilities of USAID education staff, including oversight of implementing partners, in complying with these existing rules.

U.S. GOVERNMENT AND USAID POLICY ON RESEARCH ETHICS

The Common Rule: As the short name for "The Federal Policy for the Protection of Human Subjects," this policy was adopted by a number of federal agencies in 1991. Each agency incorporated the policy into its own code of Federal Regulations (CFR), with USAID adopting it in 22 CFR Part 225. The Common Rule sets three pillars of protection of human subjects:

(1) Review of the research by a properly constituted ethics committee (Institutional Review Board, or "IRB"),

(2) An assessment of risks and benefits of the research by the IRB, and

(3) An informed consent process for research subjects.

The Common Rule recognizes that there is no formula to apply to ethical decisions and vests the responsibility for making such decisions with the IRB. The Common Rule is codified in the USAID's Scientific Research Policy and a Mandatory Reference to ADS Chapter 200.

The Common Rule applies to all USAID-funded evaluation and research projects that involve human subjects. In addition, the research or evaluation must conform to legal and other requirements governing research with human subjects in the country where it is conducted. **To satisfy USAID CFR requirement of ethics review, a study must be reviewed and approved or deemed exempt by a US-based IRB.** USAID accepts legitimate foreign procedural systems in lieu of the U.S.-based IRB review only when they are determined to provide protection "at least equivalent" to the Common Rule.

Reference: USAID's Scientific Research Policy

Reference: ADS Chapter 200

THE ROLE OF AN INSTITUTIONAL REVIEW BOARD (IRB)

The IRB is a committee established to protect the rights and welfare of human subjects involved in research and evaluation activities. IRBs review and approve all US government-funded behavioral and biomedical research involving humans. The purpose of the IRB is to assure that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research or evaluation study. IRBs are formed by organizations engaged in research activities. IRBs are governed by the Common Rule.

There are circumstances in which research or evaluation activities may be exempt from an IRB review. **Human research ethics guidelines require that decisions about exemption are made by an IRB representative, not by the investigators themselves.**

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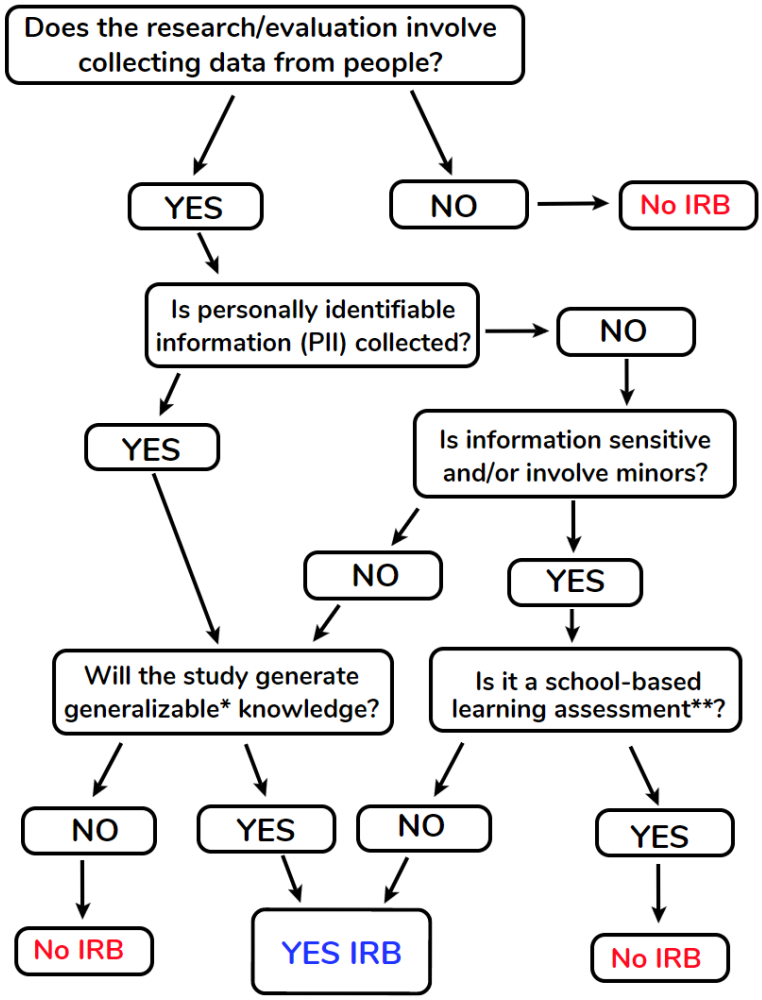
USAID's Office of Education publishes Policy Briefs to provide education-specific operational guidance related to an existing USAID Policy. For more information on this Policy Brief, contact Elena Walls at ewalls@dexisonline.com.

THE ROLE OF USAID STAFF

It is the responsibility of the Contracting Officer's Representative (COR) or Agreement Officer's Representative (AOR) to ensure that all research and evaluation activities funded by USAID comply with USAID's policy on the protection of human subjects as well as all relevant local laws and regulations. It is the responsibility of the award holder to manage the approval process and adhere to study plans approved by IRB and/or local ethics review committee. **Conducting a research or evaluation study without the appropriate ethics review constitutes a violation of USAID's policy on the protection of human subjects**.

The Frequently Asked Questions below provide additional information on definition of research activities, IRB approval process and timelines, types of studies exempt from IRB review, and illustrative award language on protection of human subjects, among other frequently asked questions.

IRB Decision Tree



*Generalizable knowledge = knowledge that can be applied to populations other than those included in the study.
**While learning assessments are usually exempt from the IRB review, if the study uses interviews or surveys in addition to student testing, those data collection activities are subject to the IRB oversight.

FREQUENTLY ASKED QUESTIONS

1. What are the main principles of the ethics review by an IRB?

Principles of the ethics review by any IRB are based on the Belmont Report issued in 1979 which was the foundation for the Common Rule. It identifies the following key principles:

Respect for Persons:

- Individuals as autonomous agents (Informed consent; Privacy and Confidentiality
- Those with diminished autonomy entitled to special protection

Beneficence:

- Do no harm
- Maximize possible benefits and minimize potential harm

Justice:

- equitable distribution of research burdens and benefits.

Based on these principles, USAID identifies the following three pillars of protection of human subjects: (1) Review of the research by a properly constituted ethical committee or Institutional Review Board (IRB); (2) A meaningful assessment of risks and benefits by the IRB; and 2 (3) A meaningful informed consent procedure for research subjects.

2. Does the Common Rule apply to USAID-funded research and evaluation activities?

USAID is one of the federal agencies that signed onto the Common Rule; consequently, all research activities involving human subjects conducted with USAID funding in and outside the United States must comply with the Common Rule as adopted by USAID (22 CFR Part 225). The Common Rule defines *research* as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. It defines a

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human subject as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual. Research involving *identifiable*, *private* information without a direct contact with individuals is also a subject to the Common Rule requirements. USAID's Cognizant Human Subjects Officer (CHSO) assists with guidance and interpretation of the Common Rule as it applies to USAID-funded work.

3. How does USAID define research?

USAID Scientific Research Policy references the definition by the Office of Management and Budget of research as "systematic and creative activities undertaken to increase the knowledge base, including understanding of humankind, culture, environment, and society, and the application of this knowledge base to devise new interventions. Being hypothesis-driven, testable, and independently replicable are typical qualities of the research process".

As a general guideline, USAID Scientific Research Policy indicates that the following types of studies are typically classified as "research": experiments; observational studies; implementation research including pilot studies; qualitative studies; population-based surveys; and product development activities including market research and acceptability studies.

The following studies are generally not characterized as "research": routine product safety and/or quality monitoring and testing and other types of quality assurance and improvement activities; performance evaluations[1]; routine program/project monitoring; descriptive geographic mapping and earth observations; assessments done for the purpose of program/project design or that contribute to strategy development; and training activities for scientific and technical personnel.

4. How is IRB approval obtained?

Ensuring an IRB approval for collecting data from human subjects is obtained is the responsibility of the prime organization leading the research/evaluation activity for which the data are collected, even if the research is conducted by a sub-contracting[2] organization. The recipient of the award is responsible for the study's compliance with USAID policies on protecting human subjects. Many US-based organizations involved in research and evaluation activities that USAID funds have their own IRB. Different IRB committees may have different requirements, but generally IRBs require the following documentation: study plan, final or near-final data collection instruments, consent forms, description of procedures for field work, procedures for protecting confidentiality of respondents, including processing and storing raw data, description of any potential harm to respondents and the plan for mitigating these threats.

5. What research/evaluation activities are exempt from a full IRB review?

Generally, human research ethics guidelines require that decisions about exemption are made by an IRB representative, not by the investigators themselves not by USAID staff[3]. There are several types of research identified for exemption from IRB review:

- Research in conventional educational settings, such as those involving the study of instructional strategies or effectiveness of various techniques, curricula, or classroom management methods. In the case of studies involving the use of educational tests, there are specific provisions in the exemption to ensure that subjects cannot be identified or exposed to risks or liabilities[4].
- Research involving the analysis of existing data and other materials if they are already publicly available, or where the data can be collected such that individual subjects cannot be identified in any way[5].
- Studies intended to assess the performance or effectiveness of public benefit or service programs[6].

6. Does the Common Rule apply to research/evaluation conducted in another country?

First and foremost, research/evaluation must conform to legal and other requirements governing research with human

[1] Performance evaluations that involve human subjects and apply methods identified as "research methods" are characterized as research.

[2] This also applies to sub-agreements.

[3] Ritter, F. et al, Running Behavioral Studies with Human Participants, Sage Publications Inc. 2013., ISBN 9781452217420.

[4] Office for Human Research Protections (January 15, 2009). "Code of Federal Regulations". hhs.gov. p. US 45 CFR 46.101. Retrieved 19 August 2014.

[5] ibid.

[6] Ibid. In the education sector examples might include the following: data collection for performance monitoring purposes, mid-term reviews, fidelity of implementation tracking, some kinds of action research and implementation research.

subjects in the country where it is conducted. USAID accepts legitimate foreign procedural systems in lieu of the Common Rule regulations only when they are determined to provide protection "at least equivalent" to the Common Rule[7]. To find a list of in-country organizations which have accepted the Common Rule and may be able to provide an IRB review, consult the OHRP online database.

In short, *both* the in-country requirements must be satisfied, *and* US-based IRB approval or equivalent in-country approved must be obtained.

7. My Mission is commissioning an education sector assessment. Do we need an IRB approval?

If the design of the education sector assessment relies on secondary data only, such as using previously collected EGRA data, host country education system data/EMIS, budget and policy reviews, then the study is not subject to IRB review since no data are collected directly from human subjects.

However, if the sector assessment involves collecting primary data from human subjects, such as administering an early grade reading assessment (EGRA) to a sample of students, then the assessment is the subject to IRB review. While the Protection of Human Subjects policy specifies that learning assessments conducted in the usual education settings are not subject to the policy, EGRAs commissioned by USAID are not equivalent to standard classroom assessments performed by the teacher for the formative or summative purpose. Since the purpose of the sector assessment is to create generalizable knowledge, it is considered research and thus requires an IRB approval. Additionally, any disclosure of the identity of study participants could potentially cause harm to subjects; therefore, an IRB review is needed to ensure appropriate protections are in place.

8. We are conducting an evaluation of an education project. Do we need an IRB approval?

Since many of USAID-funded evaluations in the education sector are complex and have a multitude of objectives, it is advisable for an implementer of the evaluation to prepare a submission for an IRB review and leave the determination of whether the study requires a full review to the IRB representative. In addition, the organization must always follow local laws and regulations relating to the ethics of research with human subjects.

As a general rule, the Protection of Human Subjects policy (§ 225.101) specifies that research and demonstration projects which are "designed to study, evaluate, or otherwise examine public benefit of programs"[8] are exempt from the policy. Therefore, *performance* evaluations that do not collect personally identifiable information, do not involve data collection from children or vulnerable individuals, and do not intend to generalize knowledge outside of the purview of the project are exempt from the full IRB review. *Impact* evaluations, on the other hand, intend to generate generalizable knowledge and therefore are considered "research" according to the Policy;[9] they are not exempt from the ethics review.

Performance evaluations involving primary data collection from children or other types of vulnerable individuals will require an IRB review. Performance evaluations operating in crisis or conflict environments and collecting potentially sensitive information may also require an IRB review. Please note that human research ethics guidelines require that decisions about exemption be made by an IRB representative, not by the investigators themselves.

9. An organization contracted to implement a study does not have their own IRB; how can they obtain an IRB approval for the study?

OHRP has an online database of iORGs registered as having accepted the Common Rule (also known as holders Federal Wide Assurance)[10]. These organizations might be able to provide an in-country IRB review. An organization may also seek an IRB review with a partner organization in the US that does have an IRB. It is also possible to contract with an organization specifically to conduct an IRB. Ultimately, it is the responsibility of the prime recipient of the award to ensure that the study has the IRB approval or exemption.

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[7] 22 CFR § 225.101 (h) https://www.gpo.gov/fdsys/pkg/CFR-2010-title22-vol1/pdf/CFR-2010-title22-vol1.pdf

[8] Ibid.

[9] ADS 200 Mandatory Reference Protection of Human Subjects Policy specifies that "a key aspect of research is that there be a systematic design in advance, generally utilizing a scientific approach or protocol, for the definite purpose of contributing to generalizable knowledge" (https://www.usaid.gov/sites/default/files/documents/1864/200mbe.pdf).

[10] https://ohrp.cit.nih.gov/search/search.aspx? styp=bsc

10. I am preparing a solicitation for research and evaluation support contract for our Mission. Do I need to include a reference to IRB approvals?

It is advisable to include a note that the contractor will be required to follow both US and local country's laws and regulations relating to ethics of research with human subjects, including, but not limited, to obtaining all necessary IRB approvals prior to beginning of any primary data collection. Below is the language recommended by OAA for inclusion in solicitations:

RAA18. Protection of Human Research Subjects (June 2012)

Applicability: This provision is applicable when human subjects are involved in research financed by this award, as defined in 22 CFR 225 and ADS 200 Mandatory Reference, "Protection of Human Subjects in Research Supported by USAID." The AO/CO should confer with the Activity Manager to determine if any research with human subjects will be included in the award.

Protection of Human Research Subjects (June 2012)

a. The recipient is responsible for safeguarding the rights and welfare of human subjects involved in research under this award, and must comply with the Common Federal Policy for the Protection of Human Subjects as found in Part 225 of Title 22 of the Code of Federal Regulations (22 CFR 225).

b. The recipient must assure USAID of its compliance with the requirements set forth in 22 CFR 225 by doing one of the following:

(1) Obtaining a Federal-Wide Assurance (FWA) from the U.S. Department of Health and Human Services. Instructions on obtaining an FWA can be found on the Office of Human Research Protection Website http://www.hhs.gov/ohrp/assurances/assurances/file/index.html; or

(2) Submitting to the Agreement/Contract Officer's Representative (AOR/COR) for USAID approval, a written assurance which includes a statement of principles governing the recipient's responsibilities, designation of one or more Institutional Review Board (IRB), a list of the IRB members, written procedures which the IRB will follow, and written procedures for ensuring prompt reporting of unanticipated problems to the IRB; or

(3) Submitting to the AOR/COR for USAID approval, a justification memorandum asserting that research conducted outside the United States provides protections at least equivalent to those in 22 CFR 225.

c. Definitions for the purposes of this award:

(1) Research means an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or to contribute to generalizable knowledge.

(2) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(i) Data through intervention or interaction with the individual, or

(ii) Identifiable private information.

(3) Intervention includes both physical procedures by which data are gathered and the changes to the subject or the subject's environment performed for research purposes.

(4) Institutional Review Board means a properly constituted ethical committee which will review the research.

d. USAID staff and consultants may independently review and inspect research and research processes and procedures involving human subjects, and based on such findings, USAID may prohibit research which presents unacceptable hazards or otherwise fails to comply with USAID procedures. Informed consent documents must include the following statement: "Subject's research records may be independently reviewed by USAID staff and consultants to ensure compliance with USAID requirements for protection of human research subjects."

11. Where can I learn more about IRB requirements?

The U.S. Department of Health & Human Services website is a good place to start: https://www.hhs.gov/ohrp/ . While tailored to medical research, not education, the website provides the most comprehensive overview of the requirement. E3/ED Evidence Team can help with specific questions relating to protection of human subjects in education research and evaluation studies.