Exempt Yourself
Educate Yourself

Exemption 45 CFR 46.101(b)(1)

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Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

From Chart 2

Is the research only** conducted in established or commonly accepted educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

If NO, continue to Research is not eligible for 45 CFR 46.101(b)(1) exemption

If YES, continue to Does the research study involve only normal education practices? (Such as research on regular and special education instructional strategies, or research on the comparison among instructional techniques, curricula, or classroom management methods.)

If NO, continue to Return to chart 2 and consider whether 45 CFR 46.101(b)(2) exemption applies.

If YES, Research is eligible for 45 CFR 46.101(b)(1) exemption from 45 CFR part 46 requirements.
Educational Setting

- Where one would go in order to have an educational experience
  - Public/private school, after school programs, Boy Scout meeting, professional educational meeting (SAEM?), teaching hospital residency
Educational Practice

• Test development
• Experimentation with instructional methods
• Evaluation of activities
  • Surveys, pre/post testing/interviews, or observations
    – Not survey about students, must be about instruction
• Affective data toward learning
• Data collection with video, audio, photo, samples
Research in hierarchical organizations as in the armed forces, institutions or hospital groups, here employees or students by nature of adjacency of work or association with investigators, may acquiesce to participate in anticipation of favoritism, consternation, retribution or compelling socioeconomic backgrounds. ERBs need to be extra cautious to make safe the environment with exigencies involved, to ensure participants be neither pressured nor persuaded. Declination to participate should not affect their careers and credits.
Education Study Risks

• Risk assessment:
  • Potential harm that will come to participants
  • Identity linkage
  • Sensitivity
  • Sacrifice
  • Obligations
Exemption Generalities

• No more than minimal risk
• Selection is equitable
• All activities must fall under exemption
• Maintaining confidentiality
• Cannot involve pregnant women, human, fetuses, in vitro fertilization, or prisoners
• No deception research
• Video/Audio recording may be acceptable
  – Consent process for disclosure

• If exempt, Subpart D does not necessarily apply
101(b)(1) vs 101(b)(2)

• 1 deals with research conducted in established or commonly accepted educational settings, involving normal educational practices

• 2 deals with public behavior or anonymous questionnaires
As part of her job at the ACO, she noticed the readmission rate for patients with heart failure is 21%. She and her care team designed a 3 month long teaching program for patients with heart failure with the goal of getting the readmission rate down to 14%. The teaching program started in Sept 2016. She wants to analyze the readmission rate of patients who have been through the training program and see if it is lower than 21%. The teaching program is evidence based, not experimental, and is being implemented to improve care for patients here at [REDACTED]. Decreasing 30 day readmission rate is a central goal for improving care of patients within [REDACTED] ACO.
101(b)(1)

- Central line placement study
- ARS systems
- Diabetes training
• Taser study

• Honesty study

• Stimulant study
• Medical students as human subjects in educational research. Med Educ Online 2013 PMCID: PMC3582695

• Medical education research and IRB review: an analysis and comparison of the IRB review process at six institutions. Acad Med. 2007 PMID: 17595560

• Clinician educators' experiences with institutional review boards: results of a national survey. Acad Med. 2008 PMID: 18520468
What to Include

• Normal class time, or outside of class time?
• Differences between educational methods
• Frequency of testing, duration of testing
• Disclosing if grades or coursework will be individually identifiable
• State whether the educational activity is solely related to research or not
• Alternative to participation
• Delineating who will be involved in processes
• Avoid coercion if at all possible
• List the risks
• Describe privacy and confidentially issues
• Consent process description
Summary

- Education exemption applies in normal educational settings for learners involving normal educational practices.

- Ethical obligations remain
  - Consent
  - Risk
  - Privacy and confidentiality
  - Address problems or complaints
  - Reevaluate exempt status as needed