Ethics Guidelines
Academic Emergency Medicine

Manuscripts reporting data involving human subjects must indicate a positive review by an Institutional Review Board (IRB) or equivalent.

This requirement includes studies that qualify for IRB expedited status.

Most institutions require IRB review of studies that qualify for exempt status and that this determination be made by the IRB, not by the authors.

Research involving human subjects or animals must meet local legal and institutional requirements and

generally accepted ethical principles such as those set out in the Nuremberg Code, the Belmont Report, or the Declaration of Helsinki.

The “Methods” section of the manuscript must explicitly state that IRB approval was obtained,

that the IRB determined the study was exempt,

or that the study did not involve human subjects (e.g. publicly available and previously de-identified information from national data sets, or other studies not meeting the definition of human subjects research as set forth in US Code of Federal Regulations, Title 45, Part 46 – additional information available at www.hhs.gov/ohrp/policy/cdebiol.html).

The “Methods” section should also indicate the type of consent used (written, verbal, or waived), and confirm that consent was obtained from all subjects (unless waived by the IRB).

Manuscripts reporting the results of investigations of live vertebrate animals must indicate approval by an Animal Care and Use Committee or equivalent.

We reserve the right to request submission of IRB or Animal Care and Use Committee documentation at any time.

Authors with any questions or concerns regarding ethics approval, particularly those from countries that have different requirements for approval, should contact Dr. Mark Hauswald, Senior Associate Editor for Global Emergency Medicine, at markhauswald@gmail.com.

Is it Research ?

- HHS regulations define *research* at 45 CFR 46.102(d) as follows:

- *Research* means a systematic investigation… designed to develop or contribute to generalizable knowledge…

Does it involve Human Subjects

- HHS regulations define human subject at 45 CFR 46.102(f) as:
- Human subject means a living individual about whom an investigator…conducting research obtains
- data through intervention or interaction with the individual, or
- identifiable private information.

- Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- Interaction includes communication or interpersonal contact between investigator and subject.

Is it Private?

- Private information includes information … in which an individual can reasonably expect that no observation or recording is taking place,
- and information [that] the individual can reasonably expect will not be made public …
- …the identity of the subject is or may readily be ascertained by the investigator or associated with the information…to constitute research involving human subjects.

This is NOT Intuitive

- 1. Research involves People but not Human Subjects – Art, History, Dead People, Interviews, etc. - no IRB needed - no HHS rules
- 2. Exempt studies are Research that involves Human Subjects but the information is public or recorded by the investigator in such a manner that subjects cannot be identified. - IRB must determine this.

Exempt Criteria

- Educational Research
- Surveys, interviews or observation of public behavior, unless the subjects can be identified and the information is personal.
- Use of existing public or de-identified data

Is QI Research?

- No, if is secret.
- Yes, if it is “designed to develop or contribute to generalizable knowledge”

- QI can generally be done as “exempt” research but this requires prior approval by an IRB…

QI vs Research

- Approval of Exempt studies can be retrospective
  - This is ethical
  - An “Institutional Official” technically makes the decision
- BUT
  - Most (All?)US institutions require prior approval
  - The Institutional Official is usually the IRB

QI is Research

- Potential Benefits and Harms are Identical
- Good QI is generalizable

- The distinction is arbitrary
- But the line must be drawn somewhere

Local and Institutional Requirements

- Local = Applicable Law
- Institutional = your employer

Generally Accepted Ethical Standards

Investigator integrity

Minimization of conflict of interest

Informed consent

Peer review

Practical vs Procedural Ethics

- Rigid procedures may reduce ethical behavior
  - Locus of ethical control is moved to group
    - Groups are often less ethical than individuals
    - Groups are often less knowledgeable than individuals
  - Procedures are expensive
- External review is essential but not sufficient

Examples

- An observational study of dispatch data. No research subject (i.e., bystander) identifiers were recorded, and no new protocols were instituted.
- A cluster randomized study of an approved treatment for bleeding in critically hemorrhaging post partum patients.

References

- Quality Improvement or Research: A Distinction Without a Difference? Doezeman D, Hauswald M, IRB Ethics and Human Research, 2002; 24:4 9-12.

- Procedural versus practical ethics. Biros MH, Hauswald M, Baren J. Acad Emerg Med. 2010 Sep;17(9):989-90.

Clearly Unethical Behavior

- Duplicate publication
- Plagiarism
- Faking data

- We now have ways to tell…

Ethical Implications of Research

- Science is:
  - Replicable
  - Falsifiable

- AEM is interested in both