FLORIDA ATLANTIC UNIVERSITY
DIVISION OF RESEARCH

Standard of Practice vs. Research: Key Elements for Review

FAU HRPP

Overview

- Definitions
- IRB Application and Informed Consent

Definitions: Risk

- Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

- Minimal risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily lives of the general population or during the performance of routine physical or psychological examinations or tests.

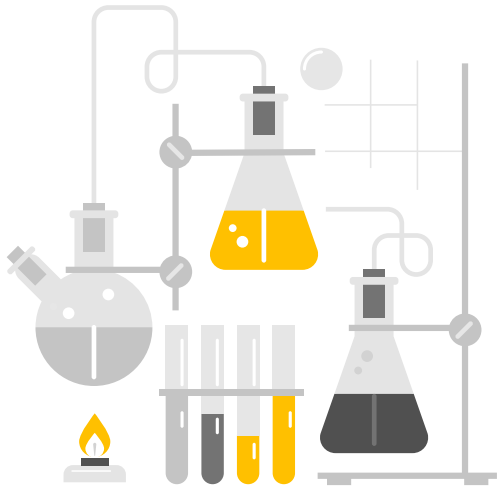
- *Risks can refer to two quite different things*:
  - those chances that specific individuals are willing to undertake for some desired goal; or
  - the conditions that make a situation harmful to a subject.

Definitions: Standard of Practice

- Standards of practice are guidelines used to determine what a professional should or should not do;
- Standards may be defined as “a benchmark of achievement which is based on a desired level of excellence” (American Nurses Association);
- In legal terms, the level at which the average, prudent professional in a given community would practice. It is how similarly qualified professionals would have managed under the same or similar circumstances.

Standard of Practice vs. Research

- Standard of practice is not human subjects research. They differ in:
  - Methodology
  - Objectives
  - Legal support
  - Ethical framework
  - Design



Standard of Practice Risks

- In standard of practice studies, the IRB generally considers the risks of a specific standard being evaluated to be risks of research if:
  - a standard of practice that at least some of the individual subjects will be assigned to receive will be different from the standard of practice that they would have received if they were not participating in the study, and
  - there might be different risks associated with those standards of practice.
- Therefore, in such studies, the possible *differences in risk being evaluated are considered risks of the research*;
- The particular risks that the subjects will be exposed to because of being assigned to a specific standard of practice are risks the subjects will be exposed to for the sake of the research.

IRB Application

Background and Significance:

- Briefly give the background to the present proposal, critically evaluate existing knowledge, and specifically identify the gaps which the project is intended to fill.
- Cite literature and include a list of references.

- Clearly defined the standard for the population from the beginning;
- Would the subject receive this standard absent the research?
- Can they back it up in the literature?
- Does local standard differ from national standards/guidelines?

IRB Application

- Statement how deviation from standard does not increase risk, impact subject voluntariness or rights;
- If randomization to either standard or research, include how this will be done and by whom;
- Justification for sample size and research methodology.

- Research involving randomization to two standards, or comparative effectiveness research, must also include risks to both standards;
- If evaluating a particular risk of research associated with a standard of practice is a purpose of the research, then in general the IRB considers that particular risk to be “reasonably foreseeable”;
- Such reasonably foreseeable risks must be disclosed as risks in the informed consent process in accordance with the regulatory requirements of 45 CFR 46.116(a)(2).

Informed Consent

- Identify risks of research and standard as necessary;
- Provide likelihood and severity of risks;
- Make very clear that participation is not required to receive standard practice.

Case Study

- It is known that treatment using surgery and radiation has a high likelihood of curing a particular form of childhood cancer, but that the radiation produces a significant risk of other cancers developing later in the child's life. Consequently, some doctors treating children with this cancer use a smaller amount of radiation.
- Both amounts of radiation are consistent with clinical care guidelines and considered to be within the standard of practice. There is little evidence available comparing the outcomes of the two treatments in terms of their cure rates or the development of later cancers.
- A randomized clinical trial is proposed with subjects to be assigned to treatment with the higher or lower amount of radiation to compare the effectiveness of the two treatments in curing the current cancer and how often later cancers occur.

Discussion

- What are the risks of the research?
- What are the risks to the standards?
- What does the IRB need to know?
- What do subjects and parents of subjects need to know?

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