Formation of University IRB

Institutional Review Board

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Historical Research Violations

Historical abuses in the name of research and knowledge production:

- Nazi War Crimes (1940s)
- US Human Radiation experiments (1944-1974)
- The Jewish Chronic Disease Hospital Study (1963)
- The Willowbrook Study (1956-71)
- Tuskegee Syphilis Study (1932 to 1972)

What is University IRB

- A university created board consisting of individuals from the fields of science, health, social science, humanity, etc.
- There should be a lay person member representing the public.
- The number is between 5 to 11 members.

IRB Objective

1. The objective is to protect the rights of ‘Human’ research participants.

2. Maintain research ethics and integrity.

3. Ensure research credibility, and quality.

Basic Research Principles

- The three basic Principles from the Belmont Report (1976) to adhere:

1. **Respect for Persons**: consider human research participants with dignity, freedom and equal rights.
2. **Beneficence**: focus on minimizing research risks and maximizing benefits.
1. **Justice**: equal distribution of research risks and benefits among the society; one group should not bear the burden of research risks while another reaps the benefit.

The IRB Board Character

- The Board is totally independent from the University administration;
- The Board is voluntary (unpaid), but
- There may be an allowance per meeting;
- For research applications outside the experience of the Board, they may hire experts from outside the university.
- There is fee per research application;

IRB Review Process

1. Research applications are submitted to the Board before the start of the research;
2. The Board meets at least once a month to review research applications;
3. Sometimes there are emergency cases for review;
4. The board may ask changes to the application or approves the application.

IRB Total Authority

- The Board should be free from any University interference.
- The board may reject to review an application for good reasons;
- Rejection comes if the researcher has already started data collection, etc., before approval;
- Total cancellation comes if the research protocol has been violated after approval;

IRB Training

After the Board committee is selected,

extensive training is provided;

The training is based on **(International ethical codes and declarations relevant to human research), plus FDA regulations relating to Good Clinical Practice and Clinical Trials, including:**

1. The principles of research ethics;
2. Research 'Standard Operating Procedures' (SOP);

IRB Training (cont..)

3. The UN Universal Declaration of Human Rights (1948);
4. The declaration of Helsinki (1964);
5. Geneva Convention medical treatment (1949);

IRB Training (cont..)

- **US FDA research regulations:**

1. Electronic Records; Electronic Signatures (21 CFR Part 11)
2. Protection of Human Subjects (Informed Consent) (21 CFR Part 50)
3. Institutional Review Boards (21 CFR Part 56)
4. Good Laboratory Practice for Nonclinical Laboratory Studies (21 CFR Part 58)

National Research Guidelines

- There are national research guidelines which are required, including but not limited to:
- Somali National Research Guidelines for health;
- Somali National Research Guidelines for Science and Technology, etc.;
- The above NRG’s are not available so we borrowed from the neighboring countries.

International Recognition

- An IRB must be internationally recognized:

- Thus all IRB Board members should complete an online CITI training Program;
- The training is free and consists of:
  1. IRB - Biomedical Research (Group 1) OR;
  2. IRB - Social & Behavioral Research (Group 2)
- Each is about 1-3 hours.
- Modules consist of a series of paragraphs and short quizzes.
- Progress is saved after each module.

www.citiprogram.org

Thank You, and Good Luck