Proposal to Establish a Program for Human Subjects Research: Background and Overview

Natividad Medical Center Bioethics Committee

NMC Research Program-Background

1. **Not New-**Research Projects and studies conducted over the years for publication, presentations and internal quality improvement projects
2. Most of our Trauma Surgeons and many of our Family Medicine Physicians are published researchers
3. Major universities have collaborated with NMC physicians and staff on various research projects over the years
4. NMC has at least two major committees that are involved in research guidance and oversight-Graduate Medical Education Committee and Bioethics Committee as well as the Department of Nursing Education
5. There is now a recognition by these various committees that it may be time to enhance, support and formalize our current Research Program by developing a local NMC Institutional Review Board for Human Subjects Research

Overview

1. What is Human Subjects Research
2. Institutional Review Boards (IRBs)
3. Benefits of Establishing a Local IRB
4. Benefits of Affiliating with a Central IRB Entity
5. Current NMC Review Process
6. Plans for the Future

Human Subjects Research

- Research-
  - Systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
- Human Subject
  - A human subject is a living individual about whom an investigator conducting research obtains
  - 1. Data through intervention or interaction with the individual, or
  - 2. Identifiable private information

Human Subjects Protection

Why Do Human Research Subjects Need Protection?

Trigger Events

The Nazi Experiments

Tuskegee Syphilis Study

Ethical Milestones

Nuremberg Code 1947

National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research 1974

*** Belmont Report 1978**
*** Common Rule 1991**

Nazi Germany (1940s)

- Involuntary human experimentation in concentration camps
- Populations involved:
  - Religious and ethnic minorities: Jewish, Romani, and Polish individuals, included children
  - Disabled and homosexual individuals
  - Soviet POWs
- Resulted in death, trauma, disfigurement, disability
- Nuremburg Trial charged participating doctors with crimes against humanity

Responses

- Nuremberg Code (1949)—guidelines for researchers
  - Voluntary consent
  - Goal of producing good for society
  - Protecting participants from injury

Tuskegee Syphilis Study (1932 to 1972)

- Goal: Study the natural progression of untreated syphilis in rural African-American men
- Study Population: impoverished, African American sharecroppers
- Recruited with promise of free health care
- Study continued after penicillin introduced
  - Infected individuals were not told they had syphilis
  - Individuals were not informed that they were being denied treatment and would never receive treatment
  - Study staff prevented participants from getting treatment elsewhere

Responses

- 1974: Congress established the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research
  - Belmont Report (1979)
    - Principles: Respect for persons, beneficence, justice
- The “Common Rule”
  - 1981, HHS and FDA revised their existing regulations
  - 1991, Published the Common Rule (Federal Policy for the Protection of Human Subjects) with corresponding regulations by 15 federal departments and agencies

Protective Mechanisms Established by The Common Rule

1. Institutional Assurances of Compliance
2. Review of Research by an IRB
3. Informed Consent of Subjects

Additional Considerations for Vulnerable Populations

- Pregnant women, human fetuses and neonates
- Prisoners
- Children
- Mentally disabled persons
- Economically or educationally disadvantaged persons

Institutional Review Board

1. Charged with the responsibility of reviewing, prior to its initiation, all research (whether funded or not) involving human participants
2. Concerned with protecting the welfare, rights, and privacy of human subjects
3. Authority to approve, disapprove, monitor, and require modifications in all research activities that fall within its jurisdiction as specified by both the federal regulations and institutional policy
4. Made up of individuals with varying backgrounds in order to provide complete and adequate review of human research and its institutional, legal, scientific, and social implications
5. Includes at least one member who is not affiliated with the institution and one member who is not a scientist

Institutional Review Board

Guidance and Process for:

1. Determining if an Investigation is categorized as Research
2. Determining the Level of Review Required for a Research Study-Exempt vs Expedited vs Full Review
3. Continuing Review
4. Reviewing Amendments
5. Providing Safety Information
6. Monitoring Unanticipated Problems to Subjects or Others and Noncompliance

Local and Central Institutional Review Board

Local IRB

1. Receives Proposals, Provides Final Approval and Oversight
   - Provides tracking and surveillance of projects
2. Provides sociocultural context
3. Provides assurance that researchers are trained and competent

Central IRB

1. Provides Administrative Support with dedicated staff and board members
2. Provides streamline operational processes
3. Provides consistent, high-quality, and efficient IRB review
4. Significantly enhances human subject protections
5. Improves the overall quality of clinical research

Current Research Review Process at NMC

- Bioethics Committee
  - Provides research oversight of NMC patients' rights, privacy and confidentiality
  - Governed by NMC hospital policy which states that,

"All requests for research, investigation or clinical trials to be performed on NMC patients shall be reviewed and approved by the Bioethics Committee"

  - Does not provide IRB Approval

How does a Bioethics Committee differ from an IRB?

- ***Purpose***:
  - The Bioethics Committee considers and educates hospital staff on ethical issues in patient care.
  - An IRB is tasked with ensuring the protection, safety, and welfare of human subjects in research.
- ***Oversight Authority***:
  - The Bioethics Committee is advisory in its functions.
  - An IRB derives its authority and responsibilities from federal regulations. Hospital/medical staff officials may review IRB determinations, but may not approve research if it has not been approved by an IRB.

Key Benefits of Engaging in Human Subjects Research and Establishing an IRB

- Improve Patient care
- Community Benefit*
- Physician Recruitment and Retention*
- Inform Advocacy and Policy for our patients/community *
- Enhance Institutional prominence
- Publication and professional development
- Community Institutions with IRB's or FWA's-SVMH, CHOMP, Clinica De La Salud, CSUMB and the majority of CA Public Safety Net Hospitals

Human Subjects Research-Areas of Risk

- Violation of Common Rule
  - Halt current research
  - Jeopardizes future research
  - Debarment
- Reimbursement (billing for research vs care)
- False claims risks (adverse events)
- Privacy risks
  - Enforcement by the Office of Civil Rights
  - Exposure under California law (including private suit)

Human Subjects Research-Areas of Risk

- California civil monetary awards for informed consent violations
- Reputational Risk
  - Actual or perceived violations of research ethics
  - Particularly involving a vulnerable population
- Kickback Risks
- Management of clinical trial agreements
- Accreditation

**IRB is designed to MITIGATE risk

Questions

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