



Research Within the Migrant Population and the IRB

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Ethics in Research: Protecting Human Subjects

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Ethics in Research: Protecting Human Subjects

- History
- Ethical Principles
- Vulnerable Populations
- Institutional Review Board



History

- Nuremberg Code
- Declaration of Helsinki
- Tuskegee Study
- Federal Regulations

Nuremberg Code

- Strict informed consent by researcher
- Voluntary participation throughout experiment
- Experiment must be more than a mere contribution to general knowledge - fruitful results for the good of society



Nuremberg Code

- Researcher must stop experiment if injury, disability, or death may occur
- Animals studies before human studies



Tuskegee Study

- 1932 to 1972
- Syphilis untreated
- Macon County, Alabama

Declaration of Helsinki

- Surrogate consent
- Therapeutic research distinguished from non-therapeutic
- “two hats” problem recognized
- Independent committee review
- Best-proven therapeutic methods must be used

Belmont Report

- Report of the National Commission for Protection of Human Subjects of Biomedical and Behavior Research
- Commissioned in 1974

Belmont Report Principles

- Respect for Persons
- Beneficence
- Justice

Belmont Report

- Separated therapy from research
- Opened up the possibility of human subject research with vulnerable populations
- IRB's established the same year

Federal Code

- U.S.C.F.R. 45 Section 46
- DHHS code - latest revision 1981
- The Common Rule - adopted by all agencies



The Common Rule

- Voluntary, informed consent
- Risks must be reasonable in relation to anticipated benefits
- Risks must be reasonable in relation to the importance of the knowledge that may be reasonably expected to result

Respect for Persons

- Autonomy
- Capacity
- Privacy and confidentiality
 - person
 - information

Benefits

- Contribution to generalizable knowledge
- Material benefit as compensation
- Psychological benefit
- Therapeutic benefit

Respect for Persons

- Informed consent
- Benefits and risks analysis
- Alternatives to minimize risks
- Full disclosure on what to expect
- Withdrawal at any time
- Therapeutic Misconception



And Risks

- Loss of time and/or boredom
- Psychological harm
- Physical harm or pain
- Economic loss if results made public
- Social loss if results made public
- Legal risk if results made public

Beneficence

- Maximize well-being
- Benefits and burdens
- Component analysis of therapeutic and not therapeutic
- Two hats problem



Good Science

- Fairness
- Scientifically valid and ethically valid strategies go hand in hand
- Meaningful



Use of Placebos

- Controversial
- Covered in the 1975 Declaration of Helsinki
- Equipoise



Placebo Trials

- Unethical when therapy shown to improve survival or decrease serious morbidity is available
- Patients must be informed of the existence of effective therapy
- Patients must be able to explore consequences of deferring such therapy



Therapeutic Misconception

- Concept of Rebecca Dresser
- Differences between research and clinical care
- Sources of Therapeutic Misconception
- Research Ethics and Therapeutic Misconception
- Reducing Therapeutic Misconception



Differences of Care

- Research goal is not the best care of patients
- Research goal is to generate data that could lead to improved care for future patients
- Research methods are not individualized
- Risks not present in clinical setting



Sources of TM

- Researchers gloss over how scientific needs will override therapeutic goals
- Research participants' expectation fueled by multiple messages



TM Messages

- Consent forms
- Phase 1 agents as treatment
- Researchers wear white coats
- Research access promotes TM
- Industry advertising
- Popular Media
- Physicians with financial incentives



TM and Ethics

- Persons are not a means but an end
(respect for persons)
- Distorted understanding
- Risks, harms, without informed consent
- Physical and privacy invasions without consent
- Giving up “The rights of personal care”

Reducing Misconception

- Neutral discloser
- Better consent forms
- More sensitive physicians
- Researchers clarify their loyalties

Reducing Misconception

- Change in financial incentives
- Change in financial disclosure
- Change in promotion
- More radical changes



Conflicts of Interest

- Different goals
- Undisclosed goals
- Undermines trust
- Distorted judgement
- Distorts funding priorities



Conflict of Interest

- Financial
- Prestige
- Promotion
- Job security
- Full disclosure - enough?



Justice

- Equitable
- Important
- Vulnerable populations

Equitable

- Not acceptable in most cases to use human research subjects when no prospect that those individuals will benefit from their participation as research subjects
- Study population
 - ▶ AIDS study

Migrant Population as Vulnerable Population

- The ideal of autonomy
- Language
- Uncertain status
- Culture
- Women
- Therapeutic misconception

Ideal of Autonomy

- Not alone in our decisions
- Group history (oppression)
 - 1. Can prevent them from exercising autonomy
 - 2. When those who lack access to care services consider their best chance for obtaining services to be through research, the ideal of voluntary participation cannot be realized
 - 3. Need to individualize

Language

- Block to communication
- block to understanding
- need for interpreter-privacy concerns
- who interprets



Culture

- Authority figures
- Machismo
- Decision makers
- Unsure of human rights in USA



Women

- Separate vulnerable population
- gender specific differences are important
- women as capable thinkers and decisionmakers



Women

- One study from *Free and Female*
- *Mexican-American* women believed they were receiving effective birth control, but some were given placebos. When questioned about this, the chief investigator responded, "If you think you can explain a placebo test to women like this, you never met Ms. Gomez from the West Side."



Women

- Informed consent issues
- Process must incorporate attention to gender norms that encourage women's subordination
- Politeness is not a sign of incapacity



Pregnant Women

- Another separate vulnerable population
- often irrational pressures
 - ▶ political groups
 - ▶ liability claims
- Risk-benefit analysis may be different
- minimize risks to fetus
- Informed consent by father may be an issue



Vulnerable Population

- Minimize Harm through
 - Level of Risk
 - Quality of Science
 - Confidentiality



Vulnerable Population

- Research on migrant population to help serve the migrant population is just and fair but to counter their vulnerability, the risks must be minimal
- For example, it would be impossible to learn about successful methods for counseling or doing outreach in this population without performing research on this population



IRB

- Institutional Review Board
- MCN has one
- Declaration of Helsinki



IRB

- Checks the science
- Checks the methods
- Checks the consents
- Checks the ethics
- Checks the use of the data
- Standards are not set, however



Informed Consent

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General Informed Consents

“Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by 45 CFR 45.116” (CFR46.111).

Developing Consent Forms

■ **Tell about Your Research**

- Make a clear statement that you plan to do research.

■ **Tell about the right not to be in the study**

- Make a clear statement that people have the right not to participate in the study.
- Let the participants know that withdrawal from the study will not effect any benefits that would normally come to expect from you or the agency.



Developing Consent Forms

- **Tell about what it means to take part in the study.**
 - It is important to tell the participant about the:
 - Estimated time involved to participate
 - Number of participants in the study
 - Procedures to be done.
 - Tell about what it means to take part in the study.
 - In simple non-technical language, tell which parts of the study are experimental, and if there are alternatives to these procedures.

Developing Consent Forms

■ **What are the risks of being in the study?**

- Every study has some form of risk to it even though the risks may be unforeseen and remote.
 - They may be discomfort or in some cases physical or psychological pain.
- Define the cost of participation in a realistic manner.
- List how you intend to provide for, or minimize the potential risks.
- Inform who is responsible for paying for treatment should adverse effects occur.

(http://www.mnstate.edu/irb/info_instructions.htm)

Developing Consent Forms

■ List the benefits of the study

- List any of the benefits or compensation that can reasonably be expected by participants.
- If there are none, include a statement that no immediate or direct benefits may be expected.
 - Can include benefits to society.
- Tell who will receive benefits from the study.

Developing Consent Forms

■ **How a participant can leave the study.**

- ▶ All participants need to know that they can leave the study at any time, for any reason.
- ▶ The researcher should state conditions that would lead him/her to terminate the participation of a participant.
- ▶ Tell the participant that there are no negative consequences for leaving the study.

Developing Consent Forms

- **Arrange to answer questions.**
 - The researcher may not be able to answer all the questions about the study when he/she first meets with a participant.
 - To help with questions that may occur later, he/she should list his/her name and how to contact him/her.
 - For questions about subjects rights list Dr. Loretta Heuer, IRB administrator, as the appropriate person (701-237-3843 or loretta.heuer@att.net).

Developing Consent Forms

■ Debriefing

- A statement should be made that participants will be debriefed orally or in writing.
- If the debriefing is to be oral, a "script" of what subjects will be told should be attached.
- If all or part of the debriefing is to be in written format, a copy of the actual debriefing statement to be given participants should be attached.

Developing Consent Forms

■ Oral and written debriefings need to contain the following information:

- A statement thanking the subject for participating.
- A statement:
 - Purpose of the study
 - Hypothesis/research questions being investigated
 - Results expected.
- Information about when and where results will be available.
- Information about whom to contact should there be further questions or should the person experience undesirable consequences from participating.

Developing Consent Forms

- **Children or minors as research subjects**
 - Permission is required from parent or guardian.
 - In addition, assent should also be obtained from the participants.
 - This will require explaining what their participation means and their rights in age appropriate language.

Developing Consent Forms

■ Other vulnerable populations as research subjects

- Vulnerable/special populations include those subjects who, as outlined in state and federal regulations, must be provided extra protection.
- This includes, but is not limited to minors, prisoners, fetuses/pregnant women, elderly and cognitively impaired.
- Others who would be considered vulnerable?

Developing Consent Forms

■ **Surveys and questionnaires**

- Questions or items on the following topics will require additional protection of subjects' privacy.
- Parents or guardians and subjects must be informed of the sensitive questions before they give permission or consent to participate.
- Generally information on these topics will be gathered anonymously.

Developing Consent Forms

■ Sensitive questions

- Information pertaining to illegal, anti-social, self-incriminating, and demeaning behavior;
- Information relating to the use of alcohol, drugs, or other addictive products;
- Information relating to sexual attitudes, preferences, or practices;
- Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;

Developing Consent Forms

■ Sensitive questions

- Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- Information pertaining to an individual's psychological well-being or mental health;
- Information relating to a subjects political affiliations;

Developing Consent Forms

■ **Audiotaping, videotaping and photographing subjects**

- ▶ Participants must be advised that their participation includes the use of audio/video taping or photographing.;
- ▶ Before consenting to being taped (audio or video) or photographed, subjects should be informed of the current and planned use of the materials including storage and access by persons other than the researcher.
- ▶ Participants must be advised when tapes or photographs will be erased or destroyed;

Developing Consent Forms

■ **Audiotaping, videotaping and photographing subjects**

- This permission will normally be included in the consent form.
 - If consent forms are not used, the elements of informed consent must be explained to the subjects and an appropriate release must be obtained. This release statement may be included as a preamble to the taped procedure.
- The researcher must make proper arrangements for secure storage of all audio and video tapes and assure that their use complies with the guidelines outlined in the informed consent/release form.
 - Plans may include storage, erasing, or destroying after a given time period.

Developing Consent Forms

■ **Other participating institutions or sites**

- In cases where subjects are recruited from other institutions (hospitals, community agencies, physicians, schools etc.):
 - The first contact with potential subjects should be made by institutional staff who, after outlining the researcher's interest and obtaining the potential subject's permission, will refer the person to the researcher or vice versa.
- A letter may also do this from the researcher that is distributed by the institution.

Developing Consent Forms

- **Other participating institutions or sites**
 - If other institutions are cooperating with the researcher a letter from the institution indicating the nature of that cooperation should be included with the IRB proposal.

Developing Consent Forms

■ Access to subjects' medical and educational records

- ▶ A researcher may have access to institutional records, i.e., hospital, health service agency, etc., if the institution agrees in writing to the accessing and conforms to state guidelines for such access.
- ▶ A copy of the permission letter to access records must be provided to the IRB.
- ▶ The researcher may not obtain names or other identifiers from the records.
- ▶ Access to medical or educational records may require additional permission from the subjects.

Elements of Informed Consent

■ **Alternative Procedures**

- Letting them know of appropriate alternative procedures or courses of treatment

■ **Confidentiality**

- The extent that confidentiality of records identifying the subject will be maintained

Elements of Informed Consent

- **Compensation or Medical Treatment**
 - More than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs

Storage of Informed Consent Forms

- Signed copies of informed consent forms must be retained by the Principal Investigator.
- Kept for three years beyond termination of the study.
- Stored in a separate locked containers from the research data.



Oral Consent

- Statement read to the subject in lieu of written consent
- The subjects agreement to participate is considered a form of consent (e.g. telephone interviews).
- Person obtaining the consent and an observer of the consent process must sign the consent form.

Documentation of Informed Consent for Non-English Speakers

- The informed consent must have language that is understandable to the subject.
- Use a certified translator
- The witness should be fluent in English and the language of the subject.

Documentation of Informed Consent for Illiterate Persons

- The elements of informed consent are presented orally to the subjects or the subject's legally authorized representative
- When using a short form, there needs to be witness to the oral presentation
- Must be a language understandable to the subject

Documentation of Informed Consent for Illiterate Persons

■ Signatures

- Only the short form is to be signed by the subject or representative.
- The witness signs both the short form and copy of the summary.
- The person obtaining the consent, signs a copy of the summary.



HIPAA Compliance



Three Rules -- Privacy Rule, Common Rule, FDA Regulations

- Privacy Rule does not replace or modify the Common Rule or FDA regulations.
- Privacy Rule is in addition to privacy protections of these regulations.
 - ▶ Applies to covered entities regardless of funding.
 - ▶ Contains standards for de-identifying health information.
 - ▶ Requires Authorization for certain uses and disclosures of certain health information.
 - ▶ Applies to decedents' information.



The Common Rule

- Voluntary, informed consent
- Risks must be reasonable in relation to anticipated benefits
- Risks must be reasonable in relation to the importance of the knowledge that may be reasonably expected to result

How Might the Privacy Rule Affect Research?

■ Depends on:

- ▶ What you do/where you work
- ▶ Type of information you use, collect, receive or release



The Privacy Rule...

- Beginning on April 14, 2003, the Privacy Rule protects the privacy of certain individually identifiable health information by establishing conditions for its use and disclosure by health plans*, health care clearinghouses, and certain health care providers.

(nih.gov/nih_ppt_priv_rule_and_research_03.asp)



The Privacy Rule...

- The Privacy Rule regulates the way certain health care groups, organizations, or businesses, called covered entities under the Rule, handle the individually identifiable health information known as protected health information (PHI).

Authorizations for Research

- Must be for a specific research study –
 - Authorization for future, unspecified research is NOT permitted but Authorization may be obtained to permit the use or disclosure of PHI to create or maintain a repository or database.
- Different from, but may be combined with, informed consent.
 - Review/approval by IRB/Privacy Board NOT needed under Privacy Rule. (But other regulations would require IRB review when combined with informed consent documents.)

Authorizations for Research

- Must contain “core elements” & “required statements,” and a signed copy must be given to the individual.
- Research Authorizations need not expire, but this must be stated.

Key Point about Research

- For research, the Privacy Rule permits covered entities to use and disclose PHI for research conducted:
 - ▶ with individual authorization, or
 - ▶ without individual authorization under limited circumstances.

*Removal of These Identifiers**

Makes Information De-identified

- Names
 - Geographic info (including city and ZIP)
 - Elements of dates (except year), ages over 89 years
 - Telephone #s
 - Fax #s
 - E-mail address
 - Social Security #
 - Medical record, prescription #s
 - Health plan beneficiary #s
- - Account #s
- Certificate/license #s
- VIN and Serial #s, license plate #s
- Device identifiers, serial #s
- Web URLs
- IP address #s
- Biometric identifiers (finger prints)
- Full face, comparable photo images
- Unique identifying #s



*Research with migrant and
seasonal farmworker
populations*

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Steps for doing a research project (medical or social science):

- Identify the problem
- Use background information to refine the question
- Determine appropriate study design
- Develop measurement devices (surveys, other)
- Obtain IRB approval

Steps in doing a research project:

- Select samples/gather data
- Code and analyze data
- Write report
- Present results
- Devise new questions for further research



What is good science?

- Not acceptable in most cases to use human research subjects when there is no prospect that those individuals will benefit from their participation as research subjects

Farmworker perspective of most research:

- Constantly asked to be a subject but get nothing out of it
- Feel researchers do not understand their perspective and may not really be interested
- Think researchers do not really listen; they do not want information that might change their pre-conceived ideas

Farmworker perspective of most research:

- Easier to tell researchers what they want to hear than what is really going on
- Do not understand how research can benefit them or their community

Migrant health center staff:

- Asked to be “community partners”
-- but not really
- Research methodology designed
without their input
- Demand too much staff and client
time
- Often never learn of research
results



Migrant health center staff:

- Feel the Center and its patients get little from the research
- Find interesting patient patterns but do not know how to research them
- Unfamiliar with academic settings, resources and personnel



Academics often:

- Unfamiliar with farmworker communities
- Feel uncomfortable with different culture, have language barriers
- Easier to use existing databases or ask others about farmworkers
- Do not know how to approach farmworker communities -- have trouble finding research subjects

** Need to involve the community
in every aspect:*

- Topic/issues identification
- Planning
- Methodological design
- Study execution/data collection
- Analysis
- Interpretation of results
- Determination of next steps



Good research can offer:

- Good science plus
- A commitment to build capacity within the community



Good research with MSFWs:

- Takes more time
 - Needs to maintain flexibility
- or
- For a tight study, commitment to extensive planning, pilot testing
 - Easy to put on paper but how does it work in the field

Special areas of consideration:

- Research question/hypotheses
 - ▶ * Relevance to target population
 - ▶ * Generalize-ability



Special areas of consideration:

- Background literature review to refine the research question
 - ▶ Little information available specific to MSFWs
 - ▶ Watch generalizations/implying similarities
 - ▶ Lack of data may dictate the research design

Special areas of consideration:

- Data gathering method (exploratory, qualitative, quantitative)
 - ▶ Existing information
 - ▶ Interview guide
 - ▶ Structured questionnaire
 - ▶ Focus group
 - ▶ Individual interview
 - ▶ Combinations

Special areas of consideration:

- Respondent type
 - ▶ Knowledgeable/informed individuals (community leaders, service providers, other)
 - ▶ Farmworkers
 - ▶ Family members

Special areas of consideration:

■ Survey method

- ▶ Less effective or ineffective: mail, telephone
- ▶ Most effective: personal interview

Special areas of consideration:

- Instrument design
 - ▶ Responses relevant to the population
 - ▶ Leading the respondent to an expected answer
 - ▶ * Translation: what languages, dialects, test/revise/retest
 - ▶ * Handling illiteracy

Special areas of consideration:

- Sampling -- good research goes beyond a convenience sample
 - ▶ Developing a sample frame
 - ▶ Narrowing the universe
 - ▶ Choosing respondents

Special areas of consideration:

- * Survey protocols
 - ▶ Interview location
 - ▶ Approach/introduction

Special areas of consideration:

- Pilot test
 - ▶ Survey instrument
 - ▶ Sampling and survey protocols

Special areas of consideration:

- * Interviewers
 - ▶ Community-based interviewers best

Special areas of consideration:

- Field monitoring/quality control: where it can all fall apart
 - ▶ Are systems instituted as designed
 - ▶ Are systems working
 - ▶ Instant feedback and correction
 - ▶ Questionnaire review pinpoints misunderstood questions
 - ▶ Remember flexibility

Special areas of consideration:

- * Analysis and interpretation of results
 - ▶ Be open to the unexpected
 - ▶ Community agents can help explain data
 - ▶ Community agents can help pinpoint associations

Special areas of consideration:

- * Present results; determine next steps
 - Obligation to report findings back to community members
 - Obligation to report findings back to community partners
 - Fulfills research prospect that involved individuals will benefit from their participation as research subjects