Responsible Conduct of Research Lecture Series

The Division of Graduate Studies

and

The College of Education and Human Development

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What is Research Compliance?

* Why do we do it?
* Consequences of Non-Compliance

Presenter:

Dr. Marlene Setze
Past Chair of the Institutional Review Board (IRB)

Tuesday, January 22, 2008

Joseph H. Jackson College of Education Building Room 100

6:00 p.m.

LIST OF HANDOUTS

1. Power Point Presentation
2. Historical Development of Legal Standards
3. Consent/Assent Documents Requirements
4. Sample Consent/Assent Documents
5. Proposal Worksheet
6. Web Sites for Additional Information

RESEARCH COMPLIANCE

Purpose and Consequences

A presentation of the Division of Graduate Studies

Jackson State University

January 22, 2008

By

Dr. Marlene A. Setze

IRB Member, Former Chair of the IRB and Consultant to the Division of Graduate Studies

TOPICS

- Definition
- Moral and Legal Standards
- Non compliance Consequences

RESEARCH COMPLIANCE DEFINED

Adherence to a set of legal and ethical guidelines and restrictions on the use of human subjects in research.

Ethical:

Code of ethics/moral restrictions of professional organizations. Not legally binding.

LEGAL:

Title 45, Part 46 of the Code of Federal Regulations (45.CFR 46) commonly referred to as the Common Rule. Violations of this code may result in the cessation of all University human subject research and the rescinding of all federal grants and research monies.

PROFESSIONAL ETHICAL STANDARDS

1. No harm to subjects
2. Voluntary participation
3. Researcher identification
4. Anonymity / confidentiality
5. Honesty in reporting
6. LEGAL ETHICAL STA NDARDS

LEGAL ETHICAL STANDARDS

1. Respect for Persons
2. Beneficence
3. Justice

VULNERABLE POPULATIONS

45CFR46

- Women
- Human fetuses
- Neonates
- Children
- Prisoners
- Persons with physical handicaps
- Persons with mental disabilities
- Persons who are disadvantaged economically
- Persons who are disadvantaged educationally

VULNERABLE POPULATIONS (Cont.)

Belmont Report

- Racial minorities
- The very sick
- The institutionalized

OHRP

- The elderly
- Pregnant women

PROPOSAL/PROTOCOL REQUIREMENTS

1. Introduction, Specific Aims, and Background
2. Scientific Design
3. Inclusion/Exclusion Criteria for Subjects
4. Recruitment of Subjects
5. Research Procedures
6. Drugs, Biologics, and Devices (Biomedical Research)

PROPOSAL/PROTOCOL REQUIREMENTS (Cont.)

7. Data Analysis and Statistical Analysis
8. Potential Risks, Discomforts, and Benefits to Subjects
9. Compensation and Costs for Subjects
10. Privacy and Confidentiality
11. Informed Consent/Assent
12. Health Insurance Portability and Accountability (HIPPA)

CONSEQUENCES

1. Student
2. Faculty
3. University

REFERENCES

Amdur, R. J. and Bankert, E. A. (2007) *Institutional Review Board Members Handbook (2nd ed.)* Sudbury, MA: Jones and Bartlett

Bankert. E. A. and Amdur, R. J. (2006) *Institutional Review Board: Management and Function* (2nd ed.). Sudbury, MA: Jones and Bartlett

Kornetsky, S. and Kahn, S. (2006). In Bankert and Amdur (eds). *Institutional Review Board: Management and Function* (2nd ed.) Sudbury, MA: Jones and Bartlett

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HISTORICAL DEVELOPMENT OF LEGAL STANDARDS
(Source: Amdur & Bankert, 2007)

1948 **Nuremberg Trials:** Conducted at the end of WWII to bring to justice the Nazi leaders who had committed crimes against humanity in their treatment of civilian prisoners. Resulted in the Nuremberg Code – a document articulating the basic requirements for conducting research in a way that respects the fundamental rights of research subjects. These ethical standards have been incorporated into most subsequent ethical codes and, to a large degree, in Federal research regulations. The basic elements are voluntary and informed consent, a favorable risk/benefit analysis, and the right to withdraw without penalty.

1955 **Wichita Jury Study:** Social science researchers at the University of Chicago directed a study to better understand the decision-making process of jurors in criminal trials. They were motivated by the concern that showmanship on the part of trial attorneys might have a major influence on the jury verdict.

They audiotaped jury deliberations in criminal trials in Wichita. To avoid influencing the jurors' behavior, the jurors were not informed they were the subjects of a research study or that their discussions were being recorded. Congressional hearings were held resulting in the passage of a Federal law prohibiting the recording of jury deliberations in any settings. There are 2 main reasons why this was a milestone in the history of research regulation in the United States:

1. This legislation marks the first time that the actions of well-meaning researchers resulted in the establishment of Federal guidelines to protect the public from exploitation.
2. This study was the first event that focused national attention on the concept that there are settings where important research questions cannot be answered without compromising the integrity of important social institutions.

1962 **Thalidomide Experience:** Thalidomide was a drug used in the 1950s to treat a variety of unpleasant symptoms associated with pregnancy. Standard practice in the United States at that time did not inform patients of the investigational nature of medicines still in the testing phase of the regulatory process. The drug caused severe birth deformities in the infants. The result was an amendment to the Food, Drug and Cosmetic Act which required investigators to obtain informed consent from potential subjects before administering investigational medications. This act was a milestone in that it was the first major step in the process of using a Federal agency to establish and enforce specific ethical standards for the conduct of research.

1964 **NIH Ethics Committee:** In the mid 1950s, the Clinical Research Committee at the National Institutes of Health (NIH) was created to oversee the conduct of clinical research. Committee policy required that all research conducted at NIH be approved by a committee focusing on ethical issues. Milestone came in 1964 with a policy that required ethics committees to review all research funded by the Public Health Service. The policy articulated the need for a formal process to ensure that all research involving human subjects be conducted according to a uniform set of ethical standards. This led to the establishment of Institutional Review Boards (IRBs).

1964 **World Medical Association Declaration of Helsinki:** This document was built on the Nuremberg Code of 1948 to describe the standards of ethical research involving human subjects. The Declaration basically consists of the standards described in the Nuremberg Code plus 2 key points:

1. The interests of the subject should always be given a higher priority than those of society.
2. Every subject in clinical research should get the best known treatment.

1973 **Congressional Hearings on the Quality of Health Care and Human Experimentation:** Senator Edward Kennedy directed a series of hearings in response to public concern about ethical problems in the way medical research was being conducted. The main catalyst for the hearings was the Tuskegee Syphilis Experiment although a long string of high-profile events involving both biomedical and social science research also provided impetus.

1. **Willowbrook Hepatitis Studies:** A series of studies in the 1950s were done to understand the transmission of the hepatitis virus in institutionalized retarded children. At issue was the research design that involved intentionally infecting healthy children with hepatitis by feeding them a solution made from the feces of children with active hepatitis. Parents were told their child may not enroll in the school unless they agreed to let their child participate in the research process.

2. **Jewish Chronic Disease Hospital Studies:** A series of experiments were performed on chronically ill, mentally demented Jewish patients in a New York hospital. These patients all had compromised immune systems. Live cancer cells were injected into the blood stream of patients to determine how a weakened immune system influenced the spread of cancer. Informed consent was not provided to patients.

3. **Milgrim Studies of Obedience to Authority:** Done in the early 1960s, these studies were designed in the aftermath of WWII when society was trying to understand the genocide occurring during the Holocaust. The purpose was to understand why people follow the directions of authority when they are told to do cruel and/or unethical things.

   The subjects were deceived into thinking that the study was designed to evaluate the role of negative reinforcement on learning. The research subject was instructed to deliver an electric shock when the "learner" (who was actually a member of the research team who experienced no serious pain from the "shock") gave an incorrect answer to a question. The research subject was ordered to give progressively stronger punishment shocks. Over half the subjects eventually gave what they thought were high-intensity, potentially lethal shocks despite expressions of serious distress on the part of the "learner".

   Upon conclusion of the study, subjects were informed of the true purpose of the study, the nature of the deception, and the potential implications of their behavior. Many experienced extreme psychological distress after understanding the level of cruelty of their actions.

4. **San Antonio Contraception Study:** In the 1970s, a study was conducted in a contraceptive clinic to evaluate the efficacy of various contraceptive pills. The subjects were predominantly indigent patients with no other resource for contraceptive advice or medication. Subjects were randomly assigned to a control group (receiving active contraception) and a research group (receiving placebo pills). The women were not told they were research subjects or that they might be receiving inactive medication (placebo pills). Unfortunately, there was a high number of unplanned pregnancies.

5. **Tearoom Trade Study:** In the 1970s, a social scientist from Harvard researched homosexual behavior in public restrooms. He functioned as a lookout ("watch queen") outside the restrooms where men engaged in anonymous homosexual behavior.

   He recorded vehicle license numbers to obtain names and addresses of participants. He followed up by going to subjects' homes and collecting data as a legitimate interviewer about the subject's background and family life. The subjects in the restrooms had no idea they were

participating in research. The level of detail in the published study was such that the identity of some participants became known.

6. **Tuskegee Syphilis Study:** A study was conducted by the U.S. Public Health Service between 1932 and 1972 to evaluate the natural history of untreated syphilis in human beings. At first considered scientifically important and ethically justifiable since there was no effective treatment for syphilis, the main problem was the research population which was one of the most vulnerable in society. The research population consisted of approximately 300 indigent, uneducated, Afro-American sharecroppers in Macon County, Alabama, who were known to have syphilis.

   The study was equally heinous both in its lack of treatment to subjects long after penicillin had been discovered and the fact that it was conducted by the Federal government. This study resulted in the principle of justice in the Belmont Report and the passage of the National Research Act of 1974.

1974 **The National Research Act and the IRB:** The basic consensus following Senator Kennedy's congressional hearings was that Federal oversight was required to protect the rights and welfare of human research subjects. It was also noted that Federal regulations should not only address medical or biomedical research but also social science (behavioral) research. The act did 2 things that have had major influence on the way research is regulated today:

1. Established the modern IRB system for regulation of research involving human subjects. In 1981, the Department of Health and Human Services (DHHS) initially developed the main IRB regulations in Title 45, Part 46 of the Code of Federal Regulations. Adopted in 1991 by 17 Federal agencies, this code became known as the Common Rule.
2. Established the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research. Consisting of a diverse group of professionals representing the fields of ethics, religion, law, industry, medicine and other disciplines, the Committee issued multiple reports which defined problems and made recommendations regarding the conduct of research in specific populations. In 1978, the Committee issued the Belmont Report, a major milestone in research ethics and regulation.

THE CONSENT/ASSENT DOCUMENT REQUIREMENTS

The CONSENT document is a Federal requirement for informing the research participant of the risks and benefits associated with the research and explains the purpose and procedures of the research. It seeks the potential participant's agreement to participate in the study.

The ASSENT document is a Federal requirement for asking children and other members of vulnerable populations to agree to participate. A CONSENT form must first be signed by the parent or guardian. Existence of the signed CONSENT form does not obligate the child or member of a vulnerable population to participate; they may still refuse to do so.

The following information was gleaned from Amdur and Bankert (2007). Also attached are a sample Consent form and Assent form approved by the JSU IRB.

INFORMATION THAT MUST BE INCLUDED IN THE CONSENT/ASSENT DOCUMENT PER FEDERAL REGULATIONS

1. **Research purpose and procedures:** a statement that the study involves research, an explanation of the purpose of the research and expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

2. **Risks and discomforts:** a description of any reasonably foreseeable risks or discomforts to the subject and identification of a referral plan/agency if they do occur.

3. **Potential benefits:** a description of any benefits to the subject or others that may reasonably be expected from the research.

4. **Alternative procedures or treatments:** a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

5. **Provisions for confidentiality:** a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

6. **Research-related injury:** for research involving more than minimal risk, an explanation as to whether any compensation and any medical/psychological treatments are available if injury occurs and, if so, what they consist of, who is responsible for payment, or where further information may be obtained.

7. **Contacts for additional information:** an explanation of whom to contact for answers to pertinent questions about the research itself and the participant's rights as a research subject and whom to contact in the event of research-related injury to the subject.

8. **Voluntary participation and the right to discontinue participation without penalty:** a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

INFORMATION THAT SHOULD BE INCLUDED WHEN APPLICABLE
(NOTE: Most of these pertain to biomedical research.)

9. **Unforeseeable risks:** a statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if subject is or may become pregnant) which are currently unforeseeable and unanticipated.

10. **Termination of participation by the investigator:** a delineation of the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

11. **Additional costs:** an explanation of any additional costs to the subject that may result from participation in the research.

12. **Consequences of discontinuing research participation:** a statement outlining the consequences of a subject's decision to withdraw from the research and an explanation of procedures for orderly termination of participation by the subject.

13. **Notification of significant new findings:** a statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

14. **Approximate number of subjects:** a statement identifying the approximate number of subjects involved in the research.

Template Consent Form

JACKSON STATE UNIVERSITY CONSENT DOCUMENT FOR
RESEARCH PARTICIPANTS

INVESTIGATOR:	Your Name Department Address City, State, Zip Telephone Number	Your Advisor (if student application) Department Address City, State, Zip Telephone Number

TITLE OF STUDY:

PURPOSE OF STUDY: You are being asked to take part in a research study to determine ***(describe the purpose of your study)***. The goal of the research project is to determine the relationship (if any) between certain ***(variables, conditions, ideas, etc.)*** and ***(any other procedures as they are explained to the participant).***

METHODS AND PROCEDURES: The entire procedure should take ***(time required for completion of forms/procedures).*** If you agree to take part, ***(explain what they are being asked to do to participate. Follow the example.)*** you will first be asked several questions about personal and background information such as your age, race, education level, and prior ***(describe instruments and what they measure. Follow the example.)*** a brief form of intelligence. The intelligence measure provides only an estimate of intelligence; therefore, results will not be provided to you. You will then be read ***(next requirement for participation until all parts are explained to subject. Follow the example.)*** a story about a person and asked to answer several questions based on the information you are given in the story. Finally, you will be asked to complete two brief self-report forms.

You may ask questions at any time during the study and you are free to contact me or my advisor should you have any questions about the research project.

RISKS AND DISCOMFORTS: We expect no risks or discomfort for people in this study ***(Explain if there are risks or discomforts. For example, some issues research investigates are private and confidential. Provide the name and number of the facility you will refer them to if the need arises.)*** However, it is possible that you may feel somewhat uneasy answering the questions involved.

BENEFITS: The information obtained in this study may not directly benefit you. However, the results may provide needed information about ***(the purpose of your study and how it relates to the variable, procedures, instruments, etc.)***.

CONFIDENTIALITY OF RECORDS: All information obtained during this study is private. That is, we protect the privacy of people by withholding their names and other personal information from all persons not connected to this study. Each person will be identified using a code number rather than your name. Raw data will be kept in a locked file cabinet for 3 years as

required by federal law. Although the information in this study is private, it may be revealed in certain rare circumstances. Confidentiality will be broken if the information obtained reveals that you intend to harm yourself or another person.

VOLUNTARY PARTICIPATION: **Taking part in this study is completely voluntary. You may refuse to answer any specific question. Participants may withdraw at any time without penalty or prejudice.**

PARTICIPATION CONSENT: I have had the purposes and procedures of this study explained to me and have had the opportunity to ask questions. My signature shows my willingness to allow my child to take part in the study under the conditions stated.

This study has been reviewed by the Institutional Review Board of Jackson State University, which ensures that research projects involving human subjects follow federal regulations. Any questions or concerns about rights as a research participant should be directed to Dr. Felix Okojie, Vice President for Research Development & Support & Federal Relations at Jackson State University, P.O. Box 17095, Jackson, Mississippi, 39217, or (601) 979-2931.

_____ _____

Participant Signature Date

_____ _____

Investigator Signature Date

Sample of HIPAA paragraph to include on consent for studies using protected health information.

Protected Health Information

Protected health information is any personal information that relates to your past, present, or future health or physical condition through which you can be identified. The data collection in this study includes such things as age, race, physical health status, and emotional adjustment. Study information collected solely for this research study and not as part of your regular care will not be included in your medical record. A decision to participate in this research means that you agree to the use of your health information for the study described in this form. This information will not be released beyond the purposes of conducting this study. The information collected for this study will be kept for a period of three years. If you decide to withdraw, the information already collected about you may still be used in this study. While this study is ongoing you may not have access to the research information, but you may request it after the information is completed.

Following are two sample assent forms. They are included as guides to you in construction of a child's assent to be used in your project. Fill in the appropriate information and adjust to the specifics of your research.

NOTE:
***Do not include a statement to the effect that "your parent has agreed to allow you to take part in the study". This implies the possibility of parental pressure for the child's participation. Instead, use "your parent is aware of this project".**
***Make sure you use age appropriate language. For example, do not use the same language for a third grade student as you would for a graduate student.**

Sample Minor Assent Document

Your parent knows we are going to ask you to ***participate in this project/fill out this survey.*** We want to know about kids' ***attitudes/experiences about topic of research.*** It will take ***amount of time*** of your time to complete the task. Your name will not be written anywhere on the ***research instrument.*** No one will know these answers came from you personally.

If you don't want to participate, you can stop at any time. There will be no bad feelings if you don't want to do this. You can ask questions if you do not understand any part of the ***study.***

Do you understand? Is this OK?

Name (Please Print): _____

Signature: _____

Date: _____

Investigator's Signature: _____ Date: _____

Sample Minor Assent Document

Project Title:
Investigator:

We are doing a research study about ***purpose in simple language.*** A research study is a way to learn more about people. If you decide that you want to be part of this study, you will be asked to ***description, including time involved.***

There are some things about this study you should know. There are ***procedures, things that take a long time, other risks, discomforts, etc.***

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. We think these benefits might be ***description.***

If you do not want to be in this research study, we will tell you what other kinds of treatments there are for you. ***This statement applies to research projects that offer treatment or intervention.***

When we are finished with this study we will write a report about what we learned. This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. If you decide to stop after we begin, that's okay too.

If you decide you want to be in this study, please sign your name.

I, _____, want to be in this research study.
(Print your name here)

(Sign your name here) (Date)

Parts in Italics should be modified for your specific project. Other parts may need to be modified as well depending on your research methods.

PROPOSAL WORKSHEET

This worksheet was originally developed by Kornetsky and Kahn (2006) as a tool to assist IRB members in reviewing research protocols. Thus, it is an excellent tool for student and faculty researchers to develop their research proposals. Explanatory questions have been included to delineate the exact information to be provided. This worksheet also contains all elements required in the submission of a protocol to JSU's IRB.

INTRODUCTION, SPECIFIC AIMS, AND BACKGROUND

- Are the specific aims (research purpose) clearly specified? (Does the statement of problem identify the dependent variable and independent variables?)
- Are there adequate preliminary data to justify the research? (What does the literature say)?
- Is there appropriate justification for the research proposal? (What will the research add to the body of scientific knowledge?)

SCIENTIFIC DESIGN

- Is the scientific design adequate to answer the research question(s)? (Does the research method fit the research?)
- Are the objectives likely to be achievable within a given time period? (Is the research done at one point in time (cross sectional) or is it longitudinal (over time?)
- Is the scientific design (e.g., randomization, placebo controls, etc.) described and adequately justified? (Is there a scientific reason for the particular design being used?)

INCLUSION/EXCLUSION CRITERIA FOR SUBJECTS

- Are inclusion and exclusion criteria clearly specified and appropriate? (Why are these subjects being targeted?)
- If women, minorities or children are included or excluded, is this justified? (Why or why not were they chosen as subjects.?)
- Is the choice of subjects appropriate for the research questions being asked? (Can these subjects provide a definite answer to the questions?)

- Is the principle of distributive justice adequately incorporated into the inclusion and exclusion criteria for the research proposal? Is subject selection equitable? (Are the people most likely to benefit from the research included?)

RECRUITMENT OF SUBJECTS

- Are the methods for recruiting potential subjects well-defined? (How will the research subjects be chosen?)

- Are the location and timing of the recruitment process acceptable? (Is the recruitment process conducive to including all potential subjects? Are the timing and location convenient for potential subjects?)

- Is the individual performing the recruitment appropriate for the process? (Does the recruiter understand the purpose of the research and the criteria for selecting subjects?)

- Are all recruitment materials submitted and appropriate? (Does the proposal include the recruitment materials and how they will be used?)

- Are there acceptable methods of screening subjects before recruitment? (Do criteria exist to insure the inclusion/exclusion of potential subjects?)

RESEARCH PROCEDURES

- Are the rationale and details of the research procedures accurately described and acceptable? (What is being done to the subjects and why?)

- Is there a clear differentiation between research procedures and the standard care? (How is the research different from what is normally done?)

- Are the individuals performing the procedures appropriately educated? (Do the researcher and any assistants have the necessary knowledge and skills to conduct the research?)

- Is the location of where the procedure will be performed acceptable? (Is the location readily accessible to all research subjects?)

- Are there adequate plans to inform subjects about specific research results if necessary (e.g., clinically relevant results, risk of depression, risk of suicide, incidental findings, etc.)? (How will subjects be apprised of research risks and is a suitable referral plan/agency in place?)

DRUGS, BIOLOGICS, AND DEVICES (BIOMEDICAL RESEARCH)

- Is the status of the drug described and appropriate (e.g., investigational, new use of an FDA-approved drug, or an FDA-approved drug within approved indications)? (Is the type of drug to be used adequately explained and justified?)

- Are the drug dosage and route of administration appropriate? (Do these research procedures meet current medical standards for the drug?)

- Are the drug or device safety and efficacy data sufficient to warrant the proposed phase of testing? (Do the data support the proposed phase of testing? Is the proposed research location appropriate for the safe use of the research drug or device?)

- Is the significant risk or nonsignificant risk status of the drug/device described and appropriate? (Do the benefits of the research findings outweigh the risks to the research subject?)

VARIABLES AND HYPOTHESES

- Are the variables adequately defined? (What is the dependent variable? What are the independent variables?)

- Do the variables relate to the research purpose? (Are the variables included in the research statement of the problem?)

- Do the variables relate to the hypotheses to be tested? (Is the dependent measured against every independent variable in the hypotheses?)

- Are the hypotheses testable? (Can they be input into statistical procedures and measured for relationship and significance?)

DATA ANALYSIS AND STATISTICAL ANALYSIS

- Are the methods of statistical analysis appropriate? (Are the analyses appropriate for testing the hypotheses?)

- Is the rationale for the proposed number of subjects reasonable? (Will the number of subjects used provide enough data for valid statistical results?)

- Are the plans for data and statistical analyses defined and justified, including the use of stopping rules and endpoints? (What amount of data and time frame of collection will provide the necessary amount of data for statistical analysis?)

- Are there adequate provisions for monitoring data? (Will the data be checked for accuracy at appropriate time intervals?)

POTENTIAL RISKS, DISCOMFORTS, AND BENEFITS FOR SUBJECTS

- Are the risks and benefits adequately identified, evaluated and described? (Will the research subjects thoroughly understand the risks and benefits of participation?)

- Are the potential risks minimized and the likelihood of benefits maximized? (Do the benefits outweigh the risks?)

- If children are involved, which regulatory category of risk/benefit does the proposal fall within, and are all criteria within the category adequately addressed? (Are all federal requirements for research with children met?)

COMPENSATION AND COSTS FOR SUBJECTS

- Is the amount or type of compensation or reimbursement reasonable? (Is the amount appropriate/acceptable for research or does it amount to coercion to participate?)

- Are there adequate provisions to avoid out-of-pocket expenses by the research subjects, or is there sufficient justification to allow subjects to pay? (Will it cost the subject to participate, e.g., for transportation, meals, etc.? If so, is this expense justified?)

- If children or adolescents are involved, who receives the compensation, and is this appropriate? (Does the payment go to the child or consenting adult? If the adult, is there an element of coercion to have them allow the child/adolescent to participate?)

PRIVACY AND CONFIDENTIALITY

- Are there adequate provisions to protect the privacy and ensure the confidentiality of the research subjects? (How will the researcher ensure that an individual participant cannot and will not be identified?

- Are there adequate plans to store and code the data? (Where will the data be stored? Who will code the data?)

- Is the use of identifiers or links to identifiers necessary, and how is this information protected? (Does the data need to be linked to the subject? If so, how will this information be protected from use by individuals outside of the research team?)

INFORMED CONSENT/ASSENT

- Are all the elements of informed consent contained in the document? (Does the consent/assent information meet the requirements of Federal regulations?)
- Is the process of obtaining consent adequately described? (How will the subjects be asked to sign the consent document?)
- Is assent required? (Are the subjects minors or other members of vulnerable populations?)
- Is waiver or modification of consent possible? (Does the research meet Federal requirements for waiving or modifying consent?)

OTHER ISSUES

- Are adequate references provided? (Has a review of literature been done, and is it included in the proposal?)
- Is there a conflict of interest? (Does the researcher stand to make a personal gain from the research? Is the researcher in some position of power over the research subject?)
- Is the research subject to HIPAA (Health Insurance Portability and Accountability Act) guidelines? (If the research is biomedical, is a HIPAA explanatory and consent form included?)

WEB SITES FOR ADDITIONAL INFORMATION

ETHICAL CODES

Nuremberg Code: http://www.hhs.gov/ohrp/references/nurcode.htm

Belmont Report: http://ohrp.osoph.dhhs.gov/humansubjects/guidance/belmont.htm

Declaration of Helsinki: http://www.wma.net/e/policy/63.htm

U. S. GOVERNMENT REGULATIONS

Department of Health and Human Services: http://www.hhs.gov/ohrp

45/CFR46: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Health Insurance Portability and Accountability Act (HIPPA): http://aspe.hhs.gov/admnismp/

Office of Human Research Protection (OHRP)

Home page: http://www.hhs.gov/ohrp/

Guidance by subjects: http://www.hhs.gov/ohrp/policy/index.html*

Compliance activities: http://www.hhs.gov/ohrp/compliance/findings.pdf

Office of Research Integrity http://ori.dhhs.gov/

PERIODICALS

ARENA Newsletter: http://140/239/168/132/arena.html

Bulletin of Medical Ethic: http://www.bullmedeth.info

The Hastings Center: http://www.thehastingscenter.org

Human Research Report: http://www.humansubjects.com

Research Practitioner: http://www.researchpractice.com/rp_about_shtml

The IRB Forum: http://www.irbforum.org

FREE VIDEO

Designed for use by IRB's but is an excellent reference for understanding the ethical principles related to human subject research

http://www.hhs.gov/ohrp/education/#materials

RESEARCH COMPLIANCE WORKSHOP PRESENTATION

FRAME 1 — Title of Presentation

FRAME 2 — Today's presentation will focus on 3 topic areas:

1. **Definition of research compliance**
2. **Moral and legal standards of compliance**
3. **Consequences of noncompliance.**

Bear in mind that, as a sociologist, I will focus on **behavioral research with human subjects** although selective information will pertain to biomedical research.

FRAME 3 — What do we mean by research compliance?

Research compliance involves the adherence to a set of ethical and legal guidelines and restrictions on the use of human subjects in research.

Research with human subjects does not exist in a vacuum. It adheres to specific ethical standards set forth by **professional organizations guiding individual disciplines** and by the legal standards set forth by the **Federal government.**

FRAME 4 — The ethical standards are embodied in **code of research ethics** set forth by professional organizations such as the American Psychological Association, the American Sociological Association, and the National Council of Social Workers, among others.

The legal standards are delineated in the **Belmont Report**, issued in 1978 by the Commission for the Protection of Human Subjects in Biomedical and Behavioral Research which was established by the National Research Act of 1974.

(**NOTE:** A copy of the Historical Development of Legal Standards can be found in your folder.)

FRAME 5

The **ethical** standards established by professional organizations delineate 5 principles:

1. **No harm to subjects** – The research should not induce any harm whether physical or emotional to the research participants. If there is a risk of harm, the benefits of the research must outweigh the harm.

2. **Voluntary participation** – The subject must be informed of the purpose of the research and must voluntarily give consent for participation.

3. **Researcher identification** – The researcher must inform the subjects that he/she is a researcher and is conducting a study for which the individual is a potential research participant.

4. **Anonymity/Confidentiality** – Anonymity is the standard. No one, including the researcher, should be able to identify the subjects. When anonymity is not possible, confidentiality must be maintained. No one but the researcher should be able to identify subjects.

5. **Honesty in reporting** – Data speak for themselves. However, a statistician can use the findings to support any hypothesis he wants to. Example: When Credell Calhoun, a black male, was running for mayor of the city of Jackson and was the first black to do so, statistical analysts used scare tactics to influence white voters to get out and vote by reporting that the population of Jackson was **over** half black. In reality, the population was basically even by race with 51% black and 49% white. The scare was enough to bring white voters out in record numbers.

FRAME 6

The **legal** standards are outlined in Title 45, Part 46 of the Code of Federal Regulations (45CFR46), widely known as the **Common Rule**. There are 3 standards:

1. **Respect for persons** – involves two standards: a.) treating individuals as autonomous agents capable of independent decision-making and b) protecting persons with diminishing autonomy. This refers to protection of vulnerable populations which will be discussed in the next frame.

This standard delineated 4 conditions which the researcher must address in consent/assent documents:
(**NOTE:** You have 2 handouts in your folder on Consent/Assent documents. One is the list of required items in the documents, and the other is a sample Consent/Assent document developed and approved by the JSU IRB.)

The 4 conditions are: 1.) Voluntary consent to participate, 2.) informed consent knowing what the research is about, 3.) protection of privacy and confidentiality, and 4.) the right to withdraw without penalty. You will notice that all of these conditions are included in the ethical standards of professional organizations.

2. **Beneficence** – refers to minimizing risks. All risks possible in the research must be justified by potential benefits to the individual and/or society, and the benefits must outweigh the risks. Bottom line for researchers: **Do no harm.**

3. **Justice** – refers to the concept that risks/benefits must be distributed equally. This includes two conditions: a.) classes of people must likely to benefit from the research cannot be excluded, and b) vulnerable subjects cannot be targeted for convenience.

FRAMES 7 & 8

Vulnerable populations can be categorized 2 ways:

1. Group membership (e.g., racial minorities, women, children, elderly, prisoners) or

2. Specific kinds of vulnerability which an individual may have (e.g., those who are physically, mentally, economically, or educationally disadvantaged, pregnant women).

The Common Rule identified 9 populations as vulnerable. The Belmont Report added 3 others, and OHRP (Office of Human Research Protection) delineated 2 more.

FRAMES 9 & 10

PROPOSAL/PROTOCOL REQUIREMENTS: In your folder is a document outlining the required areas for inclusion in a proposal/protocol document. It is also an excellent tool for preparing a protocol for submission to the IRB.

(**NOTE:** If time permits, go over these requirements. If not, make reference that an entire workshop could be devoted to just this topic.)

FRAME 11

CONSEQUENCES: Noncompliance may result in serious consequences for the researcher (student and/or faculty) and to the University itself.

Student – may be required to turn the data collection instruments and the collected data in to the IRB, resulting in

- recopying of the data collection instruments and recollection of the data, which could
- delay graduation as much as a year or two.

(**NOTE:** This has happened at JSU to both master's and doctoral level students.)

Faculty – may also have data and data collection instruments confiscated by the IRB, resulting in

- recopying of the data collection instruments and recollection of the data
- possible censure by University officials (IRB, V.P. for Research, V.P. for Academic Affairs, School Dean, and/or Department Chair)
- possible censure by professional organization
- possible loss of research funds or grant funds

University – possible loss of all University-wide research funding and grant money

– cessation of all research at the University (**NOTE:** Some centers at the University would close down since they are dependent on outside funding, e.g., the Interdisciplinary Alcohol/Drug Studies Center.) All research and grants supported by Federal funds would be halted and the assets frozen. **This has happened to both Johns Hopkins University and Duke University, among others. It <u>can</u> happen to Jackson State.**

– possible censure by professional organizations and/or Federal/State funding agencies

FRAME 12 REFERENCES (Just put up and mention.)

FRAME 13 ACKNOWLEDGMENTS

Dr. Dorris Robinson-Gardner: for allowing me to present such an important workshop and for supporting all of my endeavors

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Dr. Vicki Prosser: for providing necessary handouts

CONCLUSIONS The final handout in your folder is a list of web sites for additional information. Included are ethical codes, U.S. Government agencies, and research periodicals. Also included is a web site for a free video. It is designed for use by IRBs but it is also an excellent reference for understanding the ethical principles related to human subject research. I strongly urge you to get your Departments to order one.

In closing, I cannot emphasize the importance of research compliance enough. It is not an abstract theoretical concept. It is real, and it can have dire consequences for students, faculty and the University. I exhort each and every one of you to not only understand it but to also embrace it in all of your research endeavors.