

Lakeland College
Institutional Review Board Guidebook

CONDENSED VERSION

Preparation Date: October 2007

N.B. This document is a significantly condensed version of the Institutional Review Board Guidebook published by the United States Government Department of Health and Human Services, <http://www.hhs.gov/ohrp/irb> . Please review the original document for a more detailed presentation of the material and to answer questions not included herein. In general, information relating to biomedical research with human subjects is not included in this condensed version.

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CHAPTER 1: INTRODUCTION

Brief Statement Regarding the Use of Animals in Research: Research involving laboratory animals shall adhere to the guidelines developed by the Office of Laboratory Animal Welfare, of the National Institute of Health, Department of Health and Human Services (<http://grants.nih.gov/grants/olaw/olaw.htm>). Research involving wild animals shall adhere to Guidelines for the Use of Wild Mammals in Research developed by the American Society of Mammalogists (Journal of Mammalogy, 88(3), 809-823, 2007, click here for link to journal article, <http://www.mammalsociety.org>).

Brief History of the Human Subjects Protection System: After the Nazi's experiments were exposed, many nations began to legislate the rights of humans as subjects. In 1974, the U.S. Department of Health, Education, and Welfare (DHEW) established the Institutional Review Board (IRB) as one mechanism whereby human subjects would be protected. The regulations were revised in 1981 by the Department of Health and Human Services (DHHS, formerly DHEW) and the Food and Drug Administration to include the adoption of the Federal Policy (also known as the Common Rule) for the Protection of Human Subjects and are codified at Title 45 Part 46 of the Code of Federal Regulations. This federal law is enforced by the 16 agencies that conduct, support, and regulate human subjects research.

Basic Ethical Principles which Guide Human Subjects Research

Respect for Persons: a recognition of individuals' dignity and autonomy.

Elements of Informed Consent:

- 1) Information Disclosure - A statement about the purpose, procedures, risks, and benefits of the research, and the invitation to ask questions and/or to withdraw at any time from the research must be given to the subjects (Ss) to enable them to decide whether or not to participate.

Incomplete Disclosure is justified only if:

- (a) full disclosure prevents accomplishment of research goals, and
 - (b) the undisclosed risks are minimal; and
 - (c) Ss will be debriefed and provided research results, when appropriate.
- 2) Comprehension - Ss must be able to comprehend the information that is given to them, or consent must be obtained from third persons. See "Special Classes of Subjects."
 - 3) Voluntary Consent - Consent must be voluntarily given and free from coercion and undue influence.

Beneficence: an obligation to protect persons from *all possible harms* by maximizing benefits and minimizing risks; requires protection of Ss *and* consideration of the societal benefits of the research.

The principal investigator (PI) must provide enough information to the IRB so that it can reasonably determine a precise *Risk:Benefit* Ratio. Based upon the information provided by the PI, the IRB will determine:

- 1) the validity of the presuppositions of the research;
- 2) the nature, probability, and magnitude of risk; and
- 3) the reasonableness of the investigator's harm or benefits estimates.

Basic Principles of Risk:Benefit Assessment

- 1) risks should be minimized, including the avoidance of human Ss, if at all possible;
- 2) IRBs must insist upon sufficient justification for research involving significant risk of impairment;
- 3) the appropriateness of involving vulnerable populations must be demonstrated;
- 4) the proposed informed consent process must completely disclose relevant risks and benefits.

Justice: concerns the Ss as an individual and as a member of social, racial, sexual, or ethnic groups and requires that the benefits and burdens of research be distributed fairly. The selection of Ss must be the result of fair selection procedures.

CHAPTER 2: INSTITUTIONAL ADMINISTRATION

Jurisdiction of the Institutional Review Board

The IRB protects the rights and welfare of human Ss recruited to participate in research conducted under the auspices of Lakeland College. Once the institution adopts the federal human Ss regulation, the regulations apply to all research involving human Ss. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction. Approved research must be reevaluated at least annually. When the PI believes a project to be exempt from IRB review, the protocol must be submitted to the IRB to verify exemption. While non-IRB officials of Lakeland College have the authority to disapprove research that was previously approved by the IRB, they do not have the authority to approve research that was previously disapproved by the IRB.

Exclusions

- 1) Educational Practices: Research conducted in established educational settings, involving normal educational practices (e.g., curricula effectiveness, classroom management, etc.).

This exemption does not apply to:
 - a) *the school records of identifiable students, or*
 - b) *interviewing instructors about identifiable students.*
- 2) Educational Tests: Research involving the use of educational tests (diagnostic, achievement, etc.) is exempt, if:
 - a) in the data (private and published) Ss cannot be identified, directly or through identifiers linked to the Ss; or
 - b) the information could not place the Ss at risk of liability or be damaging to the Ss' reputation.
- 3) Surveys or Interviews: Research involving survey or interview procedures is exempt if:
 - a) in the data (private and published) Ss cannot be identified, directly or through linked identifiers;
 - b) the information could not place the Ss at risk of liability or be damaging to the Ss' reputation.
This exemption does not apply if the Ss are minor children (less than 18 years).
- 4) Observation of Public Behavior: Research involving the observation of public behavior is exempt if:
 - a) in the data (private and published) Ss cannot be identified, directly or through linked identifiers;
 - b) the information could not place the Ss at risk of liability or be damaging to the Ss' reputation;
 - c) this exemption applies to research involving minor children *only* when the investigator does not participate in the activities being observed.
- 5) Public Officials: When the Ss are elected or appointed officials or candidates for public office, all research involving educational tests, surveys, interviews, or public observations is exempt without exception.
- 6) Existing Data: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens is exempt if:
 - a) these sources are publicly available, or
 - b) in the data (private and published) Ss cannot be identified, directly or through linked identifiers;

Administration of the Institutional Review Board

Membership:

- 1) a minimum of five members of diverse backgrounds (e.g., academic specialty, gender, race, ethnicity, sensitivity to community attitudes, etc.);
- 2) persons knowledgeable in areas of institutional commitments and regulations, applicable law, and standards of professional practice and conduct;
- 3) at least one member with a scientific specialty and at least one with a non-science specialty;
- 4) one member who is neither affiliated with Lakeland College nor related to a Lakeland employee.
- 5) No IRB member will review projects if a conflict of interest exists.
- 6) A membership list including the names, degrees, expertise, and relationship to the institution must be submitted to the OPRR. (See government publication for more information.)

Record Keeping & Minutes: Records will be maintained for three years and will be available to faculty and staff as needed. The records shall include IRB procedures, membership lists, copies of all research proposals, minutes of IRB meetings, notes of continuing review activities, copies of correspondence between the IRB and investigators, and statements of significant new findings provided to Ss. Minutes of IRB meetings must include attendance, IRB actions and IRB votes (including the number for, against, and abstaining); the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

Institutional Procedures and Guidelines

Federal Policy Requirements: Written procedures and guidelines must be followed by the IRB when conducting its initial and continuing review of research, and for reporting its findings and actions to the investigator and the administration. The procedures provide guidance for determining the timing of review, for reporting changes in approved projects to the IRB, and notification any unanticipated problems involving risk to Ss or others.

The Authorized Institutional Official: An official within the institution who has the legal authority to act and speak for the institution shall be responsible for the oversight of research and IRB functions. The institution's president should appoint or delegate the appointment of the individual. This person may select the chair of the IRB.

Principal Investigators

PI Qualifications: The IRB will consider the PI's qualifications and may require those who are less experienced to be sponsored by seasoned researchers.

Research Protocols: The PI shall prepare detailed research protocols. The protocol will include the design, the scientific rationale (including the results of previous animal and human studies) underlying the proposed research, the statistical basis for the structure of the investigation, provisions for the adequate protection of the rights Ss, and samples of the informed consent documents.

PI Compliance with the IRB: PIs are responsible for complying with all IRB decisions, conditions, and requirements. PIs are responsible for reporting the progress of the research to the IRB no less than once per year.

Compliance / Noncompliance

Please see the original government publication for information regarding compliance/noncompliance by investigators, IRBs, and institutions, as well as information regarding internal and external audits.

CHAPTER 3: BASIC IRB REVIEW

Risk/Benefit Analysis

Definitions: **Benefit:** A valued or desired outcome; an advantage.

Minimal Risk: When the probability and magnitude of anticipated harm is less than those encountered in daily life or during the performance of routine physical or psychological examinations.

Risk: The probability of harm (physical, psychological, social, economic) as a result of Ss' participation.

Steps in the Risk/Benefit Analysis: The IRB must:

- 1) identify the risks associated with the research;
- 2) determine that the risks will be minimized (see Ch. 3 Risk/Benefit Analysis and Monitoring and Observation);
- 3) identify the probable benefits to be derived from the research;
- 4) determine that the risks are reasonable in relation to the benefits to Ss and the knowledge to be gained;
- 5) assure that Ss will be provided with description of risks and benefits (see Ch. 3 Informed Consent);
- 6) determine intervals of periodic review and that provisions exist for monitoring the data collected (see Ch. 3 Monitoring and Observation);
- 7) determine the adequacy of the provisions to protect the *privacy* of Ss and to maintain the *confidentiality* of the data. When Ss are members of vulnerable populations additional safeguards must be considered.

Identification and Assessment of Risks:

Physical Harms: (See government publication, unlikely to be relevant to Lakeland College).

Psychological Harms: Most psychological risks are minimal but some are significant. Stress may arise simply from thinking about one's own behavior or attitudes. Psychological harm, however, is more likely when deception is involved, particularly if it includes false feedback to the Ss about their own performance.

Invasion of privacy usually involves covert observation or "participant" observation of behavior that Ss consider private. The IRB must determine if: 1) the invasion of privacy acceptable in light of the Ss' expectations of privacy; and 2) is the research question of sufficient importance to justify the intrusion.

Breach of confidentiality of data concerns safeguarding information that has been given voluntarily by one person to another (see Privacy and Confidentiality in this chapter). Research involving the use Ss' school or employment records is generally acceptable if confidentiality is maintained.

Social and Economic Harms may result from invasions of privacy and breaches of confidentiality.

Determination that Risks are Minimized

Investigator Competence and Dual Roles: IRBs evaluate the investigators' competence in the pertinent area and whether they serve *dual roles*. Teachers who conduct research could (wittingly or unwittingly) coerce student-Ss into participating. Thus, any conflicts must be identified and resolved before approval is granted.

Research Design: While good research design itself may not reduce risks to Ss, faulty research design means that the risks are not likely to be reasonable in relation to the benefits.

Deception or Incomplete Disclosure: In these events, Ss should be *debriefed* by explaining the deception. In some cases debriefing may not be helpful and it may even be harmful.

Points to Consider

- 1) Are both risks and anticipated benefits accurately identified, evaluated, and described?
- 2) Are the risks greater than minimal risk? Does Ss vulnerability increase risk?
- 3) Has due care been used to minimize risks and maximize the likelihood of benefits?
- 4) Are there adequate provisions for a continuing reassessment of the balance between risks and benefits?

Informed Consent

Informed consent is one of the primary ethical requirements underpinning research with human Ss. It assures that Ss understand the research and *voluntarily* decide whether participate. Informed consent protects the Ss and the PI. It is forbidden to use exculpatory language through which the Ss is made to appear to waive any of the Ss' legal rights, or appears to release the investigator, sponsor, institution, or agents from liability for negligence.

Information to be Provided to Ss: The federal regulations require that certain information be provided to each Ss.

- 1) A statement including an explanation of the purposes of the research, the expected duration of the Ss participation, a description of the procedures, and identification of any procedures which are experimental;
- 2) A description of any reasonably foreseeable risks or discomforts to the Ss;
- 3) A description of any benefits the Ss or to others which may reasonably be expected from the research;
- 4) A disclosure of alternative procedures, if any, that might be advantageous to the Ss;
- 5) A description of the extent, if any, to which confidentiality of records identifying the Ss will be maintained;
- 6) An explanation regarding compensation and treatment if injury occurs, and, if so, what they consist of;
- 7) Contact information for questions regarding the research, Ss rights, and emergencies.
- 8) A statement that participation is voluntary, refusal to participate will involve no penalty to the Ss, and the Ss may discontinue participation at any time without penalty.

Documentation of Informed Consent: Federal regulations typically require the use of a written consent form (with a copy supplied to the Ss) containing all the information to be disclosed and signed by the Ss or the Ss' representative.

Waiver of written documentation: Documentation of consent may be waived when the:

- 1) principal risks are those associated with a breach of *confidentiality* concerning the Ss participation in the research (e.g., studies on sensitive topics such as drug abuse);
- 2) consent document is the only record linking the subject with the research; and
- 3) research presents no more than *minimal risks*.

At institutions that require IRB review of all research involving human Ss, the IRB may waive consent documentation for research that would be exempt from the federal regulations (e.g., most survey and observational research). Ss must still be provided adequate information about the research.

Exceptions: The IRB may approve a waiver of some or all of the consent requirements provided that:

- 1) the research involves no more than *minimal risk* to Ss;
- 2) the waiver will not adversely affect the rights and welfare of the Ss;
- 3) the research could not practicably be carried out without the waiver; and
- 4) when appropriate, Ss will be provided additional information after they have participated in the study.

Deception and Incomplete Disclosure: When research involves incomplete disclosure or deception, IRBs must decide whether the information to be withheld would influence Ss' decision to participate. Research should not be permitted *at all* if the risk to Ss is more than minimal and the incomplete disclosure would impair the decision making process.

Points to Consider

- 1) Does the research involve a vulnerable Ss population?
- 2) Are the proposed explanations of the research accurate assessments of its risks and benefits?
- 3) Is the language and presentation of the information appropriate to the Ss population?
- 4) Can Ss comprehension of the information and their ability to make a choice be enhanced?
- 5) Who should explain the research to the Ss?
- 6) Should subjects be reeducated and their consent required periodically?
- 7) Should the IRB monitor the data (supplied by the PI) to determine new information should be conveyed to Ss?
- 8) If a waiver of some or all of the consent requirements is requested, does the importance of the research justify the waiver? Is risk more than minimal? Can the design be modified to eliminate the need for deception or incomplete disclosure? Will Ss be given more information after completing their participation? Is the withheld information something Ss might reasonably want to know in making their decision about participation?

Selection of Subjects

IRBs require the selection of Ss to be *equitable* so that the burdens and benefits of research will be fairly distributed. In addition to considering risks, the IRB also considers inconvenience, embarrassment, etc. as burdens of participating. There should be an order of preference in the selection of classes of Ss: adults before children, competent before incompetent individuals, and noninstitutionalized before institutionalized persons. IRBs should consider the extent to which a proposed Ss population is already burdened by poverty, illness, etc. in determining their suitability as Ss. Some IRBs prohibit professors from utilizing students and supervisors from utilizing employees in their research. The line between protecting the vulnerable and being unduly paternalistic is difficult to draw. Avoiding the use of a group of Ss on the grounds of convenience must not prevent competent adults from volunteering to be Ss of research.

Points to Consider

- 1) Will the burdens of participating in the research fall on those most likely to benefit from the research?
- 2) Will the solicitation of Ss avoid placing a disproportionate share of the burdens of on any single group?
- 3) Does the nature of the research require or justify using the proposed Ss population?
- 4) Are there any groups who might be more susceptible to the risks and who ought to be excluded?
- 5) Are anticipated benefits fairly distributed? Do other potential Ss have a greater need to receive the benefits?
- 6) To the extent that participation in the study is burdensome, are these burdens distributed fairly
- 7) Will any physiological, psychological, or social characteristics of the Ss group pose special risks for them?
- 8) Could the study be conducted with less vulnerable Ss? Is there justification for utilizing the vulnerable Ss?
- 9) Has the selection process *overprotected* potential, vulnerable Ss (e.g., children, economically disadvantaged, students of researchers) so that they are denied opportunities to participate?
- 10) If the Ss are susceptible to pressures, are there mechanisms that might be used to reduce the pressures?

Privacy and Confidentiality

Definitions: Privacy - having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Confidentiality - pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged without permission in ways that are inconsistent with the understanding of the original disclosure.

Concerns about privacy pertain primarily to the methods used to obtain information about Ss. Researchers ordinarily use information that Ss have provided voluntarily. Thus, there is seldom a concern about privacy, other than to ensure data confidentiality. Where privacy issues do arise is in terms of information obtained for research *without* SS consent.

Privacy Issues in the Use of Personally Identifiable Records: Privacy concerns may arise when potential Ss cannot be identified from public records or from the researcher's work sources. To identify Ss, researchers must sometimes approach institutions seeking information generally regarded as confidential (e.g., students meeting a particular criterion). Sometimes, the researcher needs to contact students to obtain further data. Other times, no contact with Ss is contemplated because the obtained information is sufficient. In these cases, personal identifiers may not need to be recorded or, if recorded, can be destroyed at some stage of the research. All of these factors are relevant to IRB assessments of privacy and confidentiality in research.

When students give information to an academic institution, they do so in a relationship of trust. Colleges should respect that trust. Yet such confidences are not absolute; student records are commonly used for a variety of purposes. In studies of documents or records where the Ss are identified, informed consent may be waived if the IRB determines that the Ss' interests are adequately protected and the importance of the research justifies the invasion of privacy.

In cases where researchers gain access to identified records without the Ss explicit permission, methods for reducing the associated privacy problems should be considered. For instance, an institution possessing records on suitable Ss may be willing to contact them and ask their permission to release their names to the researcher. Another approach is for institutions to make known the uses for which its records may be put in advance. Some institutions provide an opportunity for people to consent (or withhold consent) to use at the time of the initial creation of the record. Various other creative solutions may be negotiated among researchers, institutions, and IRBs.

Observational Studies

Of all the methods used to locate Ss and obtain data, covert observation (concealed recording devices and/or concealment of the researcher) and participant observation (researcher as a participant) are especially prone to privacy concerns. Whereas covert observation of public behavior raises little concern, concealed observation of people in their homes is an entirely different matter. Some behavior that occurs in public or semi-public places (e.g., conversations which occur in parks) may not be public behavior if the individuals involved have a reasonable expectation of privacy.

Most observational research, except that involving children and minors, is exempt from federal regulations. For adult Ss, the IRB must review only the most risky observational investigations in which two conditions exist: 1) the manner in which the observations are recorded allows the Ss to be identified, directly or through linked identifiers; and 2) the observations recorded, if seen outside of the research context, could place the Ss at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or reputation. The IRB's major concern, then, should be to determine if this method of recording is necessary, and, if so, whether confidentiality provisions are adequate.

Observational research involving children and minors must be IRB reviewed if the research involves observations of public behavior and when the researchers are not participants in the activities recorded. IRB review is also required where the conditions described above apply (i.e., non-confidential and the observations could place the Ss at risk).

Confidentiality of Research Data

The need for confidentiality exists in virtually all studies in which data are collected about identified Ss. In research on sensitive topics, it is essential that researchers offer some assurance of confidentiality. These assurances sometimes require the researcher and IRB to make explicit provisions for preventing breaches of confidentiality.

Generally, assuring confidentiality is only a matter of following routine practices: substituting codes for identifiers, removing face sheets (containing names and addresses) from survey instruments containing data, properly disposing of papers, limiting access to identified data, educating staff about confidentiality, and storing materials in locked cabinets. More elaborate procedures may be necessary for studies in which data are collected on sensitive matters.

Please see the original government document for information which addresses the issue of statutory shields of protection of sensitive data from subpoena.

Points to Consider

- 1) Does the research involve observation where the Ss have a reasonable expectation of privacy? Would reasonable people be offended by such intrusion?
- 2) If privacy is to be invaded, does the importance of the research justify the intrusion? What will the Ss be told?
- 3) If the investigators want to review existing records to select Ss for further study, whose permission should be sought for access to those records (the institution? the Ss)?
- 4) Will the investigator be collecting sensitive information about individuals? If so, have they made adequate provisions for protecting the confidentiality of the data? (If the information obtained about Ss might interest law enforcement or other government agencies, see original government document).

Monitoring and Observation

The IRB reviews the researcher's plan for collection, storage, and analysis of data. Preliminary data may signal the need to change the design, or the information presented to Ss, or even to terminate the project early. If the data are not analyzed until the project is terminated, the chance to make mid-course corrections is lost. If the data are not properly analyzed, the research itself is not valid, and proper conclusions will not result.

Points to Consider

- 1) How will the research data be recorded and maintained?
- 2) Considering the degree of risk, is the plan for monitoring the research adequate?
- 3) Is there a mechanism for providing information to the IRB if unexpected results enhance the risk to Ss?
- 4) If the PI is other than full-time on the project, is the oversight and monitoring time sufficient?
- 5) Should the IRB recommend that a data and safety monitoring board be appointed for this project?

Incentives for Participation

Regulations governing research with human Ss contain no specific guidance for IRB review of payment practices. However, one of the primary responsibilities of IRBs is to ensure that a subject's decision to participate will be truly voluntary, and that consent will be sought "only under circumstances that provide the prospective Ss... sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence".

Points to Consider

- 1) Are all conditions in keeping with standards for voluntary and informed consent?
- 2) Are the incentives offered reasonable, based upon the inconveniences of the study and the Ss population?
- 3) Should the IRB monitor Ss recruitment to determine whether coercion or undue influence is a problem.

Continuing Review

IRB approval is a temporary authority that may be withdrawn at any point in time if warranted. The IRB is authorized to monitor research activities. All research must be reviewed at least annually.

Points to Consider

- 1) Are the actual risks and benefits as anticipated?
- 2) Have any Ss been seriously harmed?
- 3) Has the IRB been informed of any unforeseen problems or accidents that may have occurred?
- 4) Should the IRB request that the investigator(s) submit scheduled progress reports?
- 5) Have Ss been informed of any new information that might affect their willingness to continue participating ?
- 6) Do the consent documents need to be revised?
- 7) Has due care been used to reduce risks and increase the likelihood of benefits?
- 8) Are the procedures agreed upon at the beginning of research still being used?
- 9) Should IRB approval be continued, or should approval be suspended or withdrawn?

Chapter 4: Behavioral Research

Most IRB-reviewed research falls is either biomedical or behavioral. Only behavioral research will be discussed in this Chapter. (Please see Chapter 5 of the original government publication for a discussion of biomedical research).

The terms "behavioral research" or "the behavioral sciences" refer to studies of individuals or of the behavior of aggregates, such as groups and societies. The broad objective of the behavioral sciences is to establish a body of demonstrable, replicable facts and theory that contributes to knowledge and to the amelioration of human problems.

Behavioral research involving human Ss generates data by means of questionnaires, observation, studies of existing records, and experimental designs. Not all behavioral research involves human Ss and thus requires no IRB review.

Although most behavioral research involves no physical risk, some studies present a risk of social or psychological harm, especially if the research involves deception or provides Ss with disturbing information about themselves. In these cases, the IRB must be satisfied that the deception is necessary and that, when appropriate, Ss will be debriefed.

There is concern that IRB judgments at times seem to be influenced more by the topic than by concerns about informed consent or risks. Some research believe that IRBs are more likely to object to research on the powerful (e.g., professors) than to similar research on Ss of lower status (e.g., students). Others believe that IRBs sometimes perceive research on controversial topics, such as deviant sexual behavior, as presenting ethical problems because of the nature of the activity being studied, rather than because of methods, risks, or the rights of Ss. Still others complain of a less specific prejudice against behavioral research on the grounds that it is "soft" or concerned with trivial questions.

IRBs should resist placing restrictions on research because of its subject matter. IRBs must differentiate disapproving a research proposal because of qualms about the subject being explored or its possible findings from disapproving research involving the performance of illegal or unethical acts. The former raises serious issues of academic freedom; the later is quite appropriate. It is generally agreed that prohibiting research to protect the institution from being associated with controversial topics is not an appropriate concern for an IRB, whose function is to protect human Ss.

Fieldwork: Fieldwork involves observation of and interaction with the persons being studied in their own environment. Since fieldwork is process gains shape as the study progresses, it may be impossible to specify objectives in a protocol. In the fieldwork setting, the ongoing demands of morally sound research involve gaining trust of the persons being studied. These processes, as well as the research itself, involve complex, continuing interactions between researcher and hosts that cannot be reduced to an informed consent form. Thus, while the idea of consent is not inapplicable in fieldwork, IRBs and researchers need to adapt prevailing notions of acceptable protocols and consent procedures to the realities of fieldwork. IRBs may consider granting a waiver of informed consent.

Social Policy Experimentation: Social policy experimentation involves interventions in social systems for use in planning public policy. Such experimentation often involves studying the costs and benefits of alternative ways of providing health, educational, or welfare services at national, state, or local levels. Some of this research may be exempt from an IRB review if they are conducted by or subject to the approval of department heads, and that examine: 1) public benefit or service programs; 2) procedures for obtaining benefits or services under those programs; 3) possible changes in those programs; or 4) possible changes in methods or levels of payment for benefits under those programs.

Chapter 5: Special Classes of Subjects - Children & Minors

IRBs adhere to special criteria when reviewing research involving children and prohibit that which is contrary to the rights and welfare of child Ss.

Definitions: Assent - A child's agreement to participate. Failure to object should not be construed as assent.

Children - Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law.

Permission: The agreement of parent(s) or guardian to the participation of their child or ward.

Minimal Risk: When the probability and magnitude of anticipated harm is less than those encountered in daily life or during the performance of routine physical or psychological examinations.

Analysis of Probable Risks, Possible Benefits, and Associated Discomfort: IRBs are required to classify research involving children into one of four categories and to document their analysis of the risks and benefits:

- 1) Research not involving greater than minimal risk.
- 2) Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual Ss is approvable if: a) the risk is justified by the anticipated benefit to the Ss; and b) the relationship of risk to benefit is at least as favorable as any alternative approach.
- 3) Research involving greater than minimal risk with no prospect of direct benefit to individual Ss, but likely to yield generalizable knowledge about the Ss' disorder or condition is approvable if: a) the risk represents a minor increase over minimal risk; b) the intervention presents experiences to Ss that are commensurate with those inherent in their actual or expected medical, psychological, social, or educational settings; and c) the intervention or procedure is likely to yield generalizable knowledge about the Ss' disorder or condition that is of vital importance for the understanding or amelioration of the condition.
- 4) Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children must have special DHHS approval.

Consent Procedures

When children are involved in research, the assent of the child and the permission of the parent(s) or guardian, in place of the consent of the Ss is required. The IRB must determine whether the permission of both parents is necessary, and the conditions under which one parent may be considered "not reasonably available." The IRB will determine that provisions are made for soliciting the assent of the children, when the children are capable of providing assent.

The permission of one parent is sufficient for research that does not involve greater than minimal risk, or research involving greater than minimal risk but potentially offering direct benefit to the individual Ss (see 1 and 2 directly above). For research categories 3 and 4 above, permission must be obtained from both parents, unless one is deceased, unknown, incompetent, unavailable, or when only one parent has legal responsibility for the child.

While children may be legally incapable of giving informed consent, they nevertheless may possess the ability to assent to or dissent from participating. Children should be asked whether or not they wish to participate in the research, particularly if the research: 1) does not involve interventions likely to be of benefit to the subjects; and 2) the children can comprehend and appreciate what it means to be a volunteer for the benefit of others. The federal regulations do not require that assent be sought from children starting at a specific age, but that their assent should be sought when, in the judgment of the IRB, the children are capable of providing their assent. IRBs are to take into account the ages, maturity, and psychological state of the children involved.

When the research offers the child the possibility of a direct benefit that is important to the health or well-being of the child and is available only in the context of the research, the IRB may determine that the assent of the child is not necessary. Additionally, in such circumstances a child dissent, which should normally be respected, may be overruled by the child's parents at the IRB's discretion.

When the IRB determines that the assent of the child is required, it must also determine that there are adequate provisions for obtaining and documenting assent. An explanation of the research, including any possible discomforts, must be explained to the child in appropriate language given the child's age, maturity, and condition.

Exemption from IRB Review

There is no exemption for surveys, interviews, or observation of public behavior for research with children with the exception of observation of public behavior when there is no investigator participation in the observed activities.

Points to Consider

- 1) Does the research have an identifiable prospect of direct benefit to the individual child participant?
- 2) Does the research involve risk to the child participant? Are safeguards proposed to minimize these risks? When greater than minimal risk is anticipated, are convincing scientific and ethical justifications given?
- 3) Do placebo controls place the child at greater risk by withholding potentially therapeutic interventions?
- 5) Is it possible to study adults or animals first? Will older children participate before younger ones?
- 6) Are there legal limits on the rights of parents to consent on behalf of their children?
- 7) Is permission of both parents necessary?
- 8) Will efforts be made to ensure that parents' permission is free from coercion and/or unrealistic promises?
- 9) Are provisions made that show respect for the dignity and rights of children, such as: 1) obtaining their assent, and honoring their dissent; and 2) protecting their need for privacy and confidentiality?
- 10) Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?
- 11) Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?

Notes:

See Chapter 4 of the original "Institutional Review Board Guidebook", http://www.hhs.gov/ohrp/irb/irb_chapter4.htm, for a complete discussion of various types of research designs, identification subjects, and assignment of subjects to experimental and control groups.

See Chapter 6 of the original document for information about other special classes of subjects (e.g., women, cognitively impaired persons, prisoners, etc.)