Concord University
Human Subjects Review Board: Procedures

I. Purpose

The purpose of the Human Subjects Review Board (HSRB) is to protect the rights, dignity, welfare, and privacy of human subjects at Concord University or at other sites where human subjects research is conducted by persons affiliated with Concord University. The HSRB also ensures institutional compliance with ethical considerations contained in the U.S. Department of Health and Human Services' Code of Federal Regulations (CFR Title 45, Part 46: http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/).

II. Authority

A. The HSRB has the authority and responsibility to review and monitor for compliance with sound ethical principles and applicable regulations all research activities involving human subjects conducted by university faculty, staff or students, and all research activities involving university faculty, staff or students as subjects. The HSRB has the authority to approve, require modifications in, or disapprove any such research activities. Research that has been reviewed and approved by the HSRB may be subject to additional review and disapproval by officials of the university. However, those officials may not approve research if it has been disapproved by the HSRB [Federal Policy 46.101].

III. Research With Human Subjects

A. ***Research*** is defined in the Code of Federal Regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

1. Most case studies and most oral histories are not generalizable and, therefore, not research. Many classroom projects, if not intended to be published, are also not considered research. Many program evaluation studies are not research. Most assessment activities are not research.

2. However, if any of the aforementioned types of investigation are conducted with the intention of publication or public presentation of the data collected, they DO qualify as research and must comply with the policies stated in this document.

B. ***Human Subject*** means a living individual about whom a researcher obtains

1. Data through intervention or interaction with the individual

2. Identifiable private information

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes (e.g. experimental research).

Interaction includes communication or interpersonal contact between investigator and subject (e.g. survey research methods such as questionnaires or interviews).

Private Information includes:

- Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.
- Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

Private information must be individually *identifiable* (i.e. the identity of the subject is or may readily be ascertained by the investigator, or associated with the information) in order to constitute research involving human subjects.

Any activity that meets the definition of *research* with *human subjects* involving the collection of individually *identifiable private information* must be reviewed by the CU HSRB and comply with the policies stated in this document.

See Chart 1 of the Human Subject Regulations Decision Charts for further guidance as to whether your activity qualifies as Research with Human Subjects. (http://www.hhs.gov/ohrp/regulations-and-policy/decision-trees/)

IV. Categories of Review

Not all activities that gather information from human participants require review by the HSRB. There are three categories of review performed by the HSRB. These are Exempt Review (Category I), Expedited Review (Category II) and Full Board Review (Category III).

A. Activities that DO NOT Require HSRB Review

The HSRB reviews *research with human participants*. Not all activities that gather information from humans are considered research according to U.S. Department of Health & Human Services Code of Federal Regulations [Title 45, Part 46], and therefore, are excluded from HSRB review. In such cases the investigator does not need to apply for HSRB approval (although the investigator may choose to do so to ensure the activity meets the usual standards for research with human participants). In order to determine whether an activity requires HSRB review, the investigator should consider the following questions:

1. Is the activity a systematic investigation that gathers information about/from living human participants?

2. Is the activity intended or designed to develop or contribute to generalizable knowledge? (*This means the activity is intended to provide data and/or conclusions that generalize beyond a particular place, person, or setting. This also applies to any study intended to result in publication or public presentation.*)

   If the answer to one or both of the above questions is NO, then the activity is not research with human participants UNLESS:

   > It is a class-linked activity that uses research techniques in the collection of data from participants *not enrolled* in the course, which in other circumstances could contribute to generalizable knowledge.

   If the answer to both of the questions above is YES, then the activity is research with human participants and requires HSRB review UNLESS:

   > It examines the effectiveness of educational practices, techniques, or programs, even in settings that include minors as participants, as long as the research examines educational practices that take place in commonly accepted educational settings. Thus research on the effectiveness of instructional programs or techniques (e.g. strategies, assignments, computer exercises, content units, etc.) does not require HSRB review.

   Examples of activities NOT requiring HSRB review

   - Student Teaching
   - Clinical/educational internships and practice
   - Institutional assessment
   - Journals and informal reflections
   - Class demonstrations and laboratory exercises (using student enrolled in class)
   - Information gathered informally for class discussion
   - Journalism
   - Oral histories

B. Policy on Class Projects that Gather Data from Participants Outside the Course

In many research methods or laboratory courses students conduct projects not intended to contribute to generalizable knowledge, but that employ research techniques in the collection of data from participants not enrolled in the course, which in other circumstances could contribute to generalizable knowledge. Because such participants have not enrolled in a course where there is a reasonable expectation that they will participate in research, the participants should be treated the same as participants in any other type of human research. These research activities thus require HSRB review and approval.

The HSRB recognizes the value of such pedagogical techniques and does not wish to impose unnecessary impediments to their use. To balance the concern for protection of human participant with the desire to facilitate such pedagogical techniques, a streamlined procedure has been developed for HSRB review of such projects.

In course that gather information from human participants not enrolled in the class, a professor may submit individual HSRB proposals for projects in the course, or a single proposal describing multiple projects that will occur in a semester, along with the names of students enrolled in the course. Once these activities have been reviewed and received approval, in future semesters, the professor may submit a brief memo to the HSRB that the (unchanged) projects will be performed in the current semester, along with the names of current students. Unless the projects have been changed in a substantive way (changes beyond modifying the order of items in a questionnaire, omitting items, switching from computer to paper-based presentation, change the device used to record observed behavior, etc.) the projects do not need further review.

C. Category I (Exempt Review)

This type of research is exempt from review by the full HSRB, but the appropriate forms and information must still be submitted to the HSRB Chair for review and approval of the exemption. S/he is empowered to make the determination that the research qualifies for "exemption." To qualify for exemption, the research must not involve greater than minimal risk (see definition in Section V.B). If participants can be identified, the research must receive and expedited or full review as described below. The following research activities may qualify for exemption [45 CFR 46.101]:

1. Research conducted in established or commonly accepted educational settings, involving normal education practices such as:
   a) Research on regular and special educational instructional strategies, or
   b) Research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.
   a) If children are involved, procedures are limited to educational tests and observation of public behavior where the investigator(s) will NOT participate in the activities.
   b) Participants CANNOT be identified directly or through identifiers linked to the subjects, OR if participants CAN be identified, directly or through identifiers, any disclosure of the participants' responses outside the research could not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph B above, IF:
   a) The participants are elected or appointed public officials or candidates for public office, OR
   b) Federal statue(s) require(s) without exception that the confidentiality or other personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection of existing data, documents or records (e.g. secondary analysis of existing data) IF:
    a) These sources are publicly available OR IF,
    b) The information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of a federal agency sponsoring the research, and which are designed to study, evaluate or otherwise examine:
    a) Public benefit or service programs
    b) Procedures for obtaining benefits or services under those programs
    c) Possible changes in or alternatives to those programs or procedures
    d) Possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies IF:
    a) Wholesome foods without additives are consumed OR IF,
    b) A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Projects that have been approved by a federally recognized IRB IF:
    a) The approval meets the federal guidelines created for a federally approved OHRP IRB.
    b) The approval has occurred within the last 1 year and is still current
    c) Officially documentation of the approval is provided to the committee with all other necessary paperwork and training for a category I

In the course of evaluation the chair may elect to deny exemption and refer to partial or full committee review if s/he feels that project warrants further concern.

D. Category II (Expedited Review)

This type of research requires review by two HSRB members but does not require full review by the board. The HSRB Chair reviews the submission and if s/he determines that the research fits Category II, the submission is then forwarded to two additional members of the HSRB for their review and approval. Every effort will be made to provide a response within two weeks of submission. To qualify for expedited review, the research must (1) present no more than minimal risk to participants, (2) not involve any of the special classes of subjects, except children as noted below, and (3) involve only procedures listed in one or more of the categories below.

1. Research involving materials (data, documents, records) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

2. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs, or practices, and social behavior); OR
    a) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

E. Category III, Full Board Review

All research that does not qualify for exempt or expedited review must be reviewed and approved by the full HSRB. The basic difference between Categories II and III is that Category III research involves

1. Greater that minimal risk to the participant AND/OR

2. The use of deception AND/OR

3. Special or protected populations

The HSRB Chair may request full HSRB review of any application, even though it may otherwise qualify for exempt or expedited review if s/he has any concerns about any aspects of the application.

The HSRB has four regularly scheduled meeting each academic year. Applications for full board review should be submitted at least one week prior to a scheduled meeting. Primary investigators are often invited to attend the full board review to clarify aspects of the proposed research, but are not present during the approval process.

F. Renewal Request

Projects previously approved by Concord University HSRB or another federally recognized HSRB/IRB may be subject to modified evaluation based on the discretion of the HSRB Chair. A project renewal form will be made available to primary investigators.

V. Guiding Principles: The HSRB guidelines are based on the following general ethical principles

A. *The rights and welfare of all subjects must be adequately protected*. This principle applies to the need for safeguarding the physical and psychological well being of a subject and to the preservation of the rights of privacy and self-determination.

B. *Risks must be minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk*. Risks must be reasonable in relation to anticipated benefits to subjects or to importance of the knowledge that may be gained. The Board reviews research for scientific merit with respect to the risk or benefit to human subjects, including the anticipated benefits from the knowledge that may be expected to result.

1. According to the Office of Human Research Protections (OHRP) ***risk*** means the probability of harm, whether physical, psychological, social, legal or economic. Both the probability and magnitude of possible harm may vary from *minimal* risk to *greater than minimal*. Risks also include:
   - Immediate risks of study participation
   - Risks of breach of confidentiality
   - Inadvertent disclosures
   - Risks of long-term effects

2. Risks should be minimized by screening out prospective participants at undue risk, proper monitoring of procedures once in place, and adequate protection of individual privacy and confidentiality.

3. A ***benefit***, on the other hand, is a valued or desired outcome, an advantage. Benefits of research may accrue directly to the individual participating in the research, or benefit society as a whole, as is often the case in social, behavioral, and educational research.

4. ***Minimal risk*** means "that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Examples:
   - Tests and measures of mental status or memory functioning outside of a clinical setting
   - Standardized IQ tests
   - Personality inventories
   - Consumer preference surveys
   - Other routine information that is not sensitive such as data gathered for educational or employment purposes where there is an expectation of standardized tests or routine examinations

5. ***Greater than minimal risk*** studies include the gathering of personal information that is sensitive or where the conditions are similar to those where an individual might seek professional care or counseling, such as:
   - Parenting problems and practices
   - Depression or grief
   - Illicit drug use or alcohol abuse
   - Self-reporting of criminal behavior
   - Eating disorders
   - Sexual behavior
   - Fertility or termination of pregnancy
   - Sensitive cultural, racial or gender issues

6. Greater than minimal risk studies may also include research procedures that employ deception, covert observations in settings where privacy is expected, collection of data that could result in embarrassment or other personal harms due to a breach of confidentiality, infliction of pain or physical discomfort, use of medical records or protected health information, or the enrollment of participants with impairments, disabilities or psychological disorders.

7. Investigators conducting research that places subjects at greater than minimal risk are advised to provide subjects with contact information for appropriate professional counseling services.

C. *Recruitment and selection of subjects must be equitable and unbiased* within the confines of the purposes and design of the study. Subjects must not be arbitrarily excluded on the basis of gender, race, national origin, religion, creed, education, or socioeconomic status.

D. If an *informed consent form* is required, it must be provide to each subject or the subject's authorized legal representative and signed by each. See Section VII for further information about informed consent.

E. It is the investigator's responsibility to monitor data collected during the research to ensure the safety of subjects. Adequate provisions must be made to protect the *privacy* of subjects and the *confidentiality* of data. In addition, the HSRB must be satisfied that questionnaires and protocols involving sensitive issues (which could, if they became known outside the research, affect economic risks such as employment or place the subject at various physical or social risks) are carefully designed to avoid gathering more personal data than is absolutely essential to the research.

F. Additional safeguards must be included in the study to protect the rights and welfare of subjects who are likely to be *vulnerable* to coercion or undue influence or who belong to potentially vulnerable populations. See Section IX for further information on research with children.

VI. Membership of the HSRB

A. Federal Policy [46.107] provides that each Institutional Review Boards (IRB) shall have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Each IRB shall include at least one member not affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution.

B. Based on the above guidelines from federal policy, the Concord University HSRB will include:

1. One member from each academic college

2. One staff person from the McNair Scholars Program

3. One student

4. One university legal representative

5. One community member who is neither affiliated with the university nor an immediate family member of a person affiliated with the university

C. A list of current HSRB members must be submitted to the Office for Protection from Research Risks (OPPR) and also kept with the HSRB's records [CFR 46.103 and 46.115]. The list must identify members by name, earned degrees, representative capacity, indications of experience (such as board certifications and licenses) sufficient to describe each member's chief anticipated contributions to HSRB deliberations, and any employment or other relationship between each member and the institution (e.g. full-time employee, stockholder, unpaid consultant, or board member). Any changes to the HSRB membership must be reported to the President of the university.

D. Procedures for Selection

1. College members will be selected by their respective college

2. The McNair staff person will be the Director or someone he or she designates

3. The SGA will appoint a student representative

4. The community representative will be appointed by the committee

E. Guidelines for Operation

1. Committee members will serve two-year terms
2. The committee will select a chair at the first meeting of the year. The chair will serve for two years and may/may not be re-elected.

3. An alternate chair will also be selected at the first meeting of the year. This person will serve as chair in cases where the selected chair has a conflict of interest or is otherwise unavailable.

4. The Chair will be responsible for decisions on specific research proposals regarding type of review that is needed. These decisions will be based on the guidelines provided.

5. The university legal representative will be responsible for maintaining a running file of HSRB documents.

F. Outside Consultation

The HSRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues, which require expertise beyond or in addition to that available on the HSRB. These individuals may not vote with the HSRB.

G. Conflict of Interest

An investigator can be a member of the HSRB, however, the investigator-as-member cannot participate in the review and approval process for any project in which she or he has a present or potential conflict of interest. No HSRB member may participate in the review of any project in which the member has a conflicting interest, except to provide information requested by the HSRB. An HSRB member with a conflicting interest in a project should be absent from the meeting room during the discussion and voting phases of the review and approval process. HSRB minutes should reflect whether or not these requirements were met.

VII. Procedures for Review

A. **Submission of Application:** The CU HSRB has three forms available for downloading from the main menu of the HSRB website. The first form is a ***Cover Sheet*** that must be submitted with all proposals for review. The second form is ***FORM 1A*** and must be submitted with Category II and III proposals. The third form is the ***Project Information Sheet***. Questions 1-7 from the Project Information Sheet must be answered for Category I proposals. Questions 1-11 must be answered fro Category II submissions, and questions 1-16 must be answered for Category III submissions.

B. **How Long Will the Review Take?:** All proposals should be submitted to the HSRB chair. The chair is responsible for determining that 1) all appropriate paperwork has been submitted and 2) the review category indicated by the researcher is the appropriate category. The length of time for approval of a proposal depends upon the category of research.

1. Category I (Exempt): Reviewed by the chair only. Turnaround time for approval is usually 3-5 business days, but may longer if corrections or additions are required.

2. Category II (Expedited): Reviewed by the chair and two other members of the HSRB. The chair will keep a rotation list to determine the two additional reviewers. Turnaround time for approval is 2 weeks or less.

3. Category III (Full Board Review): Reviewed at a meeting of the full HSRB. The board meets four times a year. Dates of these meetings will be determined at the first HSRB meeting of each academic year. These dates will then be posted on the HSRB website. Researchers must submit applications to the chair at least one week prior to a scheduled meeting in order to ensure time for distribution and consideration by board members prior to the meeting.

C. Factors Considered in HSRB Reviews

1. Risks to subjects are minimized

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be reasonably expected to result

3. Selection of subjects is equitable

4. Informed consent will be sought from each prospective subject or the subject's legal representative

5. Informed consent will be documented

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

D. **Considerations of Research Design:** The responsibility of the HSRB is the protection of human subjects who participate in research activities. Usually, the authority of the HSRB does not extend to the assessment of research design and methodology. However, if the study is sufficiently flawed in design or methodology such that greater than minimal risk is present for participants, the HSRB may disapprove or require modifications to the research protocol.

E. **Re-Approvals**: HSRB approvals may be given for periods of time not exceeding 12 months. If an approved project is not completed in the time period specified in the original approval, re-approval is required. Re-approval requires the same process as the original approval. If the HSRB gave expedited approval for the original request, and if there have not been adverse incidents and if the level of risk has not changed, the Chair may give a re-approval. If the original request was approved the full HSRB, it must go back to the full HSRB for re-approval unless the following conditions apply, in which case the HSRB chair may give expedited approval:

1. The research is permanently closed to enrollment of new subjects

2. All subjects have completed all research-related intervention

3. The research remains active only for a) long-term follow-up of subjects or b) data analysis

F. **Cooperative Research:** For projects covered under this policy that involve more than one institution, each institution is responsible for protecting the rights and welfare of

human subjects and for complying with the U.S. DHHS Title 45, Part 46 Protection of Human Subjects.

G. **Suspension or Termination of HSRB Approval:** The HSRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the HSRB requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval will include a statement of the reasons for the HSRB's action and will be reported promptly to the investigator, and appropriate university officials.

VIII. HSRB Records

A. The HSRB will maintain documentation of the following activities

1. Copies of all research proposals reviewed

2. Minutes of HSRB meetings to include the following information:
   a. Attendance
   b. Actions taken
   c. The vote on these actions including the number of members voting for, against, and abstaining
   d. The basis for requiring changes in or disapproving research
   e. A summary of the discussion of issues and their resolution

3. Records of continuing review activities

4. Copies of all correspondence between the HSRB and investigators

5. A list of HSRB members

6. Written procedures for the HSRB

B. The records required by this policy shall be retained for at least 3 years, and records relating to research, which is conducted will be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the University at reasonable times and in a reasonable manner.

IX. Informed Consent

A. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legal representative. The investigator must provide the prospective subject or the representative sufficient

opportunity to consider whether or not to participate, and minimize the possibility of coercion or undue influence. The information that is given, whether written or oral, must use language that is understandable to the prospective subject or representative. No informed consent may include language through which the subject or the representative is made to waive any of the subject's legal rights, or release the investigator or the University from liability for negligence.

B. Basic elements of informed consent:

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

2. A description of reasonably foreseeable risks or discomforts to the subject.

3. A description of any benefits to the subject or to others, which may reasonably be expected from the research.

4. A disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject.

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

6. For research involving more than minimal risk, an explanation as to whether any counseling or medical treatments are available and, if so, where further information may be obtained.

7. Information about whom to contact for answers to questions about the research, research subjects' rights, and whom to contact in the event of research-related injury or harm to the subject.

8. 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.

C. The HSRB may approve a research protocol which does not include, or which alters, some or all of the elements of informed consent outlined above, or waive the requirement to obtain informed consent if the HSRB finds and documents that:

1. The research involves no more than minimal risk to subjects.

2. The waiver or alteration will not adversely affect the rights or welfare of subjects.

3. The research could not practicably be carried out without the waiver or alteration.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

D. Documentation of Informed Consent:

1. Informed consent will be documented by the use of a written informed consent form approved by the HSRB and signed by the subject or the subject's legal representative. A copy shall be given to the person signing the form.

2. The HSRB may waive the requirement for the investigator to obtain a signed consent form if it finds that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether he or she wants documentation linking the subject with the research, and the subject's wishes will govern.

X. Use of Federal Funds

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

XI. Additional Protections for Children as Subjects of Research

A. The HSRB recommends that investigators wishing to conduct research with children as subjects make every effort to design research protocols that present no more than minimal risk and, therefore, fall under Category I (exempt). All of the activities described as qualifying for Category I review apply to children EXCEPT that described in sub-section B.

1. If children are involved in research involving the use of educational tests, surveys, interviews or observation of public behavior, the investigator CANNOT participate in the activities.

B. Research involving greater than minimal risk to children as human subjects (Category II or III) must meet the following criteria:

1. The research has the potential to provide direct benefit to the individual subject.

2. The risk is justified by the anticipated benefit to the subject.

3. The risk represents only a minor increase over minimal risk.

C. Requirements for permission by parents or guardians and for assent by children

1. If children as prospective subjects of research are capable of giving assent, the researcher must create an appropriate procedure for obtaining assent.
    a. In determining whether children are capable of assenting, the ages, maturity and psychological state of the children involved should be taken into consideration.
    b. If the HSRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the research has the potential of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, assent is not a necessary condition for proceeding with the research.

2. The researcher must obtain the permission of each child's parent or guardian.

3. Documentation of assent by children, if required, and permission of parent or guardian must be maintained.

XII. Additional Protections for Prisoners as Subjects of Research

Because the constraints created by their incarceration could affect the ability of prisoners to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners as subjects in research.

A. Composition of the HSRB where prisoners are involved

1. A majority of the board will have no association with the prison(s) involved in the research.

2. At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity. (46.304(b)).

B. Necessary criteria for approving research with prisoners

1. Any possible advantages to the prisoner through participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not so great that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

2. The risks involved in the research are equivalent to the risks that would accepted by non-prisoner volunteers.

3. Procedures for selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

4. The information is presented in language, which is understandable to the subject population.

5. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole.