



Procedures for Research Involving Human Participants

Approved by
UNC's Institutional Review Board
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Preface

These policies and procedures were designed to assist faculty, staff, and students at the University of Northern Colorado (UNC) who conduct research with human participants (i.e., subjects). This document describes UNC's Institutional Review Board (IRB), the policies which govern research with human participants, and the procedures UNC researchers must follow.

Novice researchers and those new to UNC should read the entire document, whereas experienced UNC researchers may use this as a reference document when they prepare the *UNC-IRB Application*.

The use of human participants in research at the University of Northern Colorado is addressed by University Regulation 3-8-104, enacted by the Board of Trustees to ensure that all research carried out under the auspices of UNC conforms to ethical standards:

3-8-104 Human Subjects. It is the policy of the University that all research and research-related activities, in which humans are used as subjects, shall be subject to review under current Public Health Service regulations by an Institutional Review Board (IRB). The involvement of human subjects in research covered by this policy shall be prohibited until the IRB has reviewed and approved the research protocol. Current IRB procedures can be found in the Graduate School's thesis and dissertation manuals or obtained directly from the Graduate School.

The *UNC-IRB Application* is a separate document. It must be accessed at <http://www.unco.edu/research/pdf/research-integrity/irb/writing-an-irb-application-narrative.pdf> and downloaded for use. In addition, the same *UNC-IRB Application* is common for all types of IRB review (exempt, expedited, and full board), which is a change from the policy document.

Purpose of the Institutional Review Board

UNC's Institutional Review Board (IRB) reviews all proposed research, which involves human participants, and is conducted under the auspices of the institution (e.g., by faculty, students, staff). The board helps to ensure that UNC researchers conform to ethical standards and thus shares responsibility for the protection of human participants, researchers, and the university. Furthermore, the board is committed to carrying out this charge in a manner that will support and assist researchers.

For research and research-related activity involving human participants, UNC is guided by the ethical principles set forth in the *National Commission for the Protection of Human Subjects of Research: The Belmont Report* and is guided by the procedures of Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46).

The following principles are primary considerations of the UNC IRB:

1. Researchers must provide for the safety, health, and welfare of participants. Rights, including the right to privacy, must not be unduly infringed upon.
2. The direct or potential benefits to the participant and/or the importance of the knowledge gained must outweigh the inherent risks to the participant; risks are always to be minimized.
3. Participation must be voluntary and informed consent must be obtained, unless these requirements are waived by the IRB (waivers are covered in this document).
4. An individual does not give up any rights by consenting to participation and has the right to withdraw from a project at any time or may refuse to participate without loss of benefits to which the participant is otherwise entitled.
5. Information about participants is to be safeguarded (i.e., researchers must maintain confidentiality, to the extent allowed by law).

Essentials for UNC Researchers

Research Defined

The Code of Federal Regulations (CFR), which governs much of UNC's policy regarding research with human participants, contains the following definition:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. ----- 45 CFR §46.102 (d)

UNC's IRB considers "generalizable knowledge" as research results that are published, bibliographically available (e.g., theses and dissertations), presented outside the university (e.g., professional conference), or developed for others to build upon (e.g., pilot data for an investigator from another institution).

Responsibilities

The responsibility for maintaining ethical standards and protecting human rights rests with the individual researcher (and research advisors of UNC students). The IRB review is required as an added measure of assurance and as a local resource for the interpretation of ethical guidelines. Engaging in research with human participants without IRB approval puts the researcher and institution at risk and constitutes a violation of University policy.

Along with meeting the specific requirements of a particular research study, investigators are responsible for ongoing requirements in the conduct of approved research that include, in summary:

- ✓ obtaining and documenting informed consent of participants or participants' legally authorized representatives prior to participation in research, unless these requirements have been waived by the IRB;
- ✓ obtaining prior approval from the IRB for any modifications of previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to participants (in cases of emergency adjustments to informed consent, the IRB should be notified as soon as possible thereafter); and
- ✓ ensuring that progress reports and requests for continuing review and approval are submitted to the IRB in accordance with the policies, procedures, and actions of the IRB as referenced in the institution's OHRP-approved Federalwide assurance.

In certain circumstances, investigators also would be responsible for meeting the following additional regulatory requirements:

- ✓ providing to the IRB prompt reports of any unanticipated problems involving risks to participants or others;
- ✓ providing to the IRB prompt reports of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB; and
- ✓ keeping certain records as required by the HHS regulations for at least three years after completion of the study.

- ✓ complying with requests for information from the IRB about adherence to approved procedures after the onset of data collection.

(Some of the previous text is taken from the OHRP web site, <http://www.dhhs.gov/ohrp/>)

Research in the Classroom, Pilot Studies, Program Evaluations

In the classroom, research-related activity whereby data from participants who are not class members are collected by students as a class exercise or for course credit and for which the findings are not expected to be disseminated beyond the university context, is the responsibility of the instructor. Instructors supervising such research-related activity must be familiar with IRB policies and issues, as reflected in this manual, in order to ensure that participants in student projects are treated ethically (e.g., risks are low, written informed consent is obtained as necessary, confidentiality is maintained). It is recommended that instructors complete on-line training prior to supervising such projects (contact an IRB co-chair for further information).

If the students in a course are to engage in research, as defined on page 5, then the instructor is responsible for obtaining prior omnibus IRB approval for all projects (see Additional Considerations – Course-Based Research section in this manual). This omnibus approval must be renewed every four years. Instructors supervising course-related, student research must be familiar with IRB policies and issues in order to ensure that research participants are treated ethically (e.g., risks are low, written informed consent is obtained as necessary, confidentiality is maintained). Instructors must complete on-line training prior to supervising such projects and document the training as part of the omnibus IRB application process.

Pilot research may take many forms. Sometimes pilot data are disseminated by presentation or publication or in a report to a granting agency, other times they are not. Sometimes pilot research involves testing a survey instrument with colleagues or students, perhaps as part of an educational exercise. Other times it might involve an experimental manipulation with participants (sometimes from vulnerable populations) from outside the university. Researchers are urged to err on the side of caution and to consult with an IRB member if uncertain how to proceed.

IRB approval is not needed for curriculum projects, workshop evaluations, and administrative review projects (program evaluations) if results are not to be distributed outside of the institutional setting.

If, after the fact, it is thought that data collected for a non-research project are worthy of dissemination to a wider audience, then an IRB application is required for what is then considered archival research (i.e., research activity involving already-collected data).

In all cases, the definition of research, provided at the beginning of this section, should help guide researchers on whether or not IRB approval is necessary.

Considerations for UNC-IRB Approval

Overview

When the IRB reviews a protocol, it determines whether the following requirements are satisfied (45 CFR §46.111 a).

1. Risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of participants is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by 45 CFR § 46.116.
5. Informed consent will be appropriately documented.
(*see Informed Consent and The Informed Consent Document section for details*)
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, persons with mental disabilities, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

Review Categories

Research involving human participants or data derived from human participants falls into one of three categories:

EXEMPT (requires 1 reviewer → an IRB co-chair)

- ✓ approval for 4 years
- ✓ reviews typically take 2 to 3 weeks (reviews may take longer if researchers do not respond rapidly to any concerns raised by the co-chair)

EXPEDITED (requires 2 reviewers → an IRB member + an IRB co-chair)

- ✓ approval for 1 year (continuation request required for longer duration)
- ✓ reviews typically take 3 to 4 weeks (reviews may take longer if researchers do not respond rapidly to any concerns raised by the IRB member or co-chair)

FULL BOARD (requires all IRB members to review and a meeting to be convened)

- ✓ approval for 1 year (continuation request required for longer duration)
- ✓ reviews typically take 4 to 6 weeks during the academic year and are not conducted during the summer

Researchers initially select the category for their proposed research and then complete the *UNC-IRB Application* based on that determination. Final determination of the category rests with UNC's IRB. The IRB co-chair will advise the researcher if elements in the application are deemed to warrant a different category than the one selected by the researcher.

The following sections describe the three categories in some detail in order to assist researchers in determining which review category fits their proposed research.

EXEMPT

Generally, research that does not propose to disrupt or manipulate participants' normal life experiences, or incorporate any form of intrusive procedures, may be classified as exempt. According to 45 CFR §46.101 (b), research activities in which the only involvement of human participants will be in one or more of the following six categories are considered exempt:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of 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, unless: (i) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

Review Categories (continued)

EXEMPT

(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 2 above if: (i) The human participants are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) 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, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level 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.

EXEMPT STATUS DOES NOT APPLY TO RESEARCH INVOLVING pregnant women, fetuses, human in vitro fertilization, and prisoners.

EXEMPT status described in item 1 may in special circumstances apply to children, but the educational setting and procedures for data collection will be scrutinized closely by the IRB co-chair.

Furthermore, the exemption in item 2 DOES NOT APPLY TO CHILDREN, EXCEPT for research involving observations of public behavior when the researchers do not participate in the activities being observed. When observational studies with children are considered exempt, the IRB co-chair will examine the research procedures with utmost caution.

Review Categories (continued)

EXPEDITED

Research that is judged to involve **no more than minimal risk** to participants and includes appropriate informed consent procedures can be classified as expedited.

“**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” (45 CFR §46.102 (i)).

Often, research involves at least minimal levels of risk to human participants (e.g., mild anxiety, embarrassment, physical discomfort, etc.). It is the researcher's responsibility to consider ALL possible risks.

As risks arise, the researcher must implement safeguards. Examples of safeguards against improbable events are: emergency medical procedures in the event of unexpected accident, seizure, or illness during the data collection and emergency psychotherapeutic procedures in the event of unexpected psychological trauma. The greater the probability of any such risk, the greater the responsibility of the researcher to provide such safeguards for the protection of participants' safety and well being. Other risks to consider, though not an exhaustive list, would include: possible excessive negative reaction of participants to the introduction of sensitive stimulus information during the research procedures, the potential for extreme effects on participants' relationship status as a result of research participation, any strong reactions to procedures that may violate participants' belief systems, and the possibility of moral violations as perceived by the participants.

In instances where the research might cause an adverse emotional reaction in the participant, researchers should identify a contact organization (including a phone number) that can help participants work through the emotional response evoked by the research.

The following pages detail the federal criteria for expedited research.

Review Categories (continued)

EXPEDITED

Research activities that:

1. present no more than minimal risk to human participants, AND
2. involve only procedures listed in one or more of the categories described.

NOTE: Activities should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

The categories in this list apply regardless of the age of participants, except as noted.

The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing; unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Categories of Research That May Be Reviewed by the IRB through an Expedited Review Procedure (Source: 63 FR 60364-60367, November 9, 1998)

- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - (b) from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Categories of Research That May Be Reviewed by the IRB through an Expedited Review Procedure (continued)

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR §46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes. (*See Additional Considerations for exceptions*)

Categories of Research That May Be Reviewed by the IRB through an Expedited Review Procedure (continued)

(7) 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 research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 §CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB (i.e., full board review) as follows:

- (a) where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or
- (b) where no participants have been enrolled and no additional risks have been identified; or
- (c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Review Categories (continued)

FULL BOARD

Research that is judged to involve **more than minimal risk**, as defined earlier in this document, must be submitted for full-board review. Full-board review is necessary when researchers plan to use procedures that are personally intrusive and/or have the potential to produce stress or trauma beyond what is likely to be encountered by the participants in their everyday lives.

The lead investigator and all co-investigators must submit evidence of ethics training. They are to complete the CITI Training that is on-line at <http://www.unco.edu/research/research-integrity-and-compliance/responsible-conduct-of-research/citi-training-in-the-responsible-conduct-of-research.aspx>. The available certification of completion must be submitted with the IRB application.

Full-board reviews are conducted only during the fall and spring semesters. When an application for full-board review is submitted in IRBNet it is forwarded to one of the IRB Co-Chairs who verifies its status and then calls for a meeting of the entire board. The lead investigator is invited to present the proposal to the board at this meeting. After presenting the proposal and answering any questions, the lead investigator is excused from the meeting while the board deliberates and then votes to approve (as is, or with revisions), not approve, or table (e.g., if more information needs to be gathered or an expert external to the board consulted). Please note that it may take several weeks to convene a full-board meeting and full-board meetings are not conducted during the summer.

Informed Consent and The Informed Consent Document

The process of obtaining informed consent must comply with the requirements of 45 CFR §46.116. Documentation must conform to 45 CFR §46.117. *Above all, it should be noted that informed consent is a process, not just the presentation of a form or the collection of a signature.* The information provided to prospective participants must enable an individual to make an informed decision about whether to volunteer for participation. As such, the informed consent process is a fundamental mechanism demonstrating respect for the individual. Because the process is intended to inform the potential participant, “lay language” should be used and scientific jargon or “legalese” avoided to the extent that is possible. It is important to think of the informed consent document as an educational tool as well as a legal contract. The written presentation of information provides the basis for consent and, because a copy is retained by the participant, is useful for future reference.

Examples of informed consent documents are included within an appendix. Waivers to standard consent procedures and documentation are addressed in the next section.

Standard Informed Consent Documentation

Most studies require a standard, written consent document. The consent document ***must be prepared on UNC letterhead stationary (or with UNC logo)*** in language that participants can clearly understand, and it must:

1. State the following, ***verbatim***, at the top of the form:
CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH
2. Include a descriptive title, the name and phone number of the lead investigator and, ***if the lead investigator is a student, also the name and phone number of the research advisor***. Please specify school/program affiliation.
3. Describe the general purpose and nature of the study in easily understood language.
4. Describe clearly and completely what the participant will be asked to do, the type of data to be collected, where and when data collection will occur, and the expected duration of the participation. If data collection is through questionnaire or interview, please describe the types of questions to be asked or include examples of questions. If some questions will be of a sensitive nature, be explicit in your description or be sure to include as an example one of the more sensitive questions.
5. Describe the procedures for maximizing confidentiality (***do not just state that details of participation will be kept confidential and do not guarantee confidentiality***). Researchers should note that anonymity and confidentiality are not the same. When data are anonymous, researchers and others do not know from whom the information came. Because researchers usually collect data directly from participants or use other mechanisms such as the Internet that can sometimes be traced back to individuals, data are rarely anonymous. When data are kept

confidential, the researcher knows the source but strives to protect the privacy of the information.

6. Describe the risks and benefits of participation (include even minor risks/discomforts, any costs or compensation to the participants, as well as benefits to the discipline). **Do not just state that risks are minimal.** Examples of acceptable forms of the risks statement (when applicable) might be “there are no foreseeable risks” or “the risks inherent in this study are no greater than those normally encountered during regular classroom participation.” If participants are students, patients or employees of an institution in which research is being conducted, they must be informed that nonparticipation or withdrawal from the study will not affect their grade, treatment, care or employment status, etc. If researchers wish to offer student-participants extra credit for a course, an alternative source of extra credit (of equal value and comparable effort) **must be made** available for students not wishing to participate.
7. For research involving more than minimal risk (i.e., full-board review), describe the procedures to be used if the risk is realized and who will pay for treatment/assistance.
8. ***Immediately prior to the signature line, include verbatim the following statement in cases of adult participation:***

Participation is voluntary. You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please sign below if you would like to participate in this research. A copy of this form will be given to you to retain for future reference. If you have any concerns about your selection or treatment as a research participant, please contact the Office of Research, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

In cases of parents or guardians, use this verbatim statement:

Participation is voluntary. You may decide not to allow your child to participate in this study and if (s)he begins participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please sign below if you would like to participate in this research. A copy of this form will be given to you to retain for future reference. If you have any concerns about your selection or treatment as a research participant, please contact the Office of Research, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

9. Signatures – Be sure to include space and lines for signatures from both the participant and the researcher.

Standard Informed Consent Documentation (continued)

In addition to the elements of a standard informed consent document:

- ✓ All participants must read, and sign the consent form.
- ✓ Participants must be given an opportunity to have questions about the research answered prior to their participation.
- ✓ Participants must retain a complete copy of the consent form (it need not be a signed copy).
- ✓ All signed consent forms must be retained for three years after the completion of the project. When the lead investigator is a student, it is the research advisor's responsibility to maintain the signed consent forms. These forms must be kept **on the UNC campus**.

Retaining & Storing Signed Informed Consent Documents

Signed informed consent forms are legal documents, and the researcher has legal responsibilities in handling them. They should be stored in a secure location, which is accessible to the University in the event that an inquiry should require an examination of them. Access to these documents should be limited to those persons who have a need to know their contents, ordinarily the investigator (and co-investigators), a representative of the IRB, the IRB Administrator on behalf of the University, and authorized federal officials. In compliance with federal regulations consent documents must be retained for a period of three years following the completion of the research.

Consent documents become part of the IRB file of a project and, as such, are subject to Federal audit. Therefore, the IRB will review carefully both the content of and the storage provisions for all consent forms. The Project Continuing Review Form requires an account of the exact location, the method of storage, and the names or titles of individuals (other than University and federal officials) having access to the consent documents. The IRB cannot approve the continuation of projects that omit this information.

Waivers to Standard Consent Procedures

Under certain circumstances, elements of a standard consent process may be waived. All waivers must be approved by the IRB, and requests for waiver must be fully justified by the researcher when submitting an application to the IRB.

According to 45 CFR §46.116 (c) and (d), **the IRB may approve a consent procedure that does not include, or that alters, some of the elements of informed consent (i.e., the process), or waive the requirement to obtain informed consent.** This section applies to benefit and service programs and experimental studies that could not practically be carried out with standard consent procedures.

Regarding benefit and service programs, the IRB must conclude that:
see 45 CFR §46.116 (c)

(1) the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs;

AND

(2) the research could not practicably be carried out without the waiver or alteration.

Waivers to Standard Consent Procedures (continued)

In addition, the IRB may waive part or all of the normal consent requirements if:
see 45 CFR §46.116 (d)

- (1) the research involves no more than minimal risk to the participants;
- (2) the waiver or alteration of normal consent procedures will not affect adversely the rights and welfare of the participants;
- (3) the research could not be carried out practicably without the waiver or alteration;

AND

- (4) whenever appropriate, the participants will be provided with additional pertinent information after participation.

This latter category of waiver includes those cases in which an investigator desires to withhold from the participant some information about the project that, if known by the participant, would bias the results of the study. Ordinarily, the investigator will plan a debriefing session after completion of a person's participation in order to provide the participant with the missing information; the investigator will also ordinarily give the participant the option of including his/her data in the study or having it destroyed. In no case should an investigator seek to withhold information about the research or the participant's role in it solely to reduce the chances of refusal to participate by potential participants.

Waivers to Standard Consent Procedures (continued)

According to 45 CFR §46.117, **the IRB may waive the requirement for the investigator to obtain a signed consent document** for some or all participants if it finds either:

- a. that the only record linking the participant and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality.

OR

- b. that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context.

This waiver applies especially to interviews (including face-to-face and telephone interviews) where the investigator's sole knowledge of the identity of the interviewee would come from the consent document.

Waiver of written consent procedures does not imply waiver of the researcher's responsibility to obtain voluntary participation. In all cases, the researcher must provide the participant with a statement of the research that includes all relevant elements of informed consent. It is the recommendation of the UNC IRB that, wherever practical, when an Informed Consent Form is waived, a cover letter be submitted to participants that contains the same elements as the informed consent form, but which is retained by the participant rather than signed and returned. The cover letter must include a statement such as "completion of the survey and/or return of the questionnaire indicates consent to participate in the study."

This procedure is applicable when participant risk is very low and preservation of anonymity is enabled (i.e., participants' identities remain unknown to the researcher). It is recommended that researchers conducting exempt-status projects consider this approach in order to preserve anonymity and to eliminate the need for maintaining and storing consent forms for three years following completion of the project. The participant must also be given a clear and free choice to accept the invitation to participate or to refuse without prejudice or penalty. If participants are students, patients or employees of an institution in which research is being conducted, they must be informed that nonparticipation or withdrawal from the study will not affect their grade, treatment, care or employment status, etc.

Research with Children & Other Vulnerable Populations

Subparts B, C, and D of 45 CFR address research with pregnant women, human fetuses, and neonates (B), prisoners (C), and children (D). If a researcher wishes to conduct research with participants described by subparts B or C, they must contact a co-chair for clarification.

Because of UNC's focus on education-based research, the additional protections regarding children are addressed in this section, which is based on 45 CFR §46.401 – §46.409.

Research with Children

Conducting research involving children – persons under 18 years of age – requires special attention to the child's age, his/her ability to understand what is asked of him/her, and his/her relationship to parents or guardians. In all cases, the investigator must demonstrate respect for the rights of the participant within the proposed consent procedures, which should be developmentally appropriate to the age and circumstances of the participant.

Research involving greater than minimal risk must be thoroughly justified by the anticipated benefits to participants or by the anticipated generalizable knowledge.

Researchers must obtain permission from parents (guardians) **AND** assent from the minor participant. “*Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be considered as assent.” (45 CFR §46.402)

Children ages 10-18 are required to sign a **written assent form**. For older adolescents (15-17 years) this may be the same consent form signed by the parents with an additional signature space for the adolescent, provided that the language of the consent form may be easily understood by the adolescents. For 10-15 year-olds, a separate assent form, less detailed than the parents' and written in simplified language, is desirable.

Children younger than 10 are required to provide **verbal assent**. That is, the researcher must explain the project activities and ask if they wish to participate. It is a good idea to have verbal assent witnessed by an independent party such as the teacher or parent. If a child chooses not to participate, the decision must be honored. As with adult participants, the researcher must allow children the opportunity to ask any questions about their participation. Researchers must clearly describe the procedure for obtaining assent in the IRB proposal. Additionally, the investigator must use special care to discontinue the participation of children who appear to experience undue stress from the research procedures. A verbal script must be submitted as part of the protocol.

Research with infant participants is best conducted with a parent present.

If the intended participants are **wards of the state**, additional safeguards may be necessary. For example, the IRB may require for each child appointment of an advocate in addition to any other individual acting on behalf of the child. (45 CFR §46.409)

Research with Children – Parental Permission & Participant Assent

Requirements for permission by parents or guardians and for assent by children are described in detail in 45 CFR §46.408. The main points are summarized below.

Adequate provisions must be made for soliciting the assent of children for participation in research. The IRB will take into account the ages, maturity, and psychological state of children involved in research for the purpose of determining whether a child is capable of assenting to participate.

The IRB may waive the assent requirement under circumstances in which consent (for adults) may be waived (see the Waivers to Standard Consent Procedures section). This must be thoroughly justified in the IRB application.

Researchers may only need permission from one parent or guardian for research not involving greater than minimal risk or for research involving greater than minimal risk but presenting the prospect of direct benefit to individual participants.

Permission from parents or guardians shall be documented in accordance with and to the extent required by 45 CFR §46.117 of Subpart A. (45 CFR §46.408)

Under certain circumstances, the IRB may waive the requirements for obtaining parental or guardian permission if a researcher justifies and documents this need under either 45 CFR §46.116(c) or (d) (see pages 18 and 19 of these guidelines).

Additional Considerations

Audiorecordings: Exempt or Expedited?

In an effort to clarify the use of audiorecordings in a human participants research study, the IRB at UNC offers the following guidance.

For a study that proposes to use audiorecordings and would be considered for Exempt Review, the conditions of Exempt Category 2 must be met. If these conditions are not met, then the study falls under Expedited Category 6 and must undergo an Expedited Review.

As a reminder, exempt Category 2 is:

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

Expedited Category 6 is:

Collection of data from voice, video, digital, or image recordings made for research purposes.

As part of an Exempt IRB application, researchers using audiorecordings should address the following in their application:

- Does the study exhibit any characteristics of an expedited study?
- Will the topic of the research cause enough discomfort to participants that the study involves minimal risk?
- How will participants' identities be kept confidential?
- How will the data be handled and stored?
- Who will have access to recordings?
- When will audiorecordings be destroyed?

Furthermore, because participants have the right to know where and for how long audiorecordings of their interviews will be stored, investigators will include their procedures for storing and disposing of audiorecordings in consent forms along with a schedule for disposal (e.g., researchers may state either that they will dispose of audiorecordings after transcription or after a three-year period).

Deception: Expedited or Full Board?

When describing the purpose and description of research to prospective participants, researchers should not be misleading or untruthful. However, there are times when full disclosure would jeopardize the research. The nature of the deception dictates whether an **expedited review** or **full-board review** is necessary.

For example, participants might not be informed of the actual purpose of certain procedures in order to obtain unbiased results. No more than such mild deception can be tolerated in a study submitted for **expedited review**. However, researchers should be aware that information that may affect the objectives of the study may not be withheld if it relates to the risks participants may face and hence might affect their willingness to participate.

Any intentional deception involving misleading or untruthful information provided to participants must be considered in a **full-board review**. Further considerations for this type of research follow.

Intentionally misleading or providing untruthful information to participants is not considered a desirable procedure. All other possible alternative research strategies should be explored and eliminated before settling on a deceptive approach. Should a researcher choose to implement a deceptive strategy, it will be necessary to provide a clear justification of the procedure to the IRB as well as additional measures to protect participants.

Justification for the use of “more-than-mild” deception must consider:

1. *Alternatives*: Alternative research methods that would not require the adoption of deceptive practices (e.g., role playing, gaming approaches, simulation strategies, etc.).
2. *Value*: The value of the research being conducted. Though scientific gain is not a total justification, it is necessary to demonstrate increased benefit to offset the increased participant risk where deception is involved.
3. *Safety*: Steps taken to further insure participant safety. Deception is taking advantage of the participant's willingness to participate and thus renders the participant vulnerable to increased psychological or physical harm. Steps must be taken, and clearly explained in the proposal, to protect against harm to the participants.
4. *Debriefing & Apology*: Where deception is used and the consent document intentionally omits information or misleads the participant, it is important to repair this deficiency. A thorough debriefing of the participants is desirable, in which the deceptive strategy is explained and justified and an apology for the deception is issued. Deceptions with potential long-term negative implications for participants should be avoided. It is also desirable, at the time of debriefing, to allow participants to withdraw permission to include their data in the results and to destroy any records of their participation.

Course-Based Research

Requirements for Omnibus IRB Approval for a Scheduled Course

Students conducting research for course credit in a normally scheduled course (i.e., not for directed studies, thesis, dissertation credits) may have their IRB application reviewed by the course instructor if the instructor has Omnibus IRB Approval for the course. Omnibus IRB Approval for a scheduled course covers only *exempt-status* research projects conducted by students registered for the scheduled course. It is the instructor's responsibility to obtain the Omnibus IRB approval prior to the conduct of any research. Instructors of a normally scheduled course that has an existing Omnibus IRB approval may be added to the existing approval **if they have completed the required CITI** training. For information, contact Sherry May.

If students wish to engage in research that falls under *expedited* review, the student, with the instructor acting as the research advisor, must submit an application to the IRB in accordance with the guidelines outlined in this document. Instructors should notify students whose research is in the *expedited* category to put the word **OMNIBUS** at the beginning of the project title when submitting an application in IRBNet. This will inform the IRB that it is a classroom project. The instructor, by signing off on the student's research in IRBNet, gives approval as first reviewer.

Requirements for Omnibus IRB Approval for a Scheduled Course

- Instructors supervising course-related, student research should be familiar with IRB policies and issues to ensure that research participants are treated ethically (e.g., risks are low, informed consent policy is followed, confidentiality is maintained).
- Instructors should complete the Human Research Course, Social and Behavioral Research Investigators, in the on-line CITI training program (<https://www.citiprogram.org/default.asp>) prior to supervising such projects; and they must document the training as part of the Omnibus IRB application process.
- Instructors should submit an exempt-status IRB application via IRBNet (<https://www.irbnet.org>) for the course in which students will be conducting research. Types of research projects should be mentioned within the narrative of this IRB application.
- Instructors should include a copy of the course syllabus in the IRB application.
- Instructors should have students submit an exempt-status IRB application as part of the course requirements. The instructor will review these for IRB-related concerns.
- Instructors should keep a record of all exempt-status applications completed by students under their guidance.
- Instructors should send a list of student's names and project titles to the Office of Sponsored Programs, attention Sherry May, at the end of the semester.

Omnibus IRB Approvals must be renewed every four years.

Research Involving Students

Researchers conducting studies that involve recruitment of participants who are also students enrolled in courses that they teach or mentor the instructor/graduate student

teaching the course, must include a clear statement that addresses this duality and respect for students' voluntary involvement in the research. This statement is necessary for students to be informed, and to understand that when their professor/instructor is also a researcher who is recruiting their participation in a study, it is not coercive in nature and will have no impact on course/program evaluation or grade. This statement should be included in *all* communications (e.g., recruitment scripts and invitation letters) as well as informed consent forms.

An example statement to be included in an informed consent is: "Your decision to participate in this study, or not, will have no impact on your evaluation in this class or affect your course grade."

Data Security

An important part of an application to the IRB is the plan that protects data from improper disclosure. In our increasingly computerized world, that plan must address storage and processing of data on personal computers, UNC servers, and any other systems that allow access, exchange, and storage of personal information about research participants.

At UNC, the **Data Security Policy for Research Projects:**

<http://www.unco.edu/research/pdf/research-integrity/unc-data-security-policy-for-research-projects-policy-pdf.pdf> provides guidance on protection of data. In most UNC research, investigators need to be vigilant but can follow such familiar strategies as using a password-protected computer. Examples of these data that need to be protected but do not require extensive security include interviews and surveys about topics yielding data, if disclosed, would generally not put identified individuals at civil liability or material harm. Occasionally researchers handle information that, if made public, could cause significant harm or violate federal law. Examples include, but are not limited to, data that contain social security numbers, medical records, some education records, personal financial records, and admissions of criminal acts. These data obviously warrant serious precautions. Individuals who collect, store, or exchange this kind of highly sensitive information need to submit a data security clearance form to Information Management and Technology (IM&T) for approval. Researchers entering into data agreements with other institutions are also required to submit a data security clearance form to IM&T. Researchers who are working with these kinds of data are encouraged to submit simultaneous applications to IM&T and the IRB, as these two groups are coordinating their reviews to ensure timely approvals. The data security policy applies to any individual (faculty, student, or staff) working on a research project as part of his or her affiliation with the University of Northern Colorado and collecting, receiving, transmitting, or storing personally identifiable data.

On the coversheet for an IRB application, researchers are asked to testify that they have examined the data security policy and to specify the particular security level of their data (level 1 through 5, as determined in the data security policy). In a situation in which a researcher has identified a security level 3, 4, or 5 data arrangement, the researcher must submit a data security clearance form to IM&T and advise the IRB when that application is approved. All researchers are expected to follow the methods for protecting their data that are aligned with their level.

Initiation, Continuation, Revision, Conclusion of IRB Approval

Approval for UNC IRB applications will be sent to the lead investigator and the faculty advisor (if the lead investigator is a student researcher), via IRBNet Researchers must in no circumstances collect data until they have been advised that their applications have been approved.

Full Board and Expedited applications will be granted a 1 year approval. Researchers will have the opportunity to request a continuation of that approval prior to the 1-year anniversary date. Continuation Forms and Instructions can be found in IRBNet, and should be submitted electronically. Researchers will automatically receive 60 and 30 day email reminders from IRBNet of project expiration. Expired projects must be submitted as a new project for an entirely new review. Approval of the continuation is dependent on the researcher's responses to a series of questions about the progress of the study.

Exempt applications are granted a 4-year approval and there are no options for continuation.

Changes to existing protocols may be requested in IRBNet as an amendment/modification, and include a thorough description of changes to an existing, approved study, and any new or revised documentation. IRB co-chairs review these requests on an as-needed basis.

Lead investigators and research advisors will receive notification via IRBNet when IRB approvals have expired

IRB Non-Compliance and Reported Irregularities during Research

The following steps will be followed in cases where a researcher (i.e., lead investigator or research advisor) do not adhere to IRB Guidelines.

If the non-compliance is because the researcher was unaware of IRB Guidelines and federal law, an IRB co-chair will communicate via e-mail with the researcher in order to explain the nature of the non-compliance. The co-chair will propose a solution that will remedy the situation. All communication will be maintained by the IRB co-chair.

If the issue of non-compliance persists or the researcher rejects the co-chair's solution, the co-chair will request a meeting between the researcher and both IRB co-chairs. At this meeting, notes will be kept as to the nature of the non-compliance and the researcher's willingness to remedy the situation. These notes will be maintained by the IRB co-chair who initiated the meeting.

If the co-chairs deem the non-compliance to fall under the definition of "Scientific Misconduct" (University Regulations 3-8-106(1)(c)), then the procedures outlined in the University Regulations will be followed.

While IRB co-chairs must adhere to this protocol, they may also find it helpful to contact knowledgeable campus members relevant to each case. In the past, these individuals

included grant coordinators, university counsel, past IRB co-chairs, and professors with expertise in the research area. Each case is vastly different and may usually be resolved with time and wisdom without permanently jeopardizing researchers, UNC, or most importantly human research participants.

In most cases, the researcher in non-compliance is acting out of ignorance and not willful intent. In addition, most cases are resolved while maintaining compliance with federal law.

It should be noted that violation of federal law associated with these IRB Guidelines may result in drastic consequences, such as the suspension of all federal research funds. Therefore, it is imperative that all UNC researchers comply with UNC IRB Guidelines.

Reports of irregularities during the conduct of an IRB-approved study will be addressed on a case-by-case basis and with due consideration to federal requirements. As with issues of non-compliance, communication will be established between IRB co-chairs, researchers, and participants, if necessary. UNC Counsel will be consulted as necessary. If irregularities fall under the category of “Scientific Misconduct” (University Regulations 3-8-106(1)(c)), then the procedures outlined in the University Regulations will be followed. Depending on the severity and nature of the project and infraction, federal authorities may need to be contacted.

Other UNC IRB Procedures That Address Federal Requirements

The IRB has other responsibilities besides the review of new and continuing research applications.

The IRB regularly disseminates its record of approved applications to IRB members and research administrators on campus. These records will be made available to other interested parties from the University community who request them.

The IRB communicates with other offices on campus as is appropriate to the thorough review of applications and the coordination of research policies. For example, issues of biosafety will be addressed as necessary with university personnel with expertise in biosafety.

The IRB has the responsibility to examine an investigator’s adherence to planned procedures in the application under two circumstances: (1) the IRB has determined that an investigator has been previously and flagrantly non-compliant with IRB guidelines, or the IRB has encountered other convincing evidence that an investigator is currently being non-compliant, reckless, or inattentive to participants’ rights; (2) the IRB will randomly select two projects annually in which investigators will be asked to report on their fulfillment of the research and consent procedures they described in their applications. In the first case, the investigator and his or her supervisor will report on compliance. In the second case, the investigator will report on compliance.

When a serious violation has occurred that mandates reporting to the federal Office for Human Research Protections, the IRB co-chairs will assume responsibility for filing the

report at <http://www.hhs.gov/ohrp/policy/incidreport_ohrp.htm>. Likewise, co-chairs are responsible for reporting serious adverse effects on participants at <<http://www.hhs.gov/ohrp/policy/AdvEvtGuid.htm>>. Depending on the circumstances, co-chairs will attempt to alert the federal authorities as soon as is possible and not after three months after first learning about the potential serious problem.

The Ethical Basis of IRB Policy

The following is an excerpt from the **The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research**.

see <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

1. Respect for Persons. Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however,

application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. Beneficence. Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children -- even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. Justice. Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are **(1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

Frequently Asked Questions

Frequently asked questions regarding UNC IRB procedures can be found at the following UNC web site:

<http://www.unco.edu/research/research-integrity-and-compliance/institutional-review-board/frequently-asked-questions.aspx>

Frequently asked questions of a more general nature can be found at the U.S. Department of Health and Human Services web site:

<http://www.hhs.gov/ohrp/policy/faq/index.html>



Standard
consent
document with
signature
required

CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF NORTHERN COLORADO

Project Title: Sporting Garment and Motor Performance
Researcher: Joe Professor, Ph.D., School of Exercise Activity
Phone: 123-456-7890 E-mail: joe.professor@unco.edu

Purpose and Description: The primary purpose of this study is to determine the effectiveness of running tights on biomechanical and physiological measures of performance in experienced long-distance runners who are in good athletic condition and not currently injured. Over four separate visits to our lab, you will exercise at various intensities and we will measure a variety of performance-related variables. We will measure the motion of your arms and legs with multiple video cameras, the electrical activity of your muscles with electrodes attached to the surface of your skin, the strength of your knee extensor muscles, your postural stability, your rate of oxygen consumption, your perceived exertion, and your heart rate.

For session 1, you will be fitted for two pairs of tights, which will be yours to keep. For three experimental conditions (no tights - running shorts, conventional running tights, and a new brand of running tights), you will run at three predetermined speeds (5.2 mph, 6.3 mph, and 7.7 mph) on a motor-driven treadmill. After a sufficient warm-up period, you will run for a duration of 4 min for each speed. While running, we will measure heart rate, so you will wear electrodes for this purpose. In addition, during the final few minutes of running at each condition, we will measure your perceived exertion from a subjective rating scale and collect the expired gases you breathe via mouthpiece. You will also wear a noseclip for much of the running so that all expired gases may be collected. These gases will be analyzed so that a measure of your oxygen consumption will be calculated. Electrodes for measuring muscle activity will be placed over selected leg muscles and reflective markers will be placed on your joints so that the motion of body segments may be monitored more easily by video cameras.

Sessions 2-4 are designed to fatigue you to some degree. For each of these sessions, you will go through the same protocol, but will do so in different experimental conditions (see above). After a suitable warm-up, you will first perform a battery of pre-test evaluations:

- standing posture test - standing quietly for 30 sec on a force platform for measurement of postural sway
- standing vertical jump - a single maximal, vertical jump will be performed on a force platform
- maximal knee extension - while seated in a BioDex machine (muscle testing machine), you voluntarily extend your knee against a standard resistance while muscle torque is measured with the BioDex machine. This machine is similar to a weight-lifting machine, only it measures muscle torque, an indicator of strength. Several trials will be attempted.

After a brief rest, you will take part in a continuous jumping protocol. This requires maximal jumps, "one-after-the-other" for 60 sec. These jumps will be performed on a force platform. After another rest of at least 15 minutes, you will run for 30-min on a treadmill at a self-selected speed. EMG electrodes and motion analysis markers will again be used for this 30-min run and oxygen use will be measured for a 2-min duration every 5-minutes. The run will be briefly interrupted at minutes 10 and 20 for a maximal, voluntary knee extension trial, which will also be repeated at the conclusion of the 30-min run. After the run and another suitable rest, you will repeat the battery of evaluations described above (posture test, standing vertical jump, maximal knee extension). It is estimated that each of these sessions will take approximately 2 hours.

At the end of the experiment, we would be happy to share your data with you at your request. We will take every precaution in order to protect the confidentiality of your participation. We will assign a subject number to you. Only the lead investigator and his assistants will know the name connected with a subject number and when we

report data, your name will not be used. Data collected and analyzed for this study will be kept in a locked cabinet in the Biomechanics Lab, which is only accessible by the researcher and his graduate students.

Potential risks in this project are minimal. As with any exercise, risks include fatigue, localized muscle soreness, and the potential for strains and sprains of joints of the lower extremity. In addition, treadmill running poses risks because if you lose focus on the task you may fall. To counter this risk, a spotter will be stationed at all times within easy reach of a treadmill stop button and you will be allowed to walk and run at lower speeds before the treadmill belt reaches test speed. We will make sure that you are comfortable running on a treadmill before we begin the test. In addition, if you become too fatigued or uncomfortable, you may choose to stop the test at any time. In the unlikely event of an injury, we will contact appropriate medical authorities.

Upon completion, you will be permitted to keep the two pairs of running tights you wear for this study and you will be paid \$50. Coaches, athletes, sports medicine clinicians, and athletic clothing manufacturers will be the populations who most benefit from the results of this study.

Participation is voluntary. You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please sign below if you would like to participate in this research. A copy of this form will be given to you to retain for future reference. If you have any concerns about your selection or treatment as a research participant, please contact Sherry May, Office of Research, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

Subject's Signature

Date

Researcher's Signature

Date



Consent
document with
no signature
required;
suggested for
anonymous
surveys

CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF NORTHERN COLORADO

Project Title: Student Performance and Attitude Regarding Teacher Education
Researcher: Joe Teacher, Ph.D., School of Teacher Education
Phone Number: (123) 456-7890 e-mail: joe.teacher@unco.edu

With the help of several graduate student instructors I am researching student performance and attitude in TED 323 (how to teach). As a participant in this research, you will be asked to take two objective quizzes (which will not count toward your grade in the class) and a questionnaire. These will be given to you during your regularly scheduled class sometime during the course of the semester. The objective quizzes will consist of multiple-choice questions and will assess your knowledge about the topic of interest during a certain week in the semester. The questionnaire will require you to assess your attitude about various features of class exercises and activities. Some items of the questionnaire will seem more like test questions, but they are intended to assess your critical thinking skills. The quizzes will each take approximately 15-20 minutes and the questionnaire will take 10-20 minutes. At the end of the semester, you will be asked to provide some feedback about the class exercises.

For the quizzes and questionnaires, you will not provide your name, but will be asked to provide your class section, gender, and overall grade point average. Only the researcher and the other course instructors will examine individual responses. Quiz and questionnaire responses will be made on a sheet which will be computer-graded and written feedback asked for at the end of the semester will not be examined until after grades have been assigned. Results of the study will be presented in group form only (e.g., averages) and all original paperwork will be kept in locked cabinets on campus. Researchers will strive to protect the anonymity and confidentiality of your responses.

Risks to you are minimal. You may feel anxious or frustrated taking the quizzes, but we are trying to minimize these feelings because the results will have no bearing on your final grade. The benefits to you include gaining practice in taking quizzes, especially with respect to the material in this course. In addition, the approaches we present in these class exercises may help you learn the material better and therefore, make you better prepared for assessments later in the semester (e.g., final exams).

Participation is voluntary. You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please complete the questionnaire if you would like to participate in this research. **By completing the questionnaire, you give your permission to be included in this study as a participant.** You may keep this form for future reference. If you have any concerns about your selection or treatment as a research participant, please contact Sherry May, IRB Administrator, Office of Research, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.



Parental
consent
document with
signature
required

CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF NORTHERN COLORADO

Project Title: Understanding of Mind in 3-6-year-olds
Researcher: Jane Educator, Ed.D., School of Teaching
Phone Number: (123) 456-7890 E-mail: jane.educator@unco.edu

With the help of several of my students I am researching children's awareness that others may have beliefs different from their own. If you grant permission and if your child indicates to us a willingness to participate we will adjourn to a quiet area near the classroom, on two occasions separated by two or three weeks, for 20-30 minutes of game playing. There will be three activities. One involves guessing which of different pairs of containers holds a treat. First, a researcher will demonstrate how the contents of two containers can be switched such that, for example, M&Ms are found in a Crayon box and Crayons are found in an M&M bag. Next, three games will be played by your child and a researcher in which a correct guess results in that player getting a treat to eat whereas an incorrect guess results in the other player receiving the treat. We are interested in whether or not young children understand how switching the contents of two containers tricks another player. To this end a researcher will twice help your child trick another researcher (if your child does not spontaneously suggest the switch). After the switch has been made but before the other player guesses, your child will be asked several questions about the actual contents of the containers and what the other player believes are the contents. In the last game it is your child's turn to guess. In this game if your child does not guess the treat's location the other player will share her winnings with your child. The possible treats include Cheerios, Fruit Loops, M&Ms, small cookies, and raisins. Only a few treats will be awarded after each game.

A second activity is a memory game in which your child will be shown drawings of a clown with one or more parts of the drawing colored (e.g., hand, shoe, hat). Your child will then be shown a duplicate response figure and will point to the portions that had been colored.

In the visual search game your child will search through pages crowded with pictures and will point to every example of the target picture circled at the top of the page. Your child will be asked to search as quickly as possible.

I foresee no risks to subjects beyond those that are normally encountered playing games in the classroom. Your child's participation will not be solicited during snack, lunch, or nap times. The games are fairly simple and the only feedback to your child will be positive (e.g., "You're playing very well." "You did just fine." etc.). This study is not designed to improve your child's memory or understanding of others' beliefs but your child will likely enjoy the activities, the treats, and the positive attention received.

We may videotape the activities to back up the notes taken by the researchers. Be assured that we intend to keep the contents of these tapes private, unless you give permission below for their use as an instructional aid in the primary researcher's child development courses at UNC. To further help maintain confidentiality, computer files of children's performance will be created and children's names will be replaced by numerical identifiers. The names of subjects will not appear in any professional report of this research.

Please feel free to phone me if you have any questions or concerns about this research and please retain one copy of this letter for your records.

Thank you for assisting me with my research.

Sincerely,

Participation is voluntary. You may decide not to allow your child to participate in this study and if (s)he begins participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please sign below if you would like to participate in this research. A copy of this form will be given to you to retain for future reference. If you have any concerns about your selection or treatment as a research participant, please contact Sherry May, IRB Administrator, Office of Research, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

Child's Full Name (please print)

Child's Birth Date (month/day/year)

Parent/Guardian's Signature

Date

Researcher's Signature

Date

If you give permission for Dr. Educator to use the videotape of your child's game playing for instructional purposes in her child development courses please initial here:

Initials

Please indicate below if there are any restrictions on what treats we may use with your child as if, for example, your child has a food allergy.



Assent
document (for
minor) with
signature
required

ASSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF NORTHERN COLORADO

Hi!

My name is _____ and I'm a teacher at the University of Northern Colorado. I do research on health and eating. That means I study the way people eat to try to learn how to make people healthier. I would like to ask a lot of fifth-graders about their eating. If you want, you can be one of the kids I talk with.

If you want to talk with me, I'll ask you about the foods you like and don't like. I will also ask you which foods you think are the best for you and which you think are the worst for you. For each question I will want you to explain your answer. But, this isn't a test or anything like that. There are no right or wrong answers and there won't be any score or grade for your answers. I will write down what you say, but I won't even write down your name. It will take about 10 minutes for you to answer my questions about health and eating. I'll ask your teacher for the best time to talk with you so that you don't miss anything too important.

Talking with me probably won't help you or hurt you. Your parents have said it's okay for you to talk with me, but you don't have to. It's up to you. Also, if you say "yes" but then change your mind, you can stop any time you want to. Do you have any questions for me about my research?

If you want to be in my research and talk with me about health and eating, sign your name below and write today's date next to it. Thanks!

Student _____ Date _____

Researcher _____ Date _____