

IRB Policies & Procedures Manual

INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

UNIVERSITY OF NEW MEXICO MAIN CAMPUS

Federal-Wide Assurance No. 00004690

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IRB Policies & Procedures Manual

UNM Main Campus

MISSION

The University of New Mexico requires that research investigators must protect the rights, privacy and welfare of individuals recruited for participation in research. The Main Campus Institutional Review Board (IRB) holds the primary responsibility to protect human subjects involved in social, behavioral and educational research conducted by departments, centers, institutes and other units affiliated with main campus and the branches. The jurisdiction of the IRB includes the authority to review, approve, modify or disapprove research protocol applications submitted by faculty, staff and student investigators. The process of review serves to ensure the safe and ethical conduct of research that ultimately will protect the rights and welfare of human subjects in an atmosphere of mutual trust and scientific integrity in the pursuit of knowledge.

1.0 INTRODUCTION

The National Research Act of 1974 established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission published *The Belmont Report* articulating the ethical principles that guide the conduct of research with human subjects and continue to serve as the foundation of *Title 45 Code of Federal Regulations Part 46* (hereafter 45 CFR 46). In the design, conduct, approval and review of research, UNM officials, the IRB members, and investigators adhere to the basic principles set forth in *The Belmont Report*: respect for persons, beneficence, and justice.

In consideration of **RESPECT** for persons, UNM investigators must seek and obtain voluntary informed consent from potential research participants. Informed consent means that participants are given explicit assurances of the voluntary nature of their involvement in terms that are easy to understand, and that they are not under duress or pressured to serve as participants. The consent process also includes information about the research project that will assist participants in deciding whether to participate in the study or not. In addition, respect means honoring the privacy of individuals and maintaining confidentiality.

The principle of **BENEFICENCE** requires that researchers maximize the potential benefits to participants, or to society, while minimizing the potential risks of harm. The extent of protection depends on the risks and benefits of the proposed research. All participants should be treated in an ethical manner. Benefits to participants, or in the form of generalized knowledge gained from the research, should always outweigh the risks. If there are any risks resulting from participation in the research, then there must be benefits, either to the participants or society.

JUSTICE means that subjects must be selected fairly and that both the risks and benefits of research are distributed evenly. In the language of *The Belmont Report*: “Who ought to receive the benefits of research and bear its burdens?” Investigators should take precautions not to select participants simply because of convenient availability, manipulability, their compromised positions, or because of social, racial, sexual, economic, or cultural biases institutionalized in society.

1.1 Purpose of IRB Manual

The *IRB Policies & Procedures Manual* serves as a reference guide describing the policies, procedures, and regulations governing research with human subjects and the requirements for submitting protocol applications for review by the Institutional Review Board at the Main Campus of the University of New Mexico. The intended audience of users includes research administrators, principal investigators (faculty, staff and students), and IRB members. The manual describes and explains the various aspects of the review process and regulatory requirements. In particular, investigators should carefully review the section of the manual (section 2.0) that addresses the process for the submission of protocol applications.

The field of human subject’s protection is constantly evolving; some parts of the manual may be updated from time to time. The IRB office will keep the UNM research community apprised of revisions or new developments as they occur. This manual should be maintained in a ring binder in order to facilitate the updating of pertinent sections or insertion of supplemental information. In addition, the *IRB Policies & Procedures Manual*, the packet of application forms, the 45 Code of Federal Regulations 46, the OHRP/DHHS Federal-Wide Assurance document, policy updates, news flashes, and information regarding workshops and training schedules can be downloaded from the website of the UNM office of Research Compliance Services: <http://research.unm.edu/rcs>

1.2 Human Subjects Research Defined and Who Must Submit Protocols

Virtually all federally funded research with human subjects is governed by federal regulations patterned on those of DHHS, described at 45 CFR 46, and known as “the Common Rule.” This federal code defines research as: “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Human subjects themselves are defined as “living individual(s) about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information.” Systematic investigations are studies that are intended and designed to collect data about human subjects with the purpose of drawing conclusions and reporting research findings.

“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. “Interaction,” on the other hand, includes communication or

interpersonal contact between the investigator and a subject such as by way of interviews or survey questionnaires. “Private information” includes data about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, as well as information that has been provided for specific purposes by an individual in circumstances or conditions where the individual reasonably expects the information 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.

At the UNM Main Campus, all faculty and staff research that conforms to these definitions in the Common Rule must be submitted for review by the IRB regardless of funding source: federal, state, local, private or unsponsored. The Main Campus IRB reviews protocol applications in social, behavioral and educational research to include the branch campuses that conduct research in these fields. The IRB may also review studies that involve UNM Health Sciences Center faculty members as co-investigators with a Main Campus principal investigator. In accordance with the Federal-Wide Assurance (**FWA No. 00004690**) issued to the UNM Main Campus by the Office for Human Research Protections (OHRP), Department of Health and Human Services (DHHS), all human subjects research funded by the federal government must be performed in accordance with 45 CFR 46. In addition, the actions of UNM officials, researchers, and staff must conform to all applicable federal, state and local laws and regulations.

Student research intended to result in generalizable knowledge must also be submitted for review, for example, all graduate theses and dissertation proposals or other graduate or undergraduate research intended for publication or wide dissemination. Student research involving human subjects must be supervised by a UNM faculty advisor who will assume the responsibility for ensuring that all research procedures comply with federal, state and university policies designed to protect human participants. Classroom projects, problems courses, and independent studies that are exclusively for instructional or mentorship purposes need not undergo review by the IRB if the risks are NOT GREATER than minimal. However, faculty advisors and students are encouraged to follow the *IRB Policies & Procedures Manual* when designing and conducting class exercises, projects or other assignments that involve the use of human volunteers or respondents, even if not submitted for review. All student research that poses GREATER than minimal risk must be submitted for IRB review (see definition of minimal risk, section 3.2 of this manual).

1.3 Biomedical Research at the Health Sciences Center: HRRCs

For biomedical, behavioral or patient research conducted at or under the sponsorship of the UNM Health Sciences Center, investigators should contact the Office of Research, Human Research Review Committees (HRRCs). The HRRCs function as the institutional review boards for the Health Sciences Center and all of its affiliated

schools, colleges, research units, and hospital facilities. The UNM Main Campus IRB may rely on the HRRCs for review and continuing oversight in cases where the proposed studies involve a biomedical component such as research projects that include blood specimens, human tissue samples, genetic testing of human specimens, physical stress exercises, magnetic resonance imaging, electrocardiography, application of physical sensors to the surface of the body, or the use of FDA investigational devices or regulated products. Investigators from Main Campus should contact the IRB office first in order to determine if the proposed study qualifies for a referral to the HRRCs. Applicants to the HRRCs must be contracted UNM faculty or a salaried staff member with a Letter of Academic Title in an academic department. For submission guidelines and application forms, consult the *HRRC Manual for Conducting Human Subject Research* at: <http://hsc.unm.edu/som/research/HRRC/MANUAL/>

1.4 The Role of the IRB

The Main Campus IRB is composed of faculty members from diverse backgrounds, academic disciplines, and research expertise; and by federal requirement, at least one additional member represents concerns in nonscientific areas and another represents community issues outside of the university. All IRB voting members are appointed by the UNM Vice President for Research and Economic Development to serve four-year terms with an option for one renewal. The Vice President may also appoint alternates to the voting members from within the same discipline or similar backgrounds. Alternate members may exercise voting rights only when they are attending in the place of an absent voting member. The Vice President may also appoint non-voting members or advisors from research ethics, legal counsel, research policy, and other backgrounds who may participate in discussions and deliberations but without a vote. The IRB Chair or the full board may also invite consultants to participate in the review of specialized research when outside expertise is warranted.

The IRB is charged with two principal responsibilities: (a) determine and certify that all research protocols conform to the regulations and policies set forth by DHHS regarding the health, welfare, safety, rights, and privileges of human subjects; and (b) assist investigators in conducting ethical research that complies with federal and other regulations in a way that permits the accomplishment of the research activity. The IRB meets these responsibilities through a review of applications submitted by principal investigators, negotiations between the IRB and investigators for approval of research, and IRB outreach to the research community. The process of review serves to ensure the safe and ethical conduct of research that ultimately will protect the rights and welfare of human subjects. The dignity and welfare of individuals who participate in research must be a central concern of everyone involved with the protection of human subjects. The university, and all faculty, staff and student investigators share in the collective responsibility for the ethical conduct of research. This collaboration is largely decentralized, and therefore, must operate in a culture of trust, mutual assurance, and integrity by upholding the highest ethical principles in the conduct of research and the pursuit of knowledge.

1.5 Jurisdiction and Authority of the IRB

The Federal-Wide Assurance with OHRP/DHHS details the relationship of UNM Main Campus and the Office for Human Research Protections within DHHS. This agreement and other DHHS policies empower the IRB with the authority to review, approve, require modification in, or disapprove research activities conducted by Main Campus investigators, including jurisdiction over proposed changes in previously approved human subject's research. For approved research, the IRB also determines which activities require continuing review more frequently than the maximum interval of twelve months.

IRB decisions and requirements for revisions, if any, are conveyed to investigators in writing, with the provision of an opportunity for appeal by the investigator in the case of disapproval. Although research may receive IRB approval, the department chair or other administrative officials may conclude that the research project does not meet the policies and goals of the university and may disapprove, suspend, or terminate a project. However, IRB decisions to require modifications in, disapprove, suspend or terminate a project are final. No other committee or official can override these IRB decisions. Further, no committee or official can approve an investigator to conduct any human subject's research that the IRB has not approved. [See **45 CFR 46.112.**]

The IRB must insure that voluntary informed consent will be obtained by research investigators and their staff in a manner that meets the requirements of Title 45 Code of Federal Regulations Part 46, sections 116 and 117. (See section 5.0 of this manual, Informed Consent: Process and Documentation.) The IRB holds the authority to observe or have a third party observe the consent process when deemed necessary. IRB approval means that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and federal requirements.

The Main Campus IRB may also enter into authorization agreements with the review boards of other institutions such as for sub-awards or other collaborative research projects. UNM investigators should inform the IRB of any arrangements contemplated that will involve other institutions and allow time for adequate review at both institutions. The general policy of the UNM IRB is to require submission of the project to the IRB for initial review, with final approval subject to the terms of an authorization agreement executed at both institutions that details the mutual responsibilities and jurisdiction over the research.

1.6 Responsibilities of the Investigator and Departments

Federal DHHS regulations, policies, and guidance documents also describe the role of investigators, illustrating further the principles of mutual trust, collective responsibilities and the nature of decentralized accountability in human subject's research. Researchers must acknowledge and accept their own responsibilities for

protecting the rights, privacy and welfare of the human subjects. The application submitted to the IRB for review must demonstrate full compliance with federal, state, and university regulations and with all components of the UNM Main Campus federal-wide assurance for the protection of human subjects in research. Once IRB approval has been obtained, investigators must maintain updated records to include the initial application, approval letter(s) from the IRB, modifications requested and approved, continuation or re-approval progress reports, instruments completed, consent forms administered and signed, correspondence related to the study, adverse event reports, if any, etc. These records must be maintained for review or audit by the IRB for a minimum period of three years after official closure of the study.

Prior to submitting applications to the IRB for review, researchers must present a certification statement and checklist to their department or administrative unit to verify that the proposed study has been provided scientific merit review. The department chair, a designated faculty committee, or the respective center/institute Director must read the IRB application and certify with signature that: the study purposes, rationale, design and methods are clearly stated and are scientifically sound; the protocol conforms to the norms, ethical standards and methods of procedure of the scholarly discipline; the proposed study involves no known risks to human subjects other than those specified; the principal investigator and other researchers are qualified to conduct the proposed study; the study facilities and resources are adequate for the safe conduct of the research; and the subject population, sampling procedures, and data to be collected are justified and adequate to meet study objectives. Applications must affirmatively answer each of the departmental review criteria before submission to the IRB. In the case of student and visiting faculty applications, the responsible faculty member supervising the research must also review and sign the statement. The certification statement and the checklist form part of the main application to the IRB and can be viewed at the IRB website: <http://research.unm.edu/rcs/>.

If the research is approved by the IRB, investigators must obtain documented and legal informed consent from all research participants involved in each protocol, unless the IRB has granted a waiver, exception or alteration as provided for in the federal regulations and described in section 5.3 of this manual. Research investigators must also promptly report any injuries, unanticipated problems or adverse events to the IRB. Progress reports as well as any proposed modifications to previously approved activities must be submitted in writing in the manner prescribed by the IRB in this manual.

1.7 IRB Infrastructure and Resources

The Main Campus IRB is supported by an IRB Chair and other administrative staff assigned by the Vice President for Research & Economic Development. The role of the staff is to receive and log all protocol applications submitted by investigators after they have been reviewed and approved by the respective department or unit, screen applications for the necessary forms and attachments, conduct a pre-review of

the materials, maintain all records on a computerized database, document actions taken at IRB meetings by way of written minutes, and convey IRB decisions to investigators in writing. The IRB Chair provides leadership for the development and implementation of policies and procedures for the protection of human subject participants in research. The Chair is also responsible for scheduling timely reviews of the process, conducting training and outreach programs, and submitting reports required by UNM and federal agencies. The UNM University Legal Counsel, as well as the Office of the Vice President for Research and Economic Development, provides technical and administrative support as needed. The IRB Chair presides at the IRB meetings and reports to the Senior Associate Vice President for Research and Economic Development, the designated Human Protections Administrator for the Main Campus. The Vice President serves as the Institutional Signatory Official.

2.0 SUBMITTING PROTOCOL APPLICATIONS

Applicants to the Main Campus IRB must be investigators with faculty appointments who plan on conducting human subject's research under the auspices of an academic department, research center, institute or other administrative unit. Tenured, tenure-track and salaried faculty or research staff with letters of academic title may sponsor other investigators and serve as the responsible faculty member such as in the case of student research or research conducted by part-time faculty or visiting scholars from other institutions. Research staff at centers and institutes or at other program offices may also submit applications to the IRB with approval of the respective Director who will supervise the project in lieu of a faculty member. In all cases, the responsible faculty member or the unit Director must assure compliance with human research protections and IRB requirements.

Applications submitted to the UNM Main Campus IRB must adhere to the provisions of 45 Code of Federal Regulations 46 and the UNM Main Campus *IRB Policies & Procedures Manual*. Application materials can be downloaded from the IRB website of the UNM office of Research Compliance Services: <http://research.unm.edu/rcs/> Materials and forms in the application packet for initial submissions include:

- UNM Policy Statement
- IRB Policies and Procedures Manual
- Main Campus IRB Application Form
- Sample Consent and Assent Forms
- UNM Conflict of Interest in Research Policy, Conflict of Interest Disclosure Cover Sheet, and Conflict of Interest Disclosure Form.

The application packet is designed to address the most commonly asked questions for the submission of research protocols. The packet includes a standard application form that can be completed efficiently. Submission of incomplete or unsigned applications will result in the delay of the review and approval process. Attachments to the protocol application may include, as applicable: flyers, posters, advertisements, internet postings or

other materials utilized to recruit human subjects, as well as any research instruments involved in the study, such as interview guides, surveys and questionnaires. When completed, the IRB forms and all attachments should be forwarded or delivered to: Institutional Review Board, 1717 Roma NE, Mail Stop Code 05-3180, University of New Mexico, Albuquerque, New Mexico, 87131.

3.0 THE IRB REVIEW PROCESS

The review of research by the UNM Main Campus IRB is conducted in accordance with the Federal-Wide Assurance (FWA) approved by the federal Department of Health and Human Services: **FWA No. 00004690**. DHHS policies stipulate that UNM will protect the rights and welfare of human research participants through a review process that complies with the provisions in the federal regulations, 45 CFR 46. The Institutional Review Board retains the sole and final authority at UNM Main Campus for the approval of applications that involve human subjects in social, behavioral and educational research. The IRB review process applies to research conducted by faculty, students, staff, visiting scholars and others whether conducted on UNM premises, at off-campus sites, or under subcontracts to other entities. The review requirement applies to all human subjects' research conducted under the auspices of UNM Main Campus units, regardless of funding source, sponsored and unsponsored.

The IRB is responsible for ensuring that all approved research complies with the letter and spirit of the human subject protection regulations as well as the ethical principles stated in *The Belmont Report*: respect for individuals, beneficence, and justice. The IRB examines research protocols in terms of procedures to recruit human subjects, proposed remuneration if any, and adequacy of the informed consent process. In addition, the IRB evaluates the risks and potential benefits to participants as outlined in each protocol. The broad purpose of this review is to help ensure that investigators recruit subjects in an equitable manner that is non-coercive, that subjects are fully informed about the risks and benefits entailed in the research, and that subjects are not exposed to disproportionate risks.

The criteria utilized by the IRB during the review of protocol applications include:

3.1 Risks and Benefits: The IRB will assess whether the risks to participants are reasonable in relation to the anticipated benefits to the participants or to society. In particular the IRB reviews proposed studies to ensure that the risks are minimized to the greatest extent possible, and to also ensure that the benefits of research participation are maximized. To a limited extent, the IRB will consider the scientific merit of the study design, since it would be unethical to place human subjects at risk with a study where methodological procedures are flawed such that little or no reliable information will be obtained. Primary responsibility for the review of scientific merit rests with the department or unit sponsoring the research. Federal regulations also require the IRB to review any possible benefits a subject may derive from participation in research, and/or the benefits of new knowledge that may justify asking a person to undertake the risks of

the study. Payments for participation in research or other incentives are not considered and should not be described as benefits.

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, and risks of long-term effects. 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. 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.

3.2 Minimal Risk Defined: In the federal rules, 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.” For guidance to investigators the IRB considers minimal risk studies as comparable to the following examples: tests and measures of mental status or memory functioning outside of a clinical setting; standardized IQ tests, personality inventories, consumer preference surveys, and 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. 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, grief, illicit drug use, alcohol abuse, self-reporting of criminal behavior, eating disorders, sexual behavior, fertility, termination of pregnancy, and sensitive cultural, racial or gender issues. 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.

3.3 Equitable Selection of Research Participants: The selection of participants should be equitable and free of coercion. The IRB will consider the research setting and study purposes, including whether the proposed study intends to involve vulnerable and special classes of subject populations such as children, students, prisoners, subjects with cognitive disorders, or economically disadvantaged persons. Where appropriate, investigators should indicate in their protocol how they will avoid even the appearance of coercion in the recruitment of participants. They should also detail any extra precautions that will be taken to safeguard the rights and welfare of vulnerable populations.

- 3.4 Identification of Participants and Confidentiality:** The IRB will scrutinize the methods for prospective identification and contact of participants. This includes a review of the means proposed by the investigator for insuring participant privacy and confidentiality. The IRB will also examine the importance of the research, the sensitivity of any information sought from the participants, and the special procedures devised by the investigator for protecting any private or personal information.
- 3.5 Informed Consent:** The IRB will review the process described by the investigator for obtaining informed consent—when, where and how consent is obtained and any provisions for the ongoing consent of participants. (See section 5.0 of this manual for the detailed requirements of the informed consent process, methods for documentation, and any requests for waivers or alterations of written informed consent.)
- 3.6 Additional Monitoring and Safeguards:** The IRB will assess whether a project requires more than annual review and whether a project needs any additional monitoring procedures to ensure the safety of the participants. Both of these determinations generally will be based on the degree of risk in the study. Appropriate safeguards could include monitoring of the consent process, observation of the research procedures, or review of research related results. When vulnerable subjects are included in a project, the IRB will determine whether any additional safeguards are appropriate to protect their rights and welfare, and if so, whether these procedures have been included.
- 3.7 Research Involving Vulnerable Populations:** Vulnerable populations include children, students, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Subparts of the federal regulations in **45 CFR 46** require additional protections for: **Subpart B** Pregnant Women, Human Fetuses and Neonates Involved in Research; **Subpart C** Biomedical and Behavioral Research Involving Prisoners as Subjects; and **Subpart D** Children Involved as Subjects in Research. Research investigators should consult Subparts B, C, and D of the Code for a description of these special requirements.
- 3.8 Research Involving Pregnant Women, Human Fetuses and Neonates, Federal Code Subpart B:** The Main Campus IRB does not conduct reviews of research under this category of the Federal Code. Instead, the IRB will refer these protocols to the HRRCs at the UNM Health Sciences Center as biomedical or patient research.
- 3.9 Research Involving Prisoners, Federal Code Subpart C:** Some research by Main Campus investigators may involve prisoners in correctional facilities, jails, juvenile detention centers or in court ordered treatment facilities. Persons who are on probation or parole do not meet the federal definition of a prisoner. In the federal regulations, “prisoner” means any individual involuntarily confined or detained in a penal institution by virtue of criminal or civil statute or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution. The definition includes individuals who are detained pending arraignment, trial or sentencing. For the Main Campus IRB, research involving prisoners includes adults and children who are detained in jail or prison awaiting arraignment, trial or sentencing, held under court order in non-

residential treatment programs (as an alternative to incarceration), wearing a court ordered monitoring device, or held in a juvenile detention facility. Investigators conducting longitudinal studies with at-risk individuals should consider whether any of their participants might fall into the prisoner definition during the course of the study and disclose this possibility at the time of initial application submission to the IRB. Prior to the submission of applications to the IRB, investigators should consult and follow any applicable state and agency regulations of the particular jurisdiction, such as the policies of the New Mexico Corrections Department or a similar agency. Some of these agencies require the submission of applications directly to them in addition to IRB review at UNM.

Research involving prisoners does not qualify for an exemption and must be submitted to the IRB as either expedited or full review applications. To carry out its responsibilities, the IRB must insure that the majority of the Board shall have no association with the prison(s) involved, and at least one regular voting member of the IRB shall be a prisoner representative with appropriate background, experience, and awareness of the research dynamics within jails and prison organizations. In addition, if a prisoner study is conducted or supported by the federal DHHS, the IRB must certify to the Secretary that the research has been approved under the provisions of Subpart C, section 46.305.

Investigators must disclose if they anticipate enrollment of subjects who meet the definition of a “prisoner” or in cases where any of the participants will likely fit the definition during the course of the study. This would include follow-up activities where data are being collected such as in longitudinal studies. The IRB will then apply Subpart C of the federal Code during the initial review process and allow the inclusion of prisoners if the protocol is approved. If a research participant is subsequently incarcerated, and the research was not initially reviewed under Subpart C, however, the investigator must complete an Adverse Event Report and either withdraws the participant from the research or request a modification to the research to allow enrollment of prisoners and withhold further research interventions until inclusion of prisoners is granted by the IRB. In the review of protocols that involve prisoners in initial or modified applications, the IRB will adhere to the additional protections to safeguard prisoners: “prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research.”

Research involving prisoners may be submitted for review by the IRB if it falls under one of the following categories:

- Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, and research on prisons as institutions or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
- Research on conditions particularly affecting prisoners as a class (for example, medical conditions or social and psychological problems that

are more prevalent in prison populations) after DHHS publishes a notice in the federal register;

- Research on practices that are intended, and reasonably likely, to enhance the well-being of the subjects; however, if some of the prisoners will be assigned to control groups which will not benefit from the research, then the study must first be approved by DHHS.

The IRB will review eligible research and approve the study only if it finds that:

- The study falls within one of the permitted categories of research;
- Prisoners who volunteer to participate will not accrue any advantages when compared to the general living conditions and amenities afforded other prisoners in a magnitude that will impair his or her ability to weigh the risks and benefits of the research;
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- Procedures for the selection of subjects within the prison are fair, and immune from arbitrary intervention by prison authorities or prisoners; control subjects, if any, must be randomly selected from the group of available and eligible prisoners;
- The research study information is presented in language that is understandable to the subject population;
- Assurances exist that state release authorities will not take into account a prisoner's participation when making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have not effect on his or her parole; and
- The study provides adequate provisions for follow-up examinations or care of participants after the end of their participation as necessary.

3.10 Research Involving Children and Minors, Federal Code Subpart D: Federal regulations define children as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” Children in New Mexico age 14 and older may consent to treatment with psychotropic drugs, with parental notification. Otherwise, under state law, “children” are any persons under the age of 18, unless the child has been emancipated by court order or by marriage.

In 1978 the State of New Mexico enacted into law a requirement that instances of known or suspected child abuse must be reported to the appropriate law enforcement authorities (see section 5.8 of this manual for limits on confidentiality). Research investigators are not exempt, and they must inform the child (and parent or guardian) of the reporting requirement as part of the informed consent process.

Federal regulations stipulate that research involving children requires either “expedited” or “full review” and in most cases cannot be classified as “exempted” from review. The regulations further require the “assent” of a child and “permission” by a parent or legal guardian for the child to participate in a research study. Research involving children that

is greater than minimal risk must present the prospect of a direct benefit to the individual or likely to yield generalizable knowledge of vital importance to the individual's disorder or condition and must include the permission of both parents. [For studies that contemplate the recruitment of public school children, investigators should consult with the appropriate school district office. For the Albuquerque Public Schools (APS), contact the Office of Research, Development and Accountability (505-848-8710) and inquire about APS review criteria, submission guidelines and federal rules applicable to the confidentiality of student information and records or FERPA. An approval letter from the UNM IRB will be required prior to clearance by the APS Research Review Committee.]

3.11 Students and Research Course Credits: University students on the UNM Main Campus may be recruited for participation in research studies or experiments to include the prospect of earning research course credits or extra credit points for grades. However, the investigator or course instructor proposing these studies and credits must demonstrate to the IRB that the students in the subject pool are not being coerced and that their consent will be freely given. Care should be taken to eliminate any undue influence of faculty so that participation is not a course requirement without the possibility of other alternatives. In all cases there must be an educational value or benefit to students explicitly described in the protocol and in the consent form along with measures to protect student autonomy and confidentiality. Students must be provided with choices and options in order to obtain the equivalent course credits or grade incentives. Examples of alternatives include: attendance at a research seminar; writing a brief research abstract or journal article report; or other assignments with educational value and comparable to research participation in terms of time, effort and convenience. If evaluated, these projects should be graded on a "credit/no credit" scale.

Investigators should avoid any inference that volunteering to join a study will place students in good favor with the faculty in the course in terms of grading, recommendations, or future employment. In the close environment of the university, special attention should be given to the handling of data to minimize any risks of inadvertent breaches of confidentiality. For example, students should not be invited to participate in research that could reveal confidential or private information to their peers and mentors or that may embarrass or compromise the individual student. Studies that require disclosure of information on sensitive topics such as sexual behavior, mental health, and substance abuse normally are not appropriate for student participation in terms of earning research credits. Protocols that present risks greater than minimal must include protection measures to assure confidentiality and will require a convened meeting of the IRB to conduct a Full Review.

4.0 LEVELS OF IRB REVIEW & RELATED POLICIES

Applications will be processed according to one of three initial levels of review: (a) **Exempted Research**, (b) **Expedited Review**, or (c) **Full Review**. Expedited and full review protocols that have been previously reviewed but that will continue in effect beyond

the approved study period must also be submitted to the IRB for a Re-approval (Continuation) Review. When submitting applications, investigators must apply for the category of review that they believe is the most appropriate. The sections below explain each of these levels in more detail. Procedures for submitting modifications and for complying with other IRB and university policies are also included. Investigators must submit their completed applications to the IRB administrative office even in cases of exempted research. The IRB makes the final determination as to the level of review appropriate to each protocol.

4.1 Exempted Research

Federal regulations permit the IRB to exempt from review certain categories of research when the data collected is not linked or identifiable to participants and any risks present will not cause harm or discomfort beyond minimal. These exemptions do not apply to research involving prisoners, fetuses, pregnant women, human in-vitro fertilization, the mentally disabled, or for certain research involving surveys or interviews of children except where the research involves only educational tests and observations where the investigator does not participate in or manipulate the activities being observed. Also, surveys, interviews or observations involving sensitive topics (such as drug abuse, sexual behaviors, etc.) where there is a link or code between the information and the participant do not qualify for exemption.

Only the IRB may determine whether a study or research protocol qualifies for exemption. Normally, a determination can be issued within four weeks after submission of a complete application. An investigator applying for an exemption must submit a written summary of the research project following the same format as research submitted under the other categories of review. In this case, the investigator indicates he/she is requesting an exemption rather than an expedited or full review. As part of the narrative, the investigator must identify and explain which federal exemption [from the **45 CFR 46.101 (b)(1-6)** definitions summarized below] applies to the proposed research. In addition, the investigator should attach any interview guides, survey questions or other instruments to be used in the gathering of information. The IRB will evaluate the application and notify the investigator in writing as to the determination.

Research activities in which the only involvement of human subjects fits one or more of the categories listed below may qualify for exemption from review. These exempt categories do not apply to research involving deception of subjects where the investigator does not disclose the true purpose of the research and/or the results of the subject's participation in the study. Further, a claim of exemption in the application does not necessarily exempt investigators from the requirement of gaining consent or permission from subjects. Most research requires the use of an informed consent document, an approved alteration, a letter of explanation or specific instructions on how to express consent. For minimal risk studies where there are no subject identifiers (anonymous data are collected), an information sheet, cover letter or statement in the introduction to the survey or other instrument may be

substituted in place of a written and signed consent form. (See section 5.4 of this manual.)

Existing Data, Records or Specimens, Recorded Anonymously

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 subjects cannot be identified, directly or through identifiers linked to the subjects. 45 CFR 46.101 (b)(4)

This provision in the federal regulations permits the IRB to grant an exemption when all of the data, records, specimens, etc., already exist at the time the investigator proposes the research. Existing data means data from publicly available sources and applies to retrospective studies involving data that is already collected and must be “on the shelf” when the protocol is submitted. The exemption does not apply if some of the data or materials exist, but the research will gather additional data or materials. In addition, the exemption applies only if the investigator records the data in such a way that participants cannot be identified. This means that if any codes exist by which participants could be identified, the exemption does not apply. Personal identifiers linked to participants include names, initials, date of birth, social security numbers, agency record numbers, coded numbers, or other examples. Database files may qualify for exemption if there are procedures in the release of information from the source that prevent identification of individuals.

It is not enough that participants are not identifiable in the final publication. In all cases, the investigator must describe to the IRB the exact source of the data, records or specimens. “Publicly available sources” of data include examples such as telephone books and public records. Data bank, archival or other types of organizational records may be exempt depending on the policies and procedures to prevent the release of personal identifiers. The IRB will determine whether exemption can apply in each case.

Surveys, Interviews, Public Observations, and Educational Tests

*Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless**: (a) information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects; **and** (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. 45 CFR 46.101 (b)(2)*

This exemption is available for research within any of the stated categories involving adults, unless the information is both recorded in such a way that the human subjects can be identified (by links or otherwise) **and** the disclosure of the subjects' responses outside the research could place the subjects at risk or cause personal harm. Thus, surveys involving sensitive topics (such as drug or alcohol use, sexual habits, detailed health histories, illegal behavior, etc.) where there are codes or other links between the information and the subject are not exempt. In studies that will collect data by way of oral history interviews **and** are designed to create generalizable knowledge in a systematic investigation, researchers should submit an IRB application for exempted or expedited research as applicable to the level of risk on a case by case basis.

Certain educational tests are exempt from IRB review: tests of knowledge, mastery and skills that do not include individual subject identifiers or ask sensitive information from the subjects. Observational research involving sensitive aspects of human behavior, or in settings where subjects have a reasonable expectation of privacy, is not exempt. Sensitive survey research is seldom exempt. A sensitive survey includes questions about illegal activities or highly personal aspects of the subject's behavior, life experiences, or attitudes. Questionnaires or surveys covering sensitive topics, however, may qualify for exemption if they: (a) insure the anonymity of the subject; (b) inform the potential subjects as to the sensitive nature of the topics they will be asked to address; and (c) the study does not exceed minimal risk.

The exemption does not apply to research involving the observation of children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed (i.e., the investigator does not manipulate or influence the observed activities). Research under this category that would not otherwise be exempt may qualify for exemption if it involves elected or appointed public officials or candidates for public office; for example, surveys, interviews or observation of public officials or candidates for public office [**45 CFR 46.101 (b) (3)**].

Educational Settings and Normal Educational Practices

*Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **45 CFR 46.101 (b)(1)***

To qualify for exemption under this category, all of the research must be conducted in a commonly accepted educational setting and should not involve sensitive topics (e.g., sexual behavior, drug abuse, personal issues) nor increase the level of risk or discomfort beyond normal, routine educational practices. Provisions should be made to insure the existence of a non-coercive environment for all students, including

those who choose not to participate. Written permission of the school or appropriate agency should be obtained prior to the implementation of the research, including review of the proposed study by the human subject's research office or committee as applicable to or required by each school site.

Other Exempted Research: Public Benefit Service Programs, Taste and Food Quality Studies

Also exempt are research and demonstration projects which are conducted by or subject to the approval of department and agency heads and which are designed to study, evaluate, or otherwise examine public benefit or services programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs [45 CFR 46.101 (b) (5)]. This category may also be applied to evaluations of State, City or County programs provided that the program being studied delivers public benefits or services, there is statutory authority over the program, and there is no significant intrusion or invasion of participants' privacy.

The federal rules also exempt taste and food quality evaluation and consumer studies if (a) wholesome food without additives are consumed, or (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 FDA or is approved by the EPA or the Food Safety and Inspections Service of the USDA [45 CFR 46.101 (b) (6)].

4.2 Expedited Reviews

Research activities that present no more than minimal risk to participants and involve one or more of the categories below may qualify for expedited review. 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 examination or tests." (See examples of minimal risk in section 3.2 of this Manual.)

As stipulated in 45 CFR 46, the Chair of the IRB or any IRB voting member may conduct an expedited review. These reviewers may exercise all of the authority of the IRB except that they may not disapprove a study. In addition the IRB Chair may assign expedited reviews to a primary and a secondary reviewer when warranted by the study design or other considerations. Normally, an expedited review will be conducted within four weeks after submission of a complete protocol application. Incomplete applications will not be reviewed until all the requested information and attachments are submitted. When a reviewer cannot recommend approval under expedited review, the study is referred to the full IRB membership at the next scheduled meeting. Expedited reviewers must disclose any potential conflicts of interest when assigned protocols and return the applications without review for assignment to another reviewer.

Interim modifications, submitted by investigators between scheduled re-approval reviews, also may qualify for expedited review if the changes proposed are minor, for example, changes of an administrative nature, minor revisions in the text of an informed consent document or a recruitment posting, corrections in the text of documents, deletion of previously approved instruments, or the addition of instruments or measures that are not of any greater risk than those previously approved. Only changes that do not increase risks to research subjects may receive an expedited review. Modifications to approved protocols that may increase the risk to subjects are forwarded to the full IRB for review at a convened meeting.

Investigators will receive written notification of IRB actions resulting from an expedited review. Such actions may include approval as submitted or a request for further information or revisions. All research approved under expedited review (as well as exempted research) must be reported to the full IRB by the IRB Chair at a convened meeting in updated status reports.

Investigators should note that the expedited review procedure may not be used by the IRB where identification of the subjects and/or their responses would place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks are no greater than minimal. Studies that collect sensitive or highly personal information and that present GREATER than minimal risk (probability and magnitude of harm if the information were disclosed) do not qualify for Expedited Review and must be submitted as Full Review applications.

Research Categories Eligible for Expedited Review

The categories eligible for expedited review in accordance with **45 CFR 46.110** include a number of specific examples approved by the Secretary of the Department of Health and Human Services as published in the Federal Register. Among others (mostly medical devices or clinical studies of drugs not covered by the Main Campus IRB jurisdiction), research activities that may be accepted by the IRB for expedited review include:

- (1) collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds... [consult the IRB for limits of amounts drawn based on body weight, frequency, age, and for children];
- (2) prospective collection of biological specimens for research purposes by noninvasive means such as hair and nail clippings in a nondisfiguring manner, ...excreta and external secretions (including sweat), 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...;
- (3) research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes...;

- (4) collection of data from voice, video, digital, or image recordings made for research purposes;
- (5) 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 (some research in this list may be eligible for exemption);
- (6) continuing review of research previously approved by full review of the IRB where the research is permanently closed to the enrollment of new subjects, all subjects have completed research-related interventions, and the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.

4.3 Full Reviews

Most applications submitted to the Main Campus IRB qualify for either exemption or expedited review. Research that does not qualify for these two lower levels of review must be submitted to the IRB for a full review by a quorum of members at a convened meeting. The application process and forms remain the same as for the other levels, but investigators should note that a full review will take from four to six weeks after the submission of a complete and signed application. A full review requires that the investigator submit the standard application forms in multiple copies plus one copy of the complete research, dissertation or grant proposal. In the event that no additional information, clarifications or modifications are requested, the IRB may approve a study within a four week time period, but investigators should be aware that the initial full review process most often does not result in an outright approval of the research. Minor or major revisions and written clarifications are almost always requested, adding one or two weeks for final approval.

The IRB performs a detailed examination of the full review application, the proposed informed consent form, and all supporting documentation, including any recruitment materials, questionnaires, or survey instruments. IRB members with a potential conflict of interest in any review must recuse themselves from voting and participation in the deliberations. These disclosures should be stated prior to the agenda item where the protocol is presented for discussion. After a full discussion of the complete application, the Chair calls for a vote. Results of IRB decisions are then communicated in writing to the investigator within five working days following the meeting. This letter will justify any conditions required for final approval, may request additional information or revisions, and will indicate the next steps in the review process, if any.

The IRB may come to one of four determinations:

1. Approval of the study as submitted without questions or clarifications;

2. Acceptance of the protocol with requests for clarification and/or revisions (minor changes that can be reviewed and accepted by the Chair, a designated IRB member with relevant expertise, or a subcommittee of the IRB);
3. Deferral of the application pending written responses to major or substantive questions raised by the IRB during the initial review (requires convening of the full IRB for a second deliberation meeting);
4. Disapproval of the research application (the study cannot be conducted) with the right of appeal.

Investigators have the right to discuss any of the IRB outcomes directly with the Chair. In the case of disapproval, the letter of determination will include specific reasons for the disapproval with provision of an opportunity for reply and appeal by the investigator. The reply can be in writing or in person at a convened meeting of the IRB, or both. In the end, the IRB retains final authority for approval of proposed research involving human subjects.

All meetings of the IRB are documented in written minutes to include an agenda of topics, attendance, protocols reviewed, actions taken, voting results, reasons for requiring changes in a project, or reasons for disapproving, suspending, or terminating a project. These minutes are available for review and action by IRB members at subsequent meetings; when approved in final form, the minutes are available for review by the Vice President for Research and Economic Development, the signatory official for human subject's research on the UNM Main Campus, and the Senior Associate Vice President who serves as the Human Protections Administrator.

4.4 Re-Approval Reviews

Studies that have been approved as exempted from review do not need to submit for re-approval or continuation review as long as no changes or modifications are contemplated by the investigator that will no longer qualify the study for an exemption. Any substantive departures from or changes to the exempted procedures must be submitted to the IRB as modifications and could result in an upgrading of the study by the IRB to that of an Expedited or Full Review. However, if the research has been conducted according to the initial exemption, the investigator should submit only a Final Report Form upon completion of the study.

Approvals under the expedited and full review categories, on the other hand, are granted by the IRB for not more than one year. Federal regulations require the IRB to conduct "continuing review" of ongoing research, including multi-year studies, no less than annually. The IRB sets the next review date at the time of initial approval based primarily on the degree of risk of the study: the higher the risk, the earlier the IRB may set the expiration date of the initial approval. Other factors include the nature of the study and the vulnerability of the subject population. The IRB notifies the investigator of the expiration date for "re-approval," and a reminder notice is sent to the investigator at least one month in advance of the actual date.

To apply for continuation of the research, the investigator submits an IRB Progress Report requesting re-approval. By completing this report the investigator also informs the IRB of the status of the research project: (a) progress toward completion, including status of participant enrollments; (b) difficulties encountered, if any; (c) adverse events summary, if applicable; (d) unanticipated problems involving risks to subjects or the withdrawal of participants; (e) a copy of the informed consent document currently in use for the study; and (f) updated conflict of interest forms for investigators. The IRB Progress Report must be signed by the principal investigator certifying that the study will continue to be carried out as described in the re-approval application and in accordance with the research ethics, norms and standards in the respective discipline. In the case of student or visiting faculty research, the responsible faculty member must approve and sign the re-approval application. Conflict of interest forms must also be submitted with the re-approval application for all investigators whether continuing or new investigators who fit the definition of investigator in the UNM Conflict of Interest policy. .

Projects that initially required full IRB review most often will require full IRB re-approval review unless the project qualifies the study for an expedited review: no changes have been instituted or are contemplated since the initial review; the changes are minor or administrative in nature; the research is closed to the enrollment of new participants; all participants have completed research interventions, and the research remains active only for long-term follow-up of participants; no participants have been enrolled and no additional risks have been identified; or where the remaining activities are limited to data analysis.

4.5. Expiration of Approval Periods

When continuing review of research does not occur prior to the end of the approval period specified by the IRB, the IRB approval expires automatically. Failure to either close a study or apply for re-approval prior to the expiration date constitutes non-compliance. Under any of the review categories, if the ending date expires prior to submission of the re-approval application, the investigator must suspend participant contact and all data collection until the re-approval is obtained from the IRB. The investigator with an expired protocol may be subject to a protocol audit and may be required to submit an application for review and approval as a new study. No new participants may be contacted, recruited, or enrolled during the interim period, and if data has been collected, the data cannot be used in the study. If the study is formally completed, terminated, or cancelled, the investigator must submit a Final Report Form so that the study file may be closed permanently.

4.6 Modifications to Currently Approved Research

Modifications to currently approved protocols, research instruments, or to the informed consent process must be submitted to the IRB for review and approval prior to implementation. Minor changes that do not increase the risk to participants

may receive an expedited review per the eligibility criteria established for the continuation of expedited review studies (see section 4.2). Modifications that increase the risks to GREATER than minimal are forwarded to the full IRB committee for review. Changes to approved protocols cannot be implemented prior to IRB review and approval except when necessary to eliminate immediate hazards to the subject. Any unanticipated risks to subjects, emergency changes in procedures, adverse events, or instances of noncompliance with university, state or federal regulations must be reported immediately to the IRB for appropriate and timely resolution

Investigators may request modifications to currently approved research by submitting an IRB Progress Report. Modifications can be requested at any time or along with requests for re-approval if a study is about to expire. In Section F of the IRB Progress Report, investigators can specify the proposed modification(s) in terms of participant enrollments, instruments, or any proposed changes in the scope of the project, research methods, risks and benefits, or informed consent, as applicable. Changes in the risks, benefits, or research procedures may require modifications to the consent form and may, in some cases, warrant the re-consenting of participants already in the study. Revised consent forms that are proposed for use must be submitted with the modification request.

The date of approval of the modification does not change the date by which the regularly scheduled re-approval review of the project is to be completed. If a modification involves the changing of principal investigator(s), a letter from the original investigator indicating the need for the change plus a letter from the new investigator accepting responsibility for the research or study should be included along with the modification. In the case of addition or deletion or any assistant investigators, the principal investigator should inform the IRB in Section C of the IRB Progress Report. Conflict of interest forms must be submitted for all new investigators.

4.7 Final Report and Notice of Terminated Study

Approved protocols will be maintained as active files at the IRB office until the investigator submits a Final Report Form applying to close the study. Investigators may apply for closing of a study after the conclusion of the research project or anytime after enrollment is closed permanently with no prospect for any continuing human subjects' data collection, interventions or interactions. Analysis of data may continue after closing with no adverse events or unanticipated problems involving risks to research participants or to others except those previously reported to the IRB. If these conditions are met, the investigator may submit a Final Report Form available for downloading at the IRB website. The form requests a status report, a brief narrative summary of the research to date and plans for disposition of human subjects' data, and a certification statement by the principal investigator with agreement to retain all protocol records for a minimum of three years for possible audit by the IRB.

In addition, the IRB may issue a Notice of Terminated Study independently under a number of circumstances such as:

- (1) the study approval period has expired without an application from the investigator for re-approval or to close the study;
- (2) serious violations of IRB or federal compliance rules for the protection of human subjects;
- (3) unauthorized use of consent forms without notification to the IRB;
- (4) audit findings that warrant termination of a study.

4.8 IRB Appeals Policy

Any decision, review outcome, or audit finding may be appealed to the IRB. Investigators must submit their appeal in a letter to the IRB Chair outlining the reasons for the appeal and why the IRB decision, review or audit outcome should be reconsidered. If the appeal involves a relatively minor request, the Chair or a subcommittee of the IRB may consider the issue and reach an equitable determination. However, appeals of expedited and full review outcomes or any other substantive matters such as audit findings must be reviewed and decided by the full IRB at a convened meeting. The investigator may request to be present at the meeting or may be invited to do so by the IRB to clarify any issues pertinent to the written appeal. After presentation of the information and review of the documents, the full IRB will vote to approve or not approve the appeal. The decision of the IRB will be final.

4.9 Conflict of Interest Policy and Disclosures

Conflicts of interest may occur when an investigator's research responsibilities compete with his or her private interests, such as financial interests, raising concerns of objectivity and improper gain. Conflicts of interest are inevitable and may exist despite the highest standards of conduct and candor. Fortunately, most conflicts can be successfully resolved and managed without impeding research activities. The University of New Mexico has adopted a policy requiring the disclosure of actual or potential conflicts of interest. A UNM Conflict of Interest Disclosure Cover Sheet and a Conflict of Interest Disclosure Form must be completed and submitted by investigators at the time of submission of research protocols to the IRB and at the time of a re-approval application. After disclosure, if any, the UNM Conflict of Interest Committee reviews the disclosure to determine how best to manage the conflict in a manner that protects both the research participants and the investigator.

The policy applies to all investigators of faculty, staff and students conducting sponsored research, all human subject research, animal subject research and research funded by a formal award from UNM based on submission of a proposal (such as RAC awards). A conflict of interest is defined as: "A situation associated with an investigator's participation in UNM research where it reasonably appears, on an actual or potential basis, that the investigator's significant financial interest could

directly and significantly affect the design, conduct or reporting of UNM research activities; or the investigator's situation could directly and significantly compromise his or her professional commitments or allegiance to UNM.”

Potential conflicts of interest and disclosures also apply to IRB members when they are assigned protocol applications for review. IRB members should consider possible or potential conflicts of interest and determine whether a particular role or relationship could affect his or her objectivity before reviewing, participating in a protocol discussion, or voting on a protocol application. Possible relationships to consider include: the IRB member is a listed investigator or advisor on an application; the member has a familial or close personal relationship with the investigator; the member holds a financial interest in the outcome of the research; or other concerns that warrant abstaining from review, deliberation and voting on a protocol. In the event of a potential conflict of interest the IRB member should not accept the protocol for review and return the application for assignment to another member; or at full review meetings, any member(s) should disclose conflicts or simply state that participation is not appropriate and then recuse themselves from discussion and voting on the protocol.

4.10 HIPAA and the Privacy Rule

HIPAA stands for the Health Insurance Portability and Accountability Act. DHHS issued HIPAA regulations to protect the confidentiality of personal health care information effective April 14, 2003. Protected health information is defined as individually identifiable health information maintained or transmitted by a covered entity in any form or medium and includes: demographic information; medical history; information relating to the past, present or future physical or mental health or condition of an individual that is identifiable; the provision of health care to an individual or the payment for the provision of health care; physical examinations, blood tests, x-rays; and other diagnostic and medical procedures.

Privacy standards within HIPAA limit the use and disclosure of health information; restrict most disclosures to the minimum intended purpose; establish new requirements for access to records by researchers; and protect the confidentiality and integrity of health information. At UNM, the Board of Regents has determined that health care components that must comply with HIPAA regulations include four entities under the jurisdiction of the Main Campus IRB: Psychology Clinic, Department of Speech and Hearing Sciences, Center for Exercise, and the Center for Family & Adolescent Research. Effective April 14, 2003, research protocols submitted by these components to the Main Campus IRB, and which include the gathering of health or mental health information, must develop and submit a HIPAA Authorization form that contains core elements in the HIPAA Privacy Rule: description of the information to be used or disclosed; identification of the persons or class of persons authorized to make the use or disclosure of the protected health information; identification of the persons or class of persons to whom the covered entity is authorized to make the use or disclosure; and expiration date or event; the

individual's signature and date; and, if signed by a personal representative, a description of his or her authority to act for the individual. A template for a valid HIPAA Authorization form for use by Main Campus investigators is available at the IRB website for Research Compliance Services: <http://research.unm.edu/rcs/>.

4.11 Subaward Agreements with Subcontractors

For research projects and studies involving subcontractors or other subrecipients, university policy requires documentation and monitoring of human subject's compliance by way of specific language to be contained in all Subaward Agreements. Research investigators at UNM should include the following language in subawards or subcontracts:

“The SUB agrees that the rights and welfare of human subjects who may be involved in performance of this Subaward Agreement will be protected in accordance with procedures specified in a current Institutional Assurance appropriate for the research in question on file with the Office of Human Research Protection, DHHS. SUB agrees to provide UNM with a copy of its current approved Institutional Assurance and copies of all reviews, approvals, reports and any other documents created by its institutional review board relating to human subjects research conducted under this Subaward Agreement. SUB understands that human subject's research conducted under this Subaward Agreement is subject to review by UNM's institutional review board, and SUB agrees not to begin such research until it receives written approval from UNM's institutional review board. SUB further agrees that with respect to human subjects research conducted under the Subaward Agreement, it shall promptly notify UNM of any injuries to human subjects or other unanticipated problems involving risks to subjects or others; any serious or continuing noncompliance with its Institutional Assurance; or any suspension or termination of institutional review board approval.”

5.0 INFORMED CONSENT: PROCESS AND DOCUMENTATION

Informed consent is fundamental to insuring the continuous and adequate disclosure of research risks and benefits. Informed consent is an educational process between the investigator and the participant. The process begins with the initial presentation of a research activity to a prospective human subject by the investigator (or a member of the study team) and continues through the end of the research activity and the closing of the research study. Most subjects make their decision regarding whether to participate in research during the initial contact. The researcher should avoid the potential for any misunderstandings and provide the subjects with sufficient time to reflect on the nature of their proposed participation.

The second step in the consent process is the presentation of a written consent form to individuals who express an interest in participating in the study, unless the research qualifies for an exception, waiver or alteration of documented informed consent. Written

informed consent is not always necessary or appropriate in some educational, social and behavioral science research (see section 5.3 below for waivers and exceptions). When written informed consent is appropriate, a member of the study team should insure that the subject reads and understands the consent form. Federal regulations require that all consent form statements should describe the nature of the research and the request for human subjects' participation in language that is understandable to each potential subject. Consent forms should avoid technical jargon or terminology that is not defined; the forms should also adjust for educational backgrounds, mental abilities and ages of the intended participants. All subjects who agree to participate in a study should be provided their own copy of the signed consent form. Signatures of both the participant and the investigator (or study team member) are required.

The consent process does not end with the signing of the informed consent form. Research is an on-going process, which involves the constant re-evaluation of current information and procedures. Therefore, investigators are ethically obligated to keep subjects apprised of issues related to their participation in the study as appropriate. Any new information or changes in procedures that affect the participants should be presented to them in writing; in most cases this will involve the signing of a new consent form or a revision of the original form.

5.1 Description of Informed Consent Form

The consent form provides potential research subjects sufficient written information to decide whether to participate in a research study or not based on an explanation of the proposed research and the nature of the participation that is requested of them. The form should be easily identified in bold text as "Consent to Participate in Research" at the top of the first page. The title of the research should be descriptive and not overly technical. Section headings should be used to identify the basic and any additional elements of informed consent. Sample consent forms for use with adults are available at the IRB website: <http://research.unm.edu/rcs/>. Once approved, consent forms will be stamped by the IRB along with the approval and expiration dates. This master consent form is the only one that can be copied and administered to research participants. Any changes to approved consent forms must be submitted to the IRB as proposed modifications prior to their use.

5.2 Elements of Informed Consent

The federal requirements for informed consent are found at **45 CFR 46.116**. Unless an exception, waiver, or alteration applies, written consent forms shall include the following points of information:

- (a) A statement that the study involves research; the purpose of the research; a description of the procedures to be followed and the expected duration of each activity or procedure; experimental procedures must be identified as such;

- (b) A description of any reasonably foreseeable risks or discomforts to the subject;
- (c) A description of reasonably foreseeable benefits to the subjects or to society;
- (d) A description of alternative procedures or courses of treatment, if applicable;
- (e) A description of whether and how confidentiality of records and data linked to the subject will be maintained;
- (f) For research involving more than minimal risk, an explanation of what treatment or professional services are available should harms occur and whether any compensation is available for these services;
- (g) A statement that participation is voluntary; that refusal to participate will not be penalized; and that the subject may discontinue participation at any time without penalty;
- (h) For research that involves GREATER than minimal risk, the investigator is required to include a statement regarding the rights of research subjects: “By signing this consent form, you are not waiving any legal claims, rights or remedies because of your participation in this research study;”
- (i) No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence;
- (j) A final statement identifying the investigators and how to contact them for answers to questions about the research or to report any difficulties or injuries; the name and phone number of the IRB chairperson should also be included in this statement in the event of complaints or other participant concerns.

Additional elements of informed consent, when appropriate, include: a statement to the participant that a particular treatment or procedure may involve risks that are currently unforeseeable; a description of anticipated circumstances under which the participant's involvement with the study may be terminated by the investigator; an explanation of any additional costs to the participant from involvement in the study; a description of the consequences of a participant's decision to withdraw from the study and procedures for an orderly termination of participation; a statement that significant new findings developed during the course of the study that may relate to the participant's willingness to continue in the study will be provided to the participant; and a description of the approximate number of participants involved in the study. If incentives such as financial payments will be offered for participation in research, the investigator must describe the manner and circumstances under which the incentive will be provided. Incentives must not be described as benefits and should not constitute the reason for “voluntary” participation. Is the amount of the incentive commensurate with the time, effort or expenses of participation? Will financial payments be pro-rated in the event of termination? Are there reasonable alternatives to financial payments?

5.3 Exceptions, Waivers and Alterations

Written informed consent is not always appropriate in some educational, social and behavioral science research, e.g., some ethnographic, field, or qualitative research studies. The UNM Main Campus IRB may provide a waiver, an exemption or otherwise approve alterations of documented informed consent if the investigator justifies that:

- (a) The research involves no more than minimal risk; **and**
- (b) The waiver or modification will not adversely affect the rights and welfare of the subjects; **and**
- (c) The research could not be practicably carried out without the waiver or modification; **and**
- (d) Whenever appropriate, the subjects will be provided with additional, pertinent information after participation.

When applying for exceptions, waivers or alterations, the investigator must explicitly address each of the conditions above and propose alternative measures for obtaining and documenting informed consent. Deception research must always include a request for a waiver of consent and documentation since the research could not be practicably carried out without a waiver.

5.4 Documenting Informed Consent

Informed consent shall be documented by having the subject (or legally authorized representative) sign the written consent form and receive a copy. The investigator or research team member must also sign the consent form. The IRB may waive the requirement to obtain a signed consent form if it finds **either**:

- (a) That the only record linking the subject to the research would be the consent form and the most serious risk would be breach of confidentiality; **or**
- (b) That the research involves no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context;
- (c) For research studies of minimal risk involving the use of questionnaires, the required elements of informed consent may be included in an introductory letter or information attached to the instrument which includes a statement that completion and return of the questionnaire (hard copy or electronically) will constitute consent to participate in the study.

5.5 Short Form Alternative

The IRB may also approve the use of a “short form” of consent, described in **45 CFR 46.117 (b) (2)**. The investigator prepares and submits the short form for review by the IRB stating that the elements of informed consent will be presented orally to the subject or legally authorized representative. When this method is used, there must be a witness to the oral presentation. Also, the investigator must submit a written summary of what will be stated orally to the subject with signature lines for the witness and the investigator obtaining consent. The short form document must provide for a signature line for the subject or representative and the witness. The subject or representative signs only the short form but will be provided copies of both the short form and the written summary.

5.6 Parental Consent

If a subject in New Mexico is under eighteen years of age, parental consent is required, unless that person is married or emancipated by court order. Parental consent must be documented in writing. If the research involves minimal risk, the permission of one parent is sufficient. If the research involves GREATER than minimal risk, consent of both parents must be obtained unless one parent is deceased, unknown, incompetent, not reasonable available, or when one parent has legal responsibility for the care and custody of the child. Parental consent may be waived by the IRB if it is not a reasonable requirement to protect the subjects (for example, neglected or abused children). However, the investigator requesting the waiver must propose an alternative mechanism for protecting the children who will be participating in the study.

5.7 Assent By Children

Assent means a child’s affirmative agreement to participate in research. In all instances where children are capable of providing assent, the investigator shall develop a separate assent form written in language appropriate to the educational level of the child. As a guideline, children age seven and older are considered capable of assenting. Sample assent forms for use by children and minors are available at the IRB website: <http://research.unm.edu/rcs/>

5.8 Limits on Confidentiality

In general, any information obtained in connection with research that identifies particular subjects must remain confidential and may be disclosed only with written permission from the participant(s) or as required by law. Consent forms should detail the extent to which confidentiality will be protected and how specific records identifying the participant(s) will be maintained and kept secure and ultimately how and when they will be destroyed, if applicable. The more sensitive the research material, the greater the care required in obtaining, handling, coding, storing and securing the data.

Depending on the subject matter of the research, there may be limits to the investigator's promise of confidentiality to the subject(s). For example, the New Mexico Abuse and Neglect Act, 1978 NMSA 32A-4-1 *et seq* provides that "every person" who knows or has a reasonable suspicion that a child is being abused or neglected shall report the matter immediately to local law enforcement personnel. Therefore, if the research might reveal child abuse, the consent form should include a statement that under New Mexico law, the privilege of confidentiality does not extend to such information and the investigator is required to report known or suspected child abuse to the appropriate authorities.

For information concerning certificates of confidentiality, researchers on the UNM Main Campus should contact the IRB Chair. Federal law allows researchers to apply for an advance grant of confidentiality known as a "Certificate of Confidentiality." If granted by a federal agency, these certificates provide protection against compulsory disclosure, such as a subpoena, for research data about sensitive issues, e.g., illegal conduct, alcohol or drug use, mental health, or sexual practices or preferences.

6.0 RECRUITMENT AND SELECTION OF SUBJECTS

Distributive justice, the third principle of *The Belmont Report*, requires the fair selection of participants and the equitable distribution of the risks and benefits of research. The systematic selection of participants because of their availability, their compromised status, or because of social, racial, sexual, economic or cultural biases institutionalized in society, may result in an uneven distribution of the benefits and the burdens of research. For example, students, patients, clients, or employees are compromised to the extent that their grades, access or health care and other services, or their jobs are dependent on those interviewing or those investigators recruiting them for research. The research application should clearly articulate how recruitment activities will avoid even the appearance of coercion when selecting participants who are in a dependent relationship to the investigators or their agents.

To insure that certain populations are not recruited solely because of their availability, for example, prisoners or patients in mental health institutions, the National Commission for the Protection of Human Subjects recommends a hierarchy of preference in the selection of subjects for research: adults before children, competent individuals before incompetent individuals, and non-institutionalized persons before institutionalized persons. Further, the National Institute of Health has issued guidelines to ensure that the risks and benefits of participation in research extend to women and minorities. These guidelines indicate that researchers should recruit and include minorities and women in study populations so that the research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study.

There are special ethical requirements for the recruitment of children. Children are in a dependent relationship to adults and can be easily manipulated in a school or clinical setting; for this reason they are entitled to extra protections as a “vulnerable subject population” as determined in federal regulations. Investigators should take every precaution to insure that a child’s decision to participate in research is both voluntary and free from coercion. Refusal to participate should not be met with a negative response or any form of punishment. In an educational setting, school officials or teachers do not have the authority to give consent for the participation of children. Only a parent or legal guardian may allow a child, with the child’s assent, to participate in a research study.

With all populations, the process of recruitment begins at the first point of contact with a potential human participant prior to the initiation of the procedures for obtaining informed consent. In many ways, recruitment is the introduction to the consent process, and may take the form of a flyer, a newspaper advertisement, or a verbal exchange between a member of the study team and the potential participant. Recruitment techniques must respect the rights of all individuals to decide whether or not they will participate voluntarily. They should not feel coerced; nor should they fear the loss of some benefit to which they are otherwise entitled if they choose not to participate. A person in authority, for example, a teacher recruiting students, should take special precautions to ensure that a decision to participate is not based on subtle pressures such as grades or a fear of loss in benefits such as counseling services. All flyers, posters, advertisements, letters, postings on the internet or any other recruitment materials should be attached to the research protocol for examination by the IRB and must be approved prior to their use.

7.0 REPORTING ADVERSE EVENTS

Federal regulations require investigators to report unanticipated problems, complications or complaints to the IRB in a timely fashion. The Department of Health and Human Services defines an adverse event as “an undesirable and unintended, though not necessarily unexpected, result of therapy or other intervention.” The scope of the definition includes any “unanticipated problems involving risks to subjects or to others” in medical and non-medical research alike.

Under these federal requirements, investigators must report to the IRB in writing the nature of the problem within five working days of the occurrence. In addition, any injury or physical or emotional harm to a participant must be reported immediately to the IRB. Other examples include, but are not limited to, a breach in confidentiality or privacy, problems with recruitment and/or the consent form process, noncompliance with federal regulations or IRB policies, complications or complaints occurring during the research, or any other problem that presents changes in the risk-benefit ratio and affects the rights, welfare and safety of subjects. A separate report must be filed for each incident summarizing the problem or difficulty encountered along with a statement by the investigator indicating whether a change in the protocol and/or consent form is warranted and whether, in the investigator’s opinion, the adverse event was related to the research activity. Adverse event

report forms are available from the Main Campus IRB office or they may be downloaded from the website: <http://research.unm.edu/rcs/>.

Following receipt of an adverse event report, the IRB will review the information to determine whether any further actions, beyond any changes or amendments to the protocol that are proposed by the investigator, are warranted. The IRB reserves the right to review and approve all the proposed changes and determine whether the study should be continued as originally approved, modified, or discontinued. Further, the IRB is required to report to the Institutional Official, the Department of Health and Human Services, the UNM Risk Management Office, and any Sponsoring Agency, all adverse events that caused injury to human subjects or other major effects that involved unanticipated risks or problems; investigators must also comply with any reporting requirements in the protocol itself or as stipulated by the Sponsoring Agency in grant documents or agency regulations.

8.0 IRB RECORDS AND PROTOCOL MONITORING

The Main Campus IRB office maintains files in electronic or hard copy for each study to include: application forms, consent and assent forms, instruments, recruitment flyers or postings, notification of IRB decisions and outcomes, records of any modifications and re-approval reviews, reports on adverse events, correspondence with investigators, and copies of all progress and final reports. The IRB files are maintained for a minimum of three years after completion and closing of a study. Records related to HIPAA authorization forms or HIPAA waivers are retained for a minimum of six years from the date of its creation or the expiration date, whichever comes later. Investigators should maintain duplicate files for their own records and for use during IRB audits while the study is still in progress and for three years after closure of the study.

The IRB office maintains records of IRB convened meetings: agendas, minutes, protocol status reports, applications reviewed with attachments, and other related material. Copies of inquiries and miscellaneous correspondence are also maintained by the IRB. The minutes of meetings will include standard information such as attendance record; a summary of protocol discussions and the controverted issues; motions, actions and outcomes determined by the IRB; and the votes in favor of approval, disapproval or abstentions. The IRB office also maintains IRB member records to include curricula vitae of current members and a roster of names, affiliations, representation capacities, experience certifications, and terms of appointment with expiration dates.

8.1 Audits of Approved Protocols

Federal rules require that institutions and IRBs conduct self-monitoring activities in order to insure that investigators comply with regulations and carry out protocols as approved by the IRB. Verification can take place by observing research in progress, especially the enrollment and consenting of participants, auditing of research records on a random basis, and by establishing procedures for the receipt and proper review of complaints from participants in the research. The Main Campus IRB adheres to

these methods of verification and also conducts periodic reviews to determine if protocols are implemented as approved. Data reviewed at the time of audits include: the currently approved protocol; recruitment procedures as implemented; status of participant enrollments; individual subject records; consent and assent forms as implemented and filed; modifications to protocols; and the reporting of adverse events, if any. All adverse events that are attributable to study procedures will require an audit of the respective protocol to determine compliance and to evaluate whether changes in procedures or in the consent form are warranted or if the study should be suspended until further inquiry can be conducted.

8.2 IRB Non-compliance Inquiries and Reporting of Findings

The IRB may become aware of possible non-compliance by any of several venues. These may include complaints or concerns from research participants, research staff or employees of the unit; audit findings; continuing reviews for reapproval; adverse event reports submitted by investigators; or quality improvement reviews conducted by the IRB. Reports of possible non-compliance may be forwarded to the IRB by calling the administrative office or the IRB Chair at 505-277-2257; writing a memo or personal visit to the IRB office at 1717 Roma NE on the university campus; e-mail communication to the IRB address at rcs@unm.edu; or calls to the toll free long distance phone number, 1-866-844-9018. Anyone, regardless of affiliation, who suspects non-compliance may submit a complaint or concern. The person submitting the report may be asked to describe the problem or the concern in writing, unless the person chooses to remain anonymous.

Upon receipt of a report, the IRB Chair will evaluate the concern and determine next steps. Minor violations may be disposed of administratively following an initial inquiry by the Chair or an IRB subcommittee. All serious or continuing noncompliance with regulations or the determinations of the IRB will be reported promptly to the IRB members at a full review meeting and to other university officials, the federal Office of Human Research Protections (OHRP), and the federal Department or Agency Directors as applicable. Examples of non-compliance include serious violations discovered after completion of a protocol audit; instances where non-exempt research was conducted without IRB review and approval or without appropriate informed consent procedures; implementation of significant modifications without IRB prior approval; and instances of repeated or multiple problems with noncompliance by protocol investigators even after IRB warnings.

Allegations or any evidence of serious non-compliance will constitute sufficient cause for the IRB to initiate a protocol audit or investigation upon written notification to the principal investigator. Audits or investigations may be conducted by the IRB Chair or a subcommittee of the full IRB in a manner that will protect human subjects as well as the investigator's rights to due process to include the right of appeal. The seriousness of the allegations and any preliminary evidence will determine whether or not a temporary suspension of the research should be imposed by the IRB pending a full inquiry and a final determination at a convened meeting. Suspensions and final

reports detailing the implementation of corrective actions must be reported to OHRP depending on the seriousness of the violations after the IRB has determined that non-compliance has occurred. The OHPR shall be notified of the pertinent information: name of principal investigator and the project title, protocol and grant numbers, detailing description of the non-compliance, and the actions taken or planned in order to address or correct the violations. Possible outcomes or corrective actions by the IRB may include: education requirements for the investigator and research staff engaged in the research; temporary or permanent suspension of the research and/or the investigator; random audits of the research or investigator; disallowance of research use of data collected; or other actions deemed appropriate by the IRB and communicated in writing to the investigator in a final notification.

The inquiry process of the IRB will include the following stages:

1. *The Complaint or Concern*: Review by the IRB Chair to determine seriousness and validity.
2. *Initial Inquiry*: Administrative review by the IRB Chair or a Subcommittee with notification to investigator of complaint or concerns. May result in minor corrective actions for resolution, or referral to full IRB at a convened meeting.
3. *IRB Investigation*: Audit of protocol by IRB Chair or IRB Subcommittee with a report of findings at a convened meeting with notification to investigator. May result in major correction actions, suspension, or termination of study.
4. *Appeal Hearing*: Investigator responds in writing and/or in person at an IRB convened meeting.
5. *Final IRB Determination*: Report of full IRB meeting with any corrective actions, resolutions or stipulations regarding the future of the research study or its termination if warranted.

