New Mexico Junior College

Policy and Procedures

For Conducting Research

Involving Human Subjects

June 16, 2003
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NMJC Research Policy and Procedure

Introduction

New Mexico Junior College (NMJC), through the Office of Institutional Effectiveness, has established these policies and procedures for the conduct of research involving human subjects in order to protect the rights, well being, and personal privacy of individuals; to assure a favorable climate for the conduct of scientific inquiry; and to protect the interests of NMJC and its faculty, students, and staff.

NMJC has established the Institutional Review Board (IRB) to administer NMJC policies and procedures regarding research involving human subjects. The Institutional Review Board is composed of staff members performing functions of institutional research, reporting, and evaluation. Additional staff members may serve in an advisory capacity where appropriate.

The following general principles apply equally to all research involving human subjects or data related to human subjects, whether carried out solely within NMJC resources or with assistance from external sources. NMJC assumes responsibility for providing procedural guidelines; however, all individuals who anticipate conducting development, demonstration, pilot studies, or research projects involving human subjects are responsible for familiarizing themselves with the policies.

1. NMJC and the individual members of its faculty, staff, and student body recognize their responsibility for protection of the rights and welfare of human subjects.
2. No subject in a research activity shall be exposed to unreasonable risk to health or well-being.
3. No subject will be coerced in any way to participate in a research project but will do so on a strictly voluntary basis.
4. The confidentiality of information received from subjects in experiments or respondents to questionnaires shall be fully protected, both during and after the conduct of a research activity, within the limits of the law.
5. Research which involves minimal risk, stress, or discomfort shall be carefully explained to the subject before his or her participation; the investigator shall be satisfied that the explanation has been understood by the subject; and written consent of the subject, such consent containing the substance of the explanation, shall be obtained and kept as a matter of record. The elements of informed consent are established by the federal government and by NMJC (see Appendix C).
6. A request from any subject to withdraw from research activity shall be honored promptly without penalty or loss of benefits to which the subject is otherwise entitled, within the limits of the research.

Institutional Review Board Functions and Responsibilities

1. The IRB shall recommend to the Director of Research and Planning, and review on a continuing basis, NMJC policies and procedures regarding the use of human subjects in research.

2. The IRB shall review and have authority to approve, require modifications to secure approval, or disapprove all research activities involving human subjects or data related to human subjects.
3. Research activities shall be reviewed by the IRB for compliance with established federal regulations related to the protection of human subjects, as contained in the Code of Federal Regulations (CFR) 45, part 46 and the Family Educational Rights and Privacy Act (FERPA).
4. Research covered by these regulations that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by NMJC. However, those NMJC officials may not approve the research if it has not been approved by the IRB.
5. The IRB shall provide advice and guidance to investigators regarding the protection of the rights and welfare of human subjects.
6. The IRB shall ensure that investigators have been informed in the ethical principles of using human subjects in research.
7. The IRB shall require that information given to subjects as part of informed consent is in accordance with federal regulation as indicated in 45 CFR 46. The IRB may require that information in addition to that specifically mentioned in 45 CFR 46 be given to the subjects when, in the IRB's judgment, the information would meaningfully add to the protection of rights and welfare of the subjects. Documentation of that process shall also be required. The information outlining requirements for the protection of human subjects is available by contacting the NMJC Office of Institutional Effectiveness. Researchers will be required to sign for receipt of a copy of this information (see Appendix J)
8. The IRB shall notify investigators in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval. If the IRB decided to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
9. The IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year.
10. The IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator and appropriate NMJC officials.

General Procedures for Submitting An Authorization to Conduct Research Application

It is the obligation of each investigator (faculty, staff, or student) to bring any proposed research activity involving the use of human subjects or data related to human subjects to the attention of the NMJC IRB for review and approval. All IRB applications (regardless of level of review described below) must contain certain documents and information, as described at the top of the following page.

1. Completed Application for Authorization to Conduct Research (see Appendix C) must be completed in full, and must be typed for processing
    a. Protocol of Research Project - This section of the application should briefly state the study's procedures, and describe all aspects of interaction with human subjects. This section should address:
        - subject recruitment procedures
        - exclusion/inclusion criteria
        - procedures to be used to gather data
        - who will have access to the data collected
        - whether and how data will be made available to future researchers, funding organizations, or the public
        - the research framework
        - rationale for the study grounded in previous literature
        - the research questions or hypotheses
    b. Safety Measures - This is the most critical section of the application. This section should describe fully:
        - potential risks to subjects (including emotional or physical discomfort or harm, social or financial consequences, etc.)
        - justification for the use of deception and description of debriefing techniques, if applicable
        - potential benefits to subjects
        - steps that will be taken to minimize risk
        - how confidentiality or anonymity will be maintained
        - procedures for obtaining informed consent
2. Application for Exemption from Full IRB Review or Application for an Expedited IRB Review if appropriate
3. Consent/Assent Forms
4. Measures/Data Collection Instruments

Levels of IRB Review

The IRB authorizes four levels of review based on the type of research activity. These levels are 1) review by the IRB Chairperson, (2) review by a course instructor, (3) review by the IRB Chairperson and one IRB member, and (4) review by the full IRB. The following are general procedures to be followed by researchers when preparing IRB applications.

1. Review by the IRB Chairperson (for research projects exempt from full IRB review)

Research activities in which the only involvement of human subjects will be in one or more qualifying categories are exempt from full IRB review, but need to be submitted to the IRB Chairperson for approval prior to collection of data. The categories of research qualifying for an exemption from full IRB review are described on the Application for Exemption from Full IRB Review (see Appendix E). The investigator should submit an Authorization to Conduct Research (Appendix C) and an Application for Exemption from Full IRB Review (Appendix E) with appropriate supporting materials to the IRB Chairperson for review. The applications should follow the guidelines outlined above. If the IRB Chairperson determines that the research does

not meet the criteria for exemption, the investigator will be notified that the proposal must be reviewed by the full IRB. It is then the investigator's responsibility to initiate the procedures for a full IRB review, as described below.

2. Review by Course Instructor

Student research activities that are undertaken as partial fulfillment of course requirements need only be submitted to the course instructor for approval prior to collection of data, provided the instructor has an approved Certification Form for Course Instructors (see Appendix G) for that course on file with the IRB. An instructor must complete a Certification Form for Course Instructors for each course he/she teaches in which students collect data from human subjects for research projects. Once filed with the Office of Institutional Effectiveness, the certification will remain in effect for three academic years. No research within this category shall be initiated until written approval has been obtained from the faculty member. Approval by the faculty member indicates that the research involves no more than minimal risk to the human research subjects. If the research activity involves more than minimal risk to the subject(s) (see Appendix I) , the faculty member must refer the project to the IRB for the appropriate level of review. All students wishing to conduct research activity as a project within a course, for which the faculty member does not have an approved Certification on file with the IRB, must submit their project to the IRB for review and approval following the procedures described in this section. This requirement applies to all investigators who are conducting research as students of NMJC even if the activity is not taken for academic credit.

3. Review by IRB Chairperson and One other IRB Member (for research projects qualifying for an expedited review)

Research activities in which the only involvement of human subjects will be in one or more of eight qualifying categories are eligible for an expedited review by the IRB Chairperson and one other IRB member. The categories of research qualifying for an expedited review appear on the Application for Expedited IRB Review (see Appendix F). The investigator should submit an Authorization to Conduct Research (Appendix C) and an Application for an Expedited IRB Review (Appendix F) with appropriate supporting materials to the IRB Chairperson for review. The IRB application should follow the guidelines outlined above. If the IRB Chairperson determines that the research does not meet the criteria for an expedited review, the investigator will be notified that the proposal must be reviewed by the full IRB. It is then the investigator's responsibility to initiate the procedures for a full IRB review, as described below.

4. Review by Full IRB (for research projects that do not qualify for exempt or expedited reviews)

For all research which does not fall within the exempt or expedited categories or which is not part of a class project, the investigator shall submit a completed Authorization to Conduct Research (Appendix C) to the IRB Chairperson. The IRB application must follow the guidelines described above. Applications that are incomplete (e.g., missing or not fully addressing one of the sections) will be returned due to insufficient information. The chairperson will arrange a review by the full IRB, if necessary. Attendance by the investigator or a designated representative at the IRB review meeting in which his or her research activity is scheduled for

discussion is welcome. No research within the purview of the IRB shall be initiated until approval has been given.

Criteria For Approval

Research requests will be reviewed by the Institutional Review Board. Approval of the proposal will be based on the following criteria:

1. Compatibility with the college's mission and purpose
2. Soundness of rationale for conducting the research project
3. Soundness of the rationale and appropriateness of the sampling, methodology, instrumentation, and treatment of data
4. Acceptability of the potential effects the collection of data and the dissemination and use of results may have on NMJC students, personnel, operations, and the community
5. Evidence of support of other involved individuals or groups internal to NMJC
6. Evidence that the researcher understands and meets the requirements of Protection of Human Rights and Family Educational Rights and Privacy Act (FERPA)

Under certain circumstances, the Institutional Review Board will submit a request to the President for approval. This submission will occur if the project:

1. Has political or broad community implications for the college
2. Involves board policy
3. Involves established operating procedures and/or policies

Under certain circumstances, the Institutional Review Board will submit a request to the Vice-President of Instruction for approval. This submission will occur if the project involves the use of instructional class time and is not considered by the committee to be both educationally valuable and a natural part of the course content.

Actions and Time Limits Pertaining to IRB Review

1. The formal actions taken by the IRB will be communicated to investigators in writing following the review, and will take one of the following forms:

a. "Approved" indicates the researcher may begin data collection and that the project meets the IRB standards for protection of human subjects in research. Approval may be granted subject to researcher meeting conditions outlined by the IRB.

b. "Approval Withheld Pending Resubmission to the Full IRB" indicates approval by the IRB has been withheld pending revision of specific points. Research may not be undertaken until the outlined revisions are submitted to and approved by the IRB.

c. "Approval Withheld Pending Resubmission to the IRB Chairperson" indicates approval by the IRB has been withheld pending revision of specific points, to be approved upon resubmission directly to the IRB Chairperson.

d. "Disapproved" indicates the proposed research does not meet NMJC and/or federal guidelines for the protection of human subjects. The research activity may not be undertaken and will not be afforded NMJC endorsement. The investigator shall have the opportunity to respond in person or in writing to the IRB.

2. Approval of proposed research is usually granted for a period of twelve months commencing with the date approval is granted by the IRB. Based on the degree of risk to human subjects, the IRB may grant special conditions whereby the investigator has a shorter approval period or must report research progress at specific intervals. Continuation of projects past the approval period requires resubmission to the IRB. It is the responsibility of the investigator to reapply and obtain the approval of the IRB prior to expiration of the approved period. At least one month prior to the expiration of the approved period of continuing projects, a Progress Report (see Appendix H) should be submitted to the IRB. When a student is conducting the approved research, the faculty member identified on the original proposal as directing the research is responsible for ensuring that the progress report is submitted on schedule or, failing that, for suspending the research activity by the student.

3. The IRB will formally notify the investigator of IRB action in writing.

4. When the research activity involves an outside agency (e.g., hospital, public school, clinic), the investigator must secure written approval from the appropriate official within the agency prior to receipt of final approval from the IRB.

5. If the IRB gives the research proposal an Approval Withheld Pending status, the investigator must contact the IRB chair regarding the required action within 60 days or the proposal will be withdrawn from further IRB action.

Grievance Procedure

If a research subject registers a complaint, the investigator shall attempt to relieve the complaint by explanation or by a change of procedure.

1. If the research was originally approved by a student's instructor (other than master's thesis research), documentation of the procedural change should be submitted to the faculty member for review. If the faculty member determines that the procedural change remains within the purview of his or her certification, he or she has the authority to approve the change. However, if the faculty member determines the procedural change would place the subjects above "minimal risk," referral to the IRB is required. In such cases, a description of the original project and the procedural changes are required.

2. If the research activity was originally approved by the IRB, the IRB Chairperson or the IRB Chairperson and one other IRB member, documentation of the procedural change must be submitted to the IRB for action.

NEW MEXICO JUNIOR COLLEGE
INSTITUTIONAL REVIEW BOARD
POLICY DEFINITIONS

1. "Adverse Effect"
An adverse effect is a physiological, psychological, or social outcome of an investigation that is detrimental to a subject. An adverse effect may be anticipated or unanticipated. For the purpose of review, the Institutional Review Board (IRB) for Research Involving Human Subjects needs the following:
New Applications: Information on adverse effects that most likely or only possibly may occur, based on the literature, previous studies, and other reliable sources. In addition to listing possible adverse effects, applications should indicate the probability that an adverse effect could occur.
Renewal Applications: The same information is required as for new applications, as well as information on adverse effects that have occurred during the study to date.

2. "Anonymity"
In the context of these guidelines, "anonymity" means that no one knows the identity of the subject. No identification of subjects should be possible by the procedures employed or by the information solicited. An example would be a mailed questionnaire with directions for subjects not to sign their names, where no code is used, where responses to questions will not reveal identities, and where the subject group is sufficiently large to avoid inadvertent identification.

3. "Assent"
Assent is a child's affirmative agreement to participate in research after an adequate explanation is provided. The absence of a child's objection does not constitute assent.

4. "Competent"
Any adult who has not been determined by a court to be incompetent, as there is a legal presumption of competence.

5. "Confidentiality"
Where the identity of the subjects is known by name, by specific data, or by appearance, it is usually necessary to make provisions for confidentiality. Data should be stored in a locked file cabinet (or should be similarly protected) accessible only to the investigator and his/her authorized staff and representatives. No identifying information (including recordings, e.g. photographs, tapes, documents) should be released except with the explicit permission of the subject. Where confidentiality in reports of results or in reports of specific incidents of interest to the scientific community cannot be assured, this information must be included in the consent form. In those instances where unique information is received but was not anticipated at the time of consent, later consent for the release of identifying information should be obtained. Only personal information necessary to a research activity should be solicited from subjects. To avoid an inadvertent breach of confidentiality, data should be coded, with the names of participants and other identifying information retained only on a master list to be securely stored separate from the data. In double-blind studies, e.g., in drug studies, an appropriately designated individual

should retain a copy of the key to the code, a listing of the drug and the dosage to be taken by each subject, and that individual should be available to break the code if necessary. In some circumstances, it may be necessary to break confidentiality. If this is foreseen, the study subjects should be informed of this possibility on the consent form. An example would be subjects who engage in or have engaged in illegal activities. Because of legal interests, risk exists that the data or the investigators might be subpoenaed; prospective subjects must know this prior to consenting.

6. "Deception"
Deception occurs whenever information about an activity is deliberately withheld from subjects. A dilemma may arise in some research when fully informed consent may itself have injurious effects on the subject, or it may invalidate the experiment, as in the use of placebos or in double-blind studies.

7. "Decisionally Capable"
A subject who is assessed, usually without the involvement of a court, to possess the mental ability to make decisions or to participate in decision making.

8. "Decisionally Incapable"
A subject who is assessed, without the involvement of the court, to lack the mental capacity to make a particular decision.

9. "Emergency Applications"
Emergency applications are those that relate to emergencies where procedures must be initiated immediately or the opportunity lost.

10. "Incompetent"
A person who has been determined by a court of law to be unable to make and articulate rational decisions.

11. "Informed Consent"
The ethical and professional codes governing the use of human subjects in research provide that no research involving human subjects should be undertaken without the informed and voluntary consent of the human subject or the consent of his/her authorized representative if the subject lacks the capacity to consent. When a subject's consent is obtained, it must be "informed" consent, i.e., the knowing consent of an individual or his/her legally authorized representative, so situated as to be able to exercise free power of choice without the presence of excessive inducement or any element of force, fraud, duress, or other form of restraint or coercion. Further, consent should be a reasoned judgment to participate in an activity in full recognition of what will or could happen. In most cases, the investigator must discuss with the subject, in language that can be readily understood, all matters pertinent to the decision to participate. The consent form should contain the essence of the discussion between the investigator and the subject.

12. "Institutional Review Board"
Institutional Review Board (IRB) is the term used by the Department of Health and Human Services for a committee or group that has been formally designated by an institution to review and approve research involving human subjects.

13. "Personal and Sensitive"
Examples of personal and sensitive information are some demographic data, questionnaires, inventories, and scales which elicit subjective responses; opinions on sensitive issues or about other individuals or groups; and records, such as medical, academic, photographic, audiotapes, and videotapes.

14. "Right to Privacy"
The right to privacy is the right of individuals to decide for themselves how much they will share with others their thoughts, their feelings, and the facts of their personal lives.

15. "Risks"
There are different types of risks to which human subjects may be exposed that are inherent in various research procedures. Risk is most obvious in medical and behavioral science research projects involving procedures that may induce a potentially harmful altered physical or mental state or condition. Some examples are: the removal of organs or tissues for study, reference, transplantation, or banking; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of strenuous physical exercise; and subjection to deceit, public embarrassment, or humiliation. There is a wide range of medical, social, and behavioral projects in which no immediate physical or psychological risk for the subject is involved, e.g., those involving the use of personality inventories, interviews, questionnaires, observations, photographs, tapes, records, and stored data. However, some of these procedures may involve varying degrees of discomfort, harassment, or invasion of privacy, or constitute a threat to the subject's dignity, all of which pose another type of risk.

16. "Minimal Risk"
The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical, dental, or psychological examinations of healthy persons.

17. "Scientific Merit"
Scientific merit will not be considered by the IRB *except* in cases in which there would be more than minimal risk to subjects. In such cases, the IRB must consider scientific merit, that is, the potential for contributing to knowledge, in order to help determine whether or not the potential benefits of the research to individuals or to society outweigh the risks. The IRB may utilize consultants in making this determination. The IRB will not approve research when the risk is significant and the project lacks appropriate merit.

18. "Subject"
A subject is a human being whose physical, intellectual, emotional, or behavioral condition is investigated for any purpose other than for the sole purpose of benefiting the subject as an individual. If a person such as a family member, employer, or teacher is asked to provide information about another individual, then both individuals are considered to be subjects. Donors of organs, tissues, body fluids, services and records, and informants are also considered to be subjects. The subject may be an adult, a minor, a student, a patient, military personnel, a resident of an Institution for the mentally retarded, or a prison inmate. It is useful to distinguish between

normal subjects and those who are of interest because of an illness or dysfunction. A subject is considered to be a normal subject if his/her participation in the activity is NOT determined by an illness or dysfunction that he/she exhibits.

The definition of "subject" excludes all accepted and established service relationships, such as the normal relationship of patients to physicians, students to professors, and other clients to professionals, in which the patient, student, or client is receiving aid or services intended only to meet his/her own personal needs or the overriding needs of society. The professional-client relationship has the welfare of the client as its primary objective, whereas the investigator-subject relationship has the discovery of new knowledge as its primary objective. This difference may not be fully understood by the subject who is also a client and can result in the investigator's gaining consent without free decision, in part based on a trust based on a presumed role that the investigator is not necessarily fulfilling at that time. If doubt exists as to whether the procedures to be employed are for the personal needs of the client, the activity should be considered to involve subjects whose rights and welfare are to be protected in accord with these guidelines. The normal employer-employee relationship, in which legitimate services are tendered for salary, wages, or remuneration in keeping with customary written or oral contracts, is also excluded from the definition of "subject." Payment of volunteers, however, does not alter their status as subjects. If doubt exists as to whether the procedures are within the normal limits of the employee's work scope, the employees should be considered to be participating as human subjects, and their rights and welfare must be protected.

19. "Subject Advocate"

A subject advocate is an individual who participates in the consent process on behalf of an adult subject who has not been declared legally incompetent, but whose ability to give informed consent is in question. The subject advocate should be a family member, a close friend, or someone who knows the subject well enough to attest to the subject's probable agreement to participate.

NEW MEXICO JUNIOR COLLEGE
ANSWERS TO FREQUENTLY ASKED QUESTIONS
ABOUT INSTITUTIONAL REVIEW BOARD REGULATIONS

1. What is an Institutional Review Board (IRB)?
An IRB is a committee formally designated by the President of New Mexico Junior College to review, to approve the initiation of, and to conduct continuing review of research involving human subjects as required by the U.S. Department of Health and Human Services (45 CFR 46). The purpose of IRB review is to assure the following:

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits for the subjects as well as for the importance of anticipated gain in knowledge
- Informed consent will be sought from each prospective subject, or the subject's legally authorized representative, and will be documented
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

2. Why do we need an IRB anyway?
An IRB serves as an established body that protects the rights of human subjects in research and provides information to researchers to help protect them from liability.

3. Who must apply for approval from the IRB?
Any member of the faculty, student body, staff, or individual who proposes to use human subjects in a research activity sponsored by the university.

4. What kinds of activities require review?
Any research projects involving human subjects, i.e., human beings whose physical condition, responses, tissues, fluids, or records are investigated or used for any purpose other than for the purpose of benefiting the subject as an individual. The use of interviews, tests, observations, inquiries, records, and tapes that provide non-public information about individuals or groups must be reviewed. In addition to research projects, demonstration activities, pilot projects, and course projects must also be reviewed if they involve human subjects.

5. When must research involving human subjects be reviewed?
Review must occur PRIOR to initiation of the research or pilot studies, PRIOR to implementation of any changes in procedures involving human subjects, and at least annually during the lifetime of the research activity. If the research is being proposed for external funding, WHENEVER POSSIBLE review should take place PRIOR to submission of the proposal to the funding agency.

6. How does an investigator apply?
An application is submitted to the chair of the IRB, who decides whether a proposal requires full

review, or is exempt from review. *[See Question 7]*

7. Is any research exempt from review?
Yes. Federal Guidelines list research that is exempt from review. The chair of the IRB will determine if a proposal meets the criteria for exemption. This normally will take three to five business days.

8. How long does the review process take?
It is recommended that investigators allow at least one month. However, if the application is exempt or expedited, the process will not take as long. The following steps are typical in the handling of applications:

- After determination of review status (exempt, non-exempt or expedited), an application is submitted to the IRB. The IRB receives and logs in the application.
- The application is assigned to a IRB meeting date.
- The application is reviewed by the IRB.
- Feedback, if any, from the IRB is forwarded to the investigator.
- The investigator's response, if any, is received by the IRB.
- Final action is taken on the application by the IRB.
- A copy of the approved application is provided to the investigator and the original is filed in the Office of the Director of Institutional Research.

9. Who serves on the IRB?
A minimum of five members serve on the IRB. Appointments to the committee are made annually by the President. Additional staff members may be asked to serve in an advisory capacity where appropriate.

10. May one appeal decisions of the IRB?
An investigator may respond in person or in writing to the IRB regarding any IRB action. There is, however, no authority outside the IRB that can grant approval to a project that has not received IRB approval.

11. Does an IRB or institution have to compensate subjects if injury occurs as a result of participation in a research project?
No. The Food and Drug Administration (FDA) informed consent regulation (21 CFR 50.25 (a)(6)) requires that for research involving more than minimal risk, the subject must be told whether any compensation and/or any medical treatment is available if injury occurs, and, if so, what it consists of, or where further information may be obtained. Institutional policy, not FDA regulations, determines whether compensation and/or medical treatments will be offered and the conditions that might be placed on subject eligibility for compensation or treatment(s).

12. What is the college's compensation plan for adverse effects?
None. Students, faculty, and staff have liability coverage, but there are no university compensation provisions.

13. Is the purpose of the IRB review and of informed consent to protect the institution or the subject?
The fundamental purpose of IRB review and of informed consent is to assure that the rights and

welfare of the subject are protected. A signed informed consent form may be evidence that the information required by federal guidelines has been provided to a prospective subject. IRB review of the consent form is to ensure that the subject is given adequate information concerning the study and serves the dual functions of protection of the subject and documentation that the institution complied with applicable regulations.

14. Is getting the subject to sign a consent form all that is required by the informed consent regulations?

No. The consent form itself is merely an aid in insuring that adequate information is provided to the subject. The signed consent form provides documentation of a subject's consent to participate in a study. The entire informed consent process involves giving a subject adequate information concerning the study, providing adequate opportunity for the subject's questions, ensuring that the subject has comprehended the information, and obtaining the subject's voluntary consent to participate. To be effective, the process must provide an opportunity for the investigator and the subject to exchange information and ask questions. The consent form, therefore, is not an end point. It is one step in this communication process.

15. How long must consent forms be kept?

Three years.

INSTITUTIONAL REVIEW BOARD
AUTHORIZATION TO CONDUCT RESEARCH

SEE FOLLOWING 2 PAGES

NEW MEXICO JUNIOR COLLEGE
AUTHORIZATION TO CONDUCT RESEARCH
APPROVAL IS VALID FOR ONE YEAR FROM APPROVAL DATE

THIS FORM MUST BE TYPED FOR PROCESSING – DO NOT LEAVE ANY BLANKS.

Principal Investigator(s) _____ Phone _____ Date _____

Department(s) _____

Title of Research Project _____

If Principal Investigator is an NMJC student, check purpose of project: _____ Class Assignment _____Other (explain):

_____

Name of responsible faculty member: _____

If Principal Investigator is neither a faculty or staff member nor a student, please explain:_____

_____

Where will work be done? _____

When will the research begin? _____ When will the research end? _____

CHECKLIST FOR RESEARCHER

Please check appropriately. If explanation is needed, use the back of the form and additional sheets if necessary.

	YES	NO	GENERAL ISSUES
1.	____	____	Are federal funds involved? If yes, sponsor's name: _____ **(please explain on attached sheet)**
2.	____	____	Other external funds? If yes, sponsor's name: _____

			SUBJECT RELATED ISSUES
3.	____	____	Has the selection of subjects been equitable, with particular recognition of the special problems of research involving vulnerable populations such as women, children, prisoners, mentally disabled persons or economically or educationally disadvantaged persons? **(If no, please explain on attached sheet)**
4.	____	____	Are subjects minors or have diminished mental or physical capability? **(If yes, please explain on attached sheet)**
5.	____	____	Subjects have been given a choice of the following: participate or do another assignment (i.e., book review, paper, etc.)
6.	____	____	Subjects have been offered one or more of the following incentives to participate in the research: money, extra credit for the class **(If yes, please explain on attached sheet)**.
7.	____	____	Subjects will be allowed to participate in the research during regularly scheduled class time.

			INFORMED CONSENT/ASSENT ISSUES
8.	____	____	Will each subject be fully informed?
9.	____	____	Will each subject be debriefed following completion of the research?
10.	____	____	Will each subject's personal privacy be protected? **(If no, please explain on attached sheet)**
11.	____	____	Will each subject, prior to the research, indicate informed consent/assent to participate by completing and signing a written form **(If no, please explain on attached sheet) (copy of informed consent form must be attached to this application)** which includes:

a. A description of the potential risks to the subjects including physical, psychological, emotional, social, or spiritual well-being,
b. A description of how the personal privacy of the subject will be protected,
c. A description of any incentives for the subjects and restrictions for receiving such incentives,
d. An indication that the subjects' participation is entirely voluntary and that they may withdraw at anytime, and

e. A description of any debriefing that will be made available to the subjects?

If items 1, 4, 6 are checked YES please explain on attached sheet; if items 3, 10, 11 are checked NO please explain on back.

PROTOCOL OF RESEARCH PROJECT
Provide the following information on an attached sheet: brief description of research methods, time required for single session, number of sessions, psychological or medical methods to be used, research objectives or hypothesis(ses); if a survey instrument or other interview protocol is to be used, please attach a copy.

SUBJECTS: **Approximate Number of Subjects _____**

Age of Subjects Over 18 _____ Under 18 _____ If under 18, please indicate ages _____

Sex of Subjects _____Male _____Female _____Both Male and Female

SAFETY MEASURES: Outline specific safety controls. If applicable, indicate what OSHA requirements will be observed. If applicable, indicate what universal standards will be observed. If subjects are minors and/or have diminished mental capability and/or have diminished physical capability, indicate special precautions that will be observed.

_____
_____
_____
_____
_____

EXPLANATIONS FOR CHECKLIST RESPONSES (MANDATORY FOR #1, 4, 6 if checked YES; #3, 10, 11 if checked NO)

_____

_____

_____

_____

Responsible Faculty Approval/Signature _____ **Date:** _____

Dept. Head/Dean Approval Signature _____ **Date:** _____

I have read the NMJC Administrative Policies and Procedures Manual on the Authorization to Conduct Research and I certify that my proposed research is in conformity with College policy. I certify I have read the regulations for the protection of human subjects (45 CFR 46) and guidelines for Family Educational Research and Privacy Act (FERPA). Copies are available in the Office of Institutional Effectiveness.

SIGNATURE OF RESEARCHER(S)_____ **DATE** _____

Disposition of IRB: _____ **Approved** _____**Disapproved** **DATE** _____

Conditions: _____

_____

Project Approval Number: _____

Forward to: NMJC Institutional Review Board Chair

INSTRUCTIONS FOR THE PREPARATION OF AN INFORMED CONSENT DOCUMENT FOR THE INSTITUTIONAL REVIEW BOARD, NEW MEXICO JUNIOR COLLEGE

The voluntary consent of every participant is an essential condition of any research study involving human subjects. Informed consent reflects the basic principle of *respect for persons* and assures that prospective human subjects will understand the nature of the research and can *knowledgeably and voluntarily* decide whether or not to participate. Voluntary informed consent protects the subject, whose *autonomy* is respected. All researchers have an ethical obligation to ensure that all participants are fully informed about the study prior to the participant's consent and to ensure that this consent is voluntary.

Many individuals connected to the College engage in research involving human subjects. The following point to the importance of obtaining the subject's valid and informed consent and it applies to all involved researchers (for example, research in biology, psychology, or nursing). Although the elements of informed consent (i.e., full disclosure, and voluntary choice) are easy to enumerate, recent empirical studies suggest they are not so easy to achieve. Even the best intentions do not ensure against failures of communication – information may be poorly conveyed or subjects may forget that they are involved in a research project. Enhancing the likelihood that informed consent will take place is a challenge to which researchers should respond with imagination and good judgment. If it occurs that a subject's consent to participation was neither voluntary nor informed, the researcher may be subject to severe penalty both legally and professionally. Consent is valid if only if the subject understands and participates voluntarily. In normal cases, the subject can voluntarily consent to participate. However, certain populations (e.g., children or individuals with reduced mental capability or experiencing developmental disabilities) may not be able to understand the required information, and may require someone else to consent on their behalf. In such cases, researchers must obtain the assent of the subject in addition to the consent of their representative. Other populations (e.g., prisoners or institutionalized individuals) are so situated that the voluntariness of their consent may be in doubt. All of these subjects may need special protections, and great concern should be shown to these individuals in obtaining their informed consent. The following instructions for preparation of a subject consent form may be used as a guideline for the submission of protocols for approval by the IRB. Because obtaining informed consent is an educational process, researchers should do what they can to enhance the prospective subject's comprehension of the information presented. The consent process should consider the nature of the proposed subject population, the type of information to be conveyed, the circumstances under which the consent process will take place (e.g., manner, timing, place, personnel involved, timing or location of first contact with potential subjects), how others will contact subjects during or following the study, and who has access to the data.

THE REGULATIONS

The federal regulations (45 CFR 46 – Protection of Human Subjects) require that certain

information must be provided to each subject:
1. A statement that the study involves research, and an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and the identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation can be expected, and, if so, in what form and amount, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. The regulations further provide that the following additional information is to be provided to subjects, where appropriate:
1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study. Investigators may seek consent only under circumstances that provide the prospective subject or his or her representative sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence. Furthermore, the information must be written in language that is understandable to the subject or representative. The consent process may not involve the use of exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, sponsor, institution, or agent from liability for negligence.

INSTRUCTIONS FOR PREPARATION OF CONSENT FORM

The following instructions for preparation of a subject consent form may be used as a guideline for the submission of applications for approval by the IRB. Certain "boilerplate" statements are provided; these should be incorporated into each Consent Form. Other portions are dependent on the nature of the work to be performed. Through a Consent Form, a subject must be made fully

aware of the purpose of the study; the nature of the study; the sponsor of the study and nature of the work to be performed. The subject must be informed about the principal investigators and sponsors of the study, the magnitude or extent of any discomfort or potentially adverse effects to health or well-being, any personal benefits or compensation the subject can expect to receive, and the fact that the participant is free to withdraw or be withdrawn from the study at any time without penalty. This information must be presented in terms that can be comprehended by the average individual, or, if applicable, the type of individual being studied. Items in **BOLD** type should be addressed in all Consent Forms. Other items or descriptions of items are to be used as appropriate.

DESCRIPTIVE TITLE FOR THE PROTOCOL

I. DESCRIPTION OF STUDY

This section should include a comprehensive description in lay terms of the study to be performed. It should address who is conducting the study; the purpose of the study; why the subject is being asked to participate; what will be expected from the subject as a result of participation (e.g., "blood samples of one teaspoon each" or "survey questionnaire completion"); how long the subject will be expected to participate (e.g., "it will take approximately half an hour to complete the questionnaire"). This, as well as subsequent sections, should be written using the first-person pronoun "I" or "we" as appropriate to refer to the researcher(s). The potential volunteer subjects should be referred to as "you."

II. EXCLUSION CRITERIA

This section should address those preexisting conditions or other factors that would preclude the participation of an individual in the study. For example, if pregnancy would be a contraindication for participation, a statement such as "your participation in this study indicates that you are not pregnant and agree to practice an effective method of birth control for the duration of your participation in the study" would be appropriate.

III. RISKS AND BENEFITS

All potentially adverse effects of participation in the protocol must be clearly described. Any known risks associated with the study should also be stated. Examples would be "There is a chance of bruising and pain at the site of blood drawing," or "Some of the questions asked may be of a personal nature or cause some emotional discomfort." If there are no benefits to the subject, this should be clearly stated (e.g., "There are no specific benefits to you personally for participation in this study").

IV. ALTERNATIVE TREATMENT

If relevant, the subject should be made aware of any alternative treatment or participation that might be available, including no treatment or participation at all.

V. COSTS AND PAYMENTS

If it can be reasonably expected that participation in the protocol will result in additional expenses to the subject, these additional costs must be clearly indicated. This must include a statement about additional professional fees, hospital costs, laboratory fees, and device fees (for example, if as a result of participating in the study, the subject is referred to a facility for further

treatment which will not be paid for by the research protocol). If a research subject is to be compensated, the amount of compensation, the schedule of payment, and how the payment would be prorated should the subject withdraw or be withdrawn from the study should also be described. If a research subject is to receive course-credit for participation, this should also be described.

VI. AIDS TESTING

To maintain conformity with recently issued PHS guidelines, the following "boilerplate" statement should be inserted in every Subject Consent Form that involves the testing of a subject's tissue sample for the presence of HIV virus, whether it is discarded tissue or not. "The [tissue sample] will be tested for the HIV antibody (AIDS). If the result of a positive test is confirmed by a second test (Western Blot), you will be notified in writing of the positive result. At that time, the Principal Investigator will provide you with the name of a qualified individual whom you may contact for counseling as to the proper interpretation of the positive result, and for advice on how you may obtain further counseling if needed. The test result will be maintained in strictest confidence consistent with current state and federal laws unless otherwise specified in the experimental protocol for which you are consenting."

VII. NEW INFORMATION

If relevant, the following or comparable statement should be included: "Any new information obtained during the course of the research that may affect your willingness to continue participation in the study will be provided to you."

VIII. CONFIDENTIALITY

Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust, with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission. This includes obtaining information about the subject that would, if disclosed by the researcher, jeopardize their job or lead to prosecution for criminal behavior, or provide cause for legal action against a researcher or institution. Under less dramatic circumstances, a breach of confidentiality can be a moral wrong. The following or a comparable statement should be included in all Consent Forms: Any information obtained about you from the research including answers to questionnaires, history, laboratory data findings, or physical examination [choose appropriate items] will be kept strictly confidential. The information you give us will not be shared with anyone outside the research team with your name attached. We will protect your confidentiality by coding your information with a number so no one can trace your answers to your name, properly disposing of computer sheets and other papers, limiting access to identifiable information, telling the research staff the importance of confidentiality, and storing research records in locked cabinets. The data derived from this study could be used in reports, presentations, and publications but you will not be individually identified. The Consent Form should describe who has access to the confidential information and the way in which the information is recorded. The Form should also state (if appropriate) that there are limitations to confidentiality that can be granted the subject (e.g., identification of criminal wrongdoing). Specifically, where data are being collected about sensitive issues (such as

illegal behavior, alcohol or drug use, sexual attitudes, practices or preferences, psychological well-being or mental health, information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community, and information which could lead to social stigmatization or discrimination), protection of confidentiality consists of more than preventing accidental disclosures.
Careful attention should be given to a series to decisions related to confidentiality: whether the researchers will record subject identifiers at all (including consent forms; if identifiers are to be collected, whether they will be retained after the data are coded; if identifiers are not destroyed, how they are to be maintained; and what subjects will be told about these matters as part of the informed consent process. A variety of methods for protecting confidentiality are available for different situations, including situations in which there is a danger of deductive identification of otherwise anonymous subjects on the basis of separate elements of data (e.g., birth date, occupation, and zip code). Among the available methods for assuring confidentiality are statistical techniques and physical or computerized methods for maintaining the security of stored data. The more sensitive the data being collected, the more important it is for the researcher to be familiar with the state of the art in protecting confidentiality.

Under federal law, researchers can obtain an advance certificate of confidentiality that will provide protection even against a subpoena for biomedical, behavioral, clinical, or other data, or research on mental health, including the use and effect of alcohol, drugs, or other addictive products.

IX. WITHDRAWAL PRIVILEGE

The Consent Form must note that the subject may withdraw from the study at any time and that their participation is entirely voluntary. It must also note that if the subject decides not to participate, there will be no penalty or loss of benefits to him/her to which they are otherwise entitled. Lastly, it must state that if the subject decides to participate, he/she may discontinue at any time without penalty or loss of benefits to him/her to which they are otherwise entitled.

X. COMPENSATION FOR ILLNESS OR INJURY

If relevant, the following or a comparable statement should be included: In the unlikely event of a physical injury or physical illness resulting from the research protocol, no monetary compensation will be made, but any emergency medical treatment which may be necessary will be made available to you without charge by the investigators. If any injury should result from your participation in this research project, New Mexico Junior College, (NMJC) provides no insurance coverage, compensation plan, or free medical care plan to compensate you for such injuries. In the event that you believe that you have suffered an injury as a result of your participation in a NMJC research program, you may contact the Office of Institutional Effectiveness (505) 392-3487. The informed consent form may not contain any exculpatory language. Subjects may not be asked to waive any of their legal rights, nor may they be asked to release the investigator, sponsor, or institution (or its agent) from liability for negligence.

XI. VOLUNTARY CONSENT:

The following or comparable statement should be included in all Consent Forms:
"Your signature below means that you have freely agreed to participate in this research study. You should consent only if you have read this form or it has been read to you and you understand its contents. If you have any questions pertaining to the research or your rights as a research subject, you may contact (Principal Investigator) whose phone number is (505) 646-xxxx, or the Office of Institutional Effectiveness at (505) 392-3478."
Include signature and date block.

If the subject is a minor or requires a guardian, the following should be added: "Your signature certifies that you are the lawful guardian of _____ and that you have the legal authority to consent to his/her participation in this study. You hereby grant consent for him/her to participate in this study." Include signature and date block. Witnessing of consent signatures by subjects or their guardians is not generally required. However, if you have a concern that subjects in your study may not remember that they have signed the consent document; you may wish to have the signature witnessed. Witnessing may be done by you as the investigator or by your designee (a competent adult, over the age of 18). If you wish to have the subject's consent witnessed, you may use the following wording (or a similar variation): "I certify that I have explained to the above individual(s) the nature and purposes of the research and the potential benefits and possible risks associated with participation in this study. I have answered any questions that have been raised and have witnessed the above signature. I have explained the above to the volunteer on the date stated on this consent form." Include a signature and date block.

XII. EXAMPLE OF CONSENT FORM:

Sample consent form follows.

Sample Consent Form #1

THOUGHTS AND FEELINGS OF TEENAGE MOTHERS WHO HAVE HAD PREMATURE INFANTS

CONSENT FORM

PRINCIPAL INVESTIGATOR:
Dr. John Doe
Professor, Department of Psychology
NEW MEXICO JUNIOR COLLEGE
(505) 392-XXXX

DESCRIPTION:
I am interested in the thoughts and feelings of teenage mothers of premature infants. You, as the mother of a newborn premature infant, are the best person to describe these thoughts and feelings. This research study will involve one or two interviews with you, each lasting approximately 30 minutes. The interviews will be audio taped using a micro cassette recorder. The tapes will be typed out for word-for-word transcripts of the interviews. The tapes will then be erased.

CONFIDENTIALITY:
Your name will not be attached to your interview responses. Your name and any other identifiers will be kept in a locked file that is only accessible to me or my research associates. Any information from this study that is published will not identify you by name.

BENEFITS:
The results of this study may benefit other teenage mothers of premature infants by influencing the health care they receive. There will be no direct benefit to you from participating in this study.

RISKS:
It is possible that the discussion of thoughts or feelings about the birth of your baby might make you feel sad or uncomfortable. However, there are no other known risks to you.

CONTACT PEOPLE:
If you have any questions about this research, please contact the Principal Investigator and the phone number listed above. If you have any questions about your rights as a research subject, please contact the Office Institutional Effectiveness at New Mexico Junior College at (505) 392-3478.

VOLUNTARY NATURE OF PARTICIPATION:
Your participation in this study is voluntary. If you don't wish to participate, or would like to end your participation in this study, there will be no penalty or loss of benefits to you to which you are otherwise entitled. In other words, you are free to make your own choice about being in this study or not, and may quit at any time without penalty.

SIGNATURE:
Your signature on this consent form indicates that you fully understand the above study, what is being asked of you in this study, and that you are signing this voluntarily. If you have any questions about this study, please feel free to ask them now or at any time throughout the study.

Signature _____

Date _____

A copy of this consent form is available for you to keep.

June 2003
Revised September 26, 2005

APPENDIX E

INSTITUTIONAL REVIEW BOARD
NEW MEXICO JUNIOR COLLEGE
APPLICATION FOR EXEMPTION FROM FULL IRB REVIEW

Name of Principle Investigator _____
Title of Project _____
Date:_____

Selected From the Code of Federal Regulations Title 45, Part 46.101. Please check one or more categories below under which this research qualifies for exemption from full IRB review. Attach this application to your proposal to the IRB Chair requesting exemption. If the IRB Chair determines that the proposal is not exempt, it will be scheduled for review by the full board.

_____ *(1). Educational research Conducted in Educational Settings*
Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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

_____ *(3). Studies involving surveys, interviews, observation of public behavior or educational tests NOT EXEMPTED IN (2), ABOVE*
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt in (2) above may be exempt if:
1) the human subjects are elected or appointed officials or candidates for public office, OR,
2) the data contains personally identifiable information, but federal statutes require without exception that the confidentiality of that material must be maintained.

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

_____ *(5). Evaluation and demonstration projects of federal programs*
Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate or otherwise examine: (i) public benefit or service programs, (ii) procedures for obtaining benefits or

services under those programs, (iii) possible changes in or alternatives to those programs or procedures, or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

APPENDIX F

INSTITUTIONAL REVIEW BOARD
NEW MEXICO JUNIOR COLLEGE
APPLICATION FOR EXPEDITED IRB REVIEW

Name of Principal Investigator: _____

Title of Project:_____

Date:_____

Selected From the Code of Federal Regulations Title 45, Part 46.110 and Title 21 Part 56.110. Research activity may be reviewed by the Institutional Review Board through the expedited review procedure authorized in 45 CFR 46.110 and 21 CFR 56.110 if it involves no more than minimal risk *and* the only involvement of human subjects is in one or more of the categories described below. Please check one or more of the categories below under which this research qualifies for expedited IRB review. Attach this application to your proposal to the IRB Chair requesting expedited review. If the IRB Chair determines that the proposal does not qualify for an expedited review, it will be scheduled for review by the full board.

_____ (1). Recording data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors applied either to the surface of the body or at a distance **and do not involve** input of matter or significant amounts of energy into the subject or electrocardiography, electroencephalography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

_____ (2). Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an 8 week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health, and are not pregnant.

_____ (3). Moderate exercise by healthy volunteers.

_____ (4). The study of existing data, documents, records, pathological specimens, or diagnostic specimens. Note: If these sources are publicly available, or if the information is recorded in such a manner that subjects cannot be identified (directly or through identifiers linked to the subjects), the research may be *exempt* from IRB review. Please see the application for exemption from full IRB review.

_____ (5). Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior, and the research does not involve stress to subjects. [Pertains to 45 CFR 46.110, but not to 21 CFR 56.110]

_____ (6). Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

_____ (7). Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

_____ (8). Voice recordings made for research purposes such as investigations of speech defects.

APPENDIX G

INSTITUTIONAL REVIEW BOARD
DATA REQUEST PROPOSAL

SEE FOLLOWING 2 PAGES

NEW MEXICO JUNIOR COLLEGE

Data Request Proposal

Instructions: This form should be submitted for any request for NMJC data that includes elements not controlled (owned) by the requesting division, department, or individual. Approval by the Institutional Review Board (IRB) is required. If additional space is needed please use attachments.

Date submitted:

Name and title of individual initiating request:

Project Title:

Project Description:

Potential Risks and Benefits:

Data Elements Requested:

Data Format Requested

Method(s) for keeping data secure:

List all individuals who will have access to data:

Final disposition of data:

Date data needed: Estimated end date:

_____ _____

Signature of Project Iinitiator: Date:

_____ _____

Signature of Department Head/Vice-President/President Date:

IRB Action Taken

Approved □ *Denied* □ *Request additional information* □

_____ _____

Signature IRB Chair: Date

APPENDIX H

INSTITUTIONAL REVIEW BOARD
PROGRESS REPORT

SEE FOLLOWING 2 PAGES

INSTITUTIONAL REVIEW BOARD
NEW MEXICO JUNIOR COLLEGE
PROGRESS REPORT

Project Title: _____

Project Approval Number: _____ Original Approval Date: _____

Principal Investigator: _____

Department: _____

Telephone: _____

Check one: [ ] Student [ ] Faculty [ ] Staff [ ] Other

If Student, Responsible Faculty Member:_____

STATUS OF RESEARCH ACTIVITIES

Enrollment of new subjects is continuing? [ ]YES [ ]NO

Date data collection was initiated:_____

If no subjects have been enrolled, explain why: _____
_____

Number of subjects in the study to date: _____

How many subjects have withdrawn from the study? _____
For what reasons? _____
_____

Number of **unanticipated** adverse reactions: _____

Were these reactions promptly reported to the IRB? [ ]YES [ ]NO
Was consent obtained for/from all subjects? [ ]YES [ ]NO
Did all subjects receive a copy of the consent form? [ ]YES [ ]NO
Did you encounter any problems obtaining consent? [ ]YES [ ]NO

Where are signed consent forms stored? _____
_____

Have any changes been made in the following:

Number of anticipated subjects?	[ ]YES	[ ]NO
Protocol methods?	[ ]YES	[ ]NO
Consent form?	[ ]YES	[ ]NO
Investigators?	[ ]YES	[ ]NO

If YES, describe: _____
_____

At this time I am requesting:

[ ] Extension of approval with no change from the original protocol.
[ ] Extension of approval with the changes outlined in this report. (Major changes may require submission of a new proposal).

YOUR SIGNATURE INDICATES THAT YOU ARE TAKING EVERY PRECAUTION TO MINIMIZE ALL RISKS TO HUMAN SUBJECTS.

Principal Investigator _____ _____
Signature Date

Dean or Department Head _____ _____
Signature Date

IRB Decision: Approved _____ Denied _____

IRB Chair _____ _____
Signature Date

APPENDIX I

NEW MEXICO JUNIOR COLLEGE
INSTITUTIONAL REVIEW BOARD
CERTIFICATION FORM FOR COURSE INSTRUCTORS

Please submit completed form to the Institutional Review Board Chairperson.

My signature below indicates that I am familiar with the Institutional Review Board policies and procedures outlined in the NMJC Research Policy and Procedure. The policies regarding the utilization of human subjects in research will be reviewed with all students involved in this course prior to the beginning of all research projects. I will exercise proper instructor supervision to ensure student compliance with the policies for the protection of human subjects. This certification may apply to all courses taught at NMJC, including independent study, directed study courses, distance education, and area vocational high school courses. **This certification will remain in effect for three academic years.**

Instructor Signature and Course Information

Date _____

Name of Instructor_____
(*Print or Type)*

Signature of Instructor_____

Title of Course_____

Course
Number_____

Dean Signature and Course Confirmation

Date_____

Dean's Signature_____

Department_____

Appendix J

NEW MEXICO JUNIOR COLLEGE
CERTIFICATION OF EDUCATION IN THE USE OF
HUMAN SUBJECTS IN RESEARCH

Please submit completed form attached to completed application to the Institutional Review Board.

My signature below certifies that I have received and read the following documents

- Human Participant Protections Education for Research Teams prepared by the National Institutes of Health [http://ohsr.od.nih.gov/cbt/]
- Family Education Rights and Privacy Act (FERPA) prepared by the U.S. Department of Education [http://www.ed.gov/offices/OII/fpco/ferpa/]
- How to Interpret the Federal Policy for the Protection of Human Subjects or "Common Rule" prepared by United States Agency for International Development, Global Health [http://www.usaid.gov/pop_health/resource/phncommonrule2.htm]

I will ensure that the proper polices for the protection of human subjects are followed and will implement the recommendations and regulations in my research. **This certification will remain in effect for three academic years or until other educational materials are put into practice.**

_____ _____

Principal Investigator Signature Date