New Mexico Junior College

Policy and Procedures for Conducting Research Involving Human Subjects

Revised July 10, 2025

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1. Introduction

New Mexico Junior College (NMJC) is committed to the ethical conduct of research involving human subjects. In accordance with 45 CFR 46 (the "Common Rule"), 21 CFR 50/56, the HIPAA Privacy Rule (45 CFR 160–164), and FERPA (20 U.S.C. 1232g), NMJC requires review and approval of all human-subjects research by its Institutional Review Board (IRB).

Purpose

- Protect the rights, welfare, and privacy of research participants
- Foster responsible, transparent, and reproducible research
- Ensure compliance with federal regulations and NMJC policies

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2. Guiding Ethical Principles

Adapted from the Belmont Report and federal regulations:

1. **Respect for Persons**
    - Voluntary participation, informed consent, special protections for those with diminished autonomy.
2. **Beneficence**
    - Minimize risks, maximize potential benefits.
3. **Justice**
    - Equitable selection of subjects; fair distribution of research burdens and benefits.

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3. Institutional Review Board (IRB)

3.1 IRB Composition

- Minimum of five members with varying backgrounds (scientific and non-scientific)
- At least one member unaffiliated with NMJC
- Expertise in ethics, statistics, law, medicine, and community perspectives
- Annual appointment by the President of NMJC

3.2 IRB Functions & Responsibilities

- Establish, review, and update human-subjects policies
- Review, approve, require modifications, or disapprove research protocols
- Ensure compliance with 45 CFR 46, 21 CFR 50/56, FERPA, HIPAA
- Monitor continuing review and oversee adverse-event reporting
- Provide guidance to investigators and ensure CITI training completion

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4. Scope & Applicability

Applies to all NMJC faculty, staff, students, and external collaborators who:

- Conduct research using NMJC resources or data
- Recruit NMJC students, employees, or visitors as subjects
- Access NMJC education records or protected health information

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5. Key Definitions

(See Appendix G for complete glossary.)

- **Human Subject**: Living individual about whom an investigator obtains data through intervention or identifiable private information.
- **Research**: Systematic investigation designed to contribute to generalizable knowledge.
- **Minimal Risk**: Harm or discomfort not greater than encountered in daily life or routine exams.
- **Vulnerable Population**: Children, prisoners, pregnant persons, cognitively impaired, economically or educationally disadvantaged.
- **IRB Chairperson**: Leads expedited and administrative reviews.

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6. Required Training

All key personnel (investigators, students, staff) must complete NMJC-approved human-subjects training (e.g., CITI Program: “Basic Course in Human Subjects Research”). Certification is valid for three years (see Appendix H).

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7. Levels of Review & Submission Procedures

7.1 Exempt Research

- Categories defined in 45 CFR 46.104(d) (see Appendix B)
- Investigator submits:
  - Exemption Request Form (Appendix B)
  - Protocol synopsis
  - Data instruments
- IRB Chair reviews and grants determination within 5 business days

7.2 Expedited Review

- Categories in 45 CFR 46.110 (see Appendix C)
- Investigator submits:
  - Full Application Form (Appendix D) marked “Expedited”
  - Consent form(s), recruitment materials
- Reviewed by IRB Chair + one designated member
- Decision within 15 business days

7.3 Full Board Review

- All non-exempt, higher-than-minimal-risk protocols
- Investigator submits:
  - Full Application Form (Appendix D)
  - Informed Consent Document(s)
  - Risk/Benefit Analysis
  - Training certifications
  - External approvals (if applicable)
- Scheduled at next convened IRB meeting
- Investigator or designee encouraged to attend

7.4 Reliance on External IRBs / Single-IRB Mandate

- Federally funded multi-site research must use a single IRB (sIRB) unless waiver approved
- NMJC may rely on external IRB via formal reliance agreement; investigator initiates through IRB Office

8. Informed Consent Requirements

8.1 Elements of Informed Consent (45 CFR 46.116)

1. Purpose, duration, procedures, and experimental aspects
2. Risks and discomforts
3. Benefits to subjects or society
4. Alternatives to participation
5. Confidentiality measures
6. Compensation and medical treatment for research-related injury
7. Contact information (investigator & IRB Office)
8. Statement of voluntary participation and right to withdraw

8.2 Electronic & Broad Consent

- **Electronic Consent**: Permitted if allows auditing, secure storage, print-outs.
- **Broad Consent**: For future use of identifiable data/biospecimens under 45 CFR 46.116(d); investigator submits separate broad-consent document.

8.3 Waiver or Alteration of Consent

- May waive signature or entire consent under 45 CFR 46.117(c) when:
    - Minimal risk
    - Documenting consent poses risk to confidentiality
    - Research impracticable without waiver and does not adversely affect rights

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9. Continuing Review & Reporting

9.1 Continuing Review

- Not required for minimal-risk protocols that qualify for expedited review, unless the IRB mandates
- All other protocols: at intervals no greater than one year

9.2 Noncompliance & Adverse Event Reporting

- **Unanticipated Problems** (45 CFR 46.103(b)(5)): Report to IRB within 5 business days
- **Protocol Deviations** & **Serious or Continuing Noncompliance**: Prompt IRB notification
- IRB may suspend or terminate approval; investigator may respond in writing

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10. Data Privacy & Security

10.1 HIPAA & FERPA Compliance

- Research involving Protected Health Information (PHI) requires HIPAA authorization or waiver
- Education record research governed by FERPA; consent required for identifiable data

10.2 Confidentiality Safeguards

- Secure storage (locked cabinets, encrypted drives)
- Limited access to coded data; master key stored separately
- Certificates of Confidentiality strongly encouraged for sensitive biomedical research

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11. Special Populations

11.1 Pregnant Persons & Fetuses

Research permitted under Subpart B of 45 CFR 46 when criteria for minimal risk and potential benefit are met.

11.2 Prisoners

Additional safeguards under Subpart C of 45 CFR 46; IRB must include a prisoner-representative member.

11.3 Children

Assent and parental permission rules per Subpart D of 45 CFR 46; risk-benefit categories I–IV determine allowable research.

11.4 Cognitively Impaired Persons

Legally authorized representatives may consent; assent obtained from subject when possible.

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12. Appeals & Grievance Procedures

- Investigator may submit a written appeal to the IRB within 30 days of a disapproval or major modification request
- IRB conducts an ad hoc meeting or refers to full board for final determination
- Complainants may escalate to the Vice President for Academic Affairs

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13. Appendices

- **A. IRB Application Checklist**
- **B. Exemption Categories**
- **C. Expedited Review Categories**
- **D. Full Board Application Form**
- **E. Sample Consent Forms** (including e-consent templates)
- **F. Continuing Review Form**
- **G. Definitions Glossary**
- **H. CITI Training Certification Form**

For questions or to submit materials

Office of Institutional Effectiveness & IRB
New Mexico Junior College
4701 College Blvd., Hobbs, NM 88240
(575) 475-2611

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Appendix A. IRB Application Checklist

Before submission, ensure your application includes:

1. Completed Full-Board Application Form (Appendix D) or Exemption/Expedited Request (Appendix B/C).
2. Protocol Summary
    - Background & rationale
    - Objectives/hypotheses
    - Study design & procedures
    - Subject population, inclusion/exclusion criteria
3. Recruitment Materials
    - Flyers, scripts, emails
4. Informed Consent Document(s) (see Appendix E)
    - All required elements (45 CFR 46.116)
    - Assent forms & permission scripts (if minors)
5. Data Collection Instruments
    - Surveys, interview guides, questionnaires
6. Data Privacy & Security Plan
    - Coding, storage, access controls
7. Investigator & Key Personnel Training Certificates (Appendix H)
8. External Approvals (if applicable)
    - Site permissions, department chairs, community partners
9. HIPAA Authorization/Waiver (if PHI used)
10. FERPA Authorization (if educational records used)

Submit one electronic PDF of all materials to IRB@nmjc.edu. Expect determination in 5–15 business days for Exempt/Expedited, next convened meeting for Full Board.

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Appendix B. Exemption Categories (45 CFR 46.104(d))

Research activities in which the only involvement of human subjects falls into one or more of these categories are exempt from full IRB review. Check all that apply:

1. **Educational Practices**
   • Research on teaching methods or curricula in established educational settings.
2. **Surveys, Interviews, Observations in Public Settings**
   • No identifiers; disclosure would not place subjects at risk.
3. **Public Officials or Statutorily Protected Records**
   • Subjects are elected/appointed public officials, or federal statute requires confidentiality.
4. **Existing Data, Documents, Records, Specimens**
   • Publicly available or de-identified.
5. **Demonstrations/Evaluations of Federal or State Programs**
   • Conducted or approved by agency heads; designed to study benefits or procedures.
6. **Taste and Food Quality Evaluation**
   • Involving wholesome foods without additives.
7. **Benign Behavioral Interventions**
   • Brief, harmless tasks in non-sensitive contexts; subjects can opt out.
8. **Secondary Research Uses of Identifiable Private Information**
   • Research regulated under HIPAA with a data-use agreement, or biobank specimens with broad consent.

If you qualify, complete the Exempt Request Form and submit to the IRB Chair.

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Appendix C. Expedited Review Categories (45 CFR 46.110)

Studies involving no more than minimal risk and only procedures in these categories may be reviewed by the IRB Chair + one member:

1. **Clinical Specimen Collection**
   • Blood draws ≤ 2×/week, ≤ 550 mL/8 weeks, from healthy adults.
2. **Noninvasive Clinical Procedures**
   • EKG, EEG, ultrasonic, routine physical measures.
3. **Data/Specimen Collection**
   • Anonymized data; noninvasive specimens (hair, saliva, swabs).
4. **Behavioral Research**
   • Cognitive psychology, surveys, interviews, focus groups, if non-sensitive.
5. **Existing Data Review**
   • Records/specimens with identifiable information, provided privacy safeguards.
6. **Drug Trials**
   • FDA Phase I studies of already-marketed drugs at ≤ maximum approved dose.
7. **Rapid Autopsy/Tissue Collection**
   • From deceased individuals where death was not study-related.
8. **Minor Equipment Modification**
   • E.g., magnetic positioners off-label in imaging.

Complete the Expedited Request Form and submit all supporting documents to the IRB Office.

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Appendix D. Full Board Application Form

Please type or fill in legibly. Attach extra pages as needed.

Project Title:
Principal Investigator: Name, Department, Email, Phone
Co-Investigators:
Student Investigator? ☐ Yes ☐ No If yes, Faculty Sponsor:

Funding Source: ☐ None ☐ Federal ☐ State ☐ Private Sponsor:

Study Population & Sample Size:

- Target demographics (age, sex, special groups)
- Inclusion/exclusion criteria

Study Procedures:

- Detailed step-by-step enrollment, interventions, assessments
- Total time per subject, number of visits

Risks & Discomforts:

- Physical, psychological, social, legal
- Probability & severity estimates

Potential Benefits:

- To subjects, to science, to society

Alternatives to Participation:

Informed Consent Process:

- Who obtains consent, where, when
- Consent materials enclosed: ☐ Yes ☐ N/A

Data Management & Confidentiality:

- Identifiers collected? ☐ Yes ☐ No

- Coding strategy, storage location, access controls

HIPAA/FERPA Considerations:

- PHI used? ☐ Yes ☐ No Authorization or waiver attached? ☐ Yes
- Education records used? ☐ Yes ☐ No FERPA waiver/consent attached? ☐ Yes

Training:

- CITI or equivalent certificates attached? ☐ Yes

External Approvals (List and attach):

- Clinical sites, community organizations, tribal entities

Signature of PI: _____ Date: _____
Department Chair/Dean: _____ Date: _____

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Appendix E. Sample Consent Forms

E.1 Minimal-Risk Survey Consent

You are invited to complete a 10-minute anonymous survey about student study habits.
Participation is voluntary; you may stop at any time. No identifiers will be collected.
All responses are confidential and stored on a password-protected server.
There is no direct benefit, but your responses will help us improve academic support services.
Questions? Contact Dr. Jane Smith at jane.smith@nmjc.edu or (505) 392-3478.

☐ I have read the above and agree to participate.

Signature: _____ Date: _____

E.2 Blood-Draw Study Consent

Title: Exercise & Blood Biomarkers in Healthy Adults
Investigator: Dr. John Doe, Biology Dept.

Purpose: Examine changes in blood biomarkers before & after moderate exercise.

Procedures:

- One visit, 60 minutes total
- Pre-exercise blood draw (10 mL)
- 30 minutes cycling at 60% max heart rate
- Post-exercise blood draw (10 mL)

Risks: Bruising, soreness at needle site; low risk of lightheadedness.

Benefits: No direct benefit; benefits to scientific understanding of exercise physiology.

Confidentiality: Samples labeled with code; key stored separately. Data in locked cabinet.

Voluntary & Withdrawal: You may withdraw at any time without penalty.

Injury: Emergency care will be provided; no NMJC compensation plan.

Contacts:

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- Questions: Dr. Doe, john.doe@nmjc.edu, (505) 392-XXXX
- Rights: IRB Office, irb@nmjc.edu, (505) 392-3478

By signing, you consent to participate under the terms above.

Participant: _____ Date: _____
Investigator/Witness: _____ Date: _____

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Appendix F. Continuing Review Form

Project Title:
IRB # / Approval Date:
PI:

1. **Enrollment Status**
   - Started on: _____
   - Enrolled to date: _____
   - Withdrawals & reasons:
2. **Unanticipated Problems or Adverse Events**
   - Number / Description / Reporting date
3. **Protocol Changes Since Last Approval**
   - ☐ None ☐ Modified procedures (describe below)
4. **Consent Form Revisions**
   - ☐ None ☐ Updated (attach tracked version)
5. **Data Security Changes**
   - ☐ None ☐ Updated (describe)
6. **Next Progress Report Due:** _____

PI Signature: _____ Date: _____
IRB Office Use: Reviewed by: _____ Action: ☐ Approved ☐ Modifications Required ☐ Suspended Date: _____

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Appendix G. Definitions Glossary

- **Adverse Event:** Unanticipated harm to a subject.
- **Assent:** Child's affirmative agreement to participate.
- **Anonymous:** No identifiers collected.
- **Cognitively Impaired:** Diminished capacity to consent; requires LAR.
- **CRF:** Case Report Form or data collection sheet.
- **HIPAA:** Health Insurance Portability & Accountability Act.
- **Informed Consent:** Voluntary agreement after understanding risks/benefits.
- **Legally Authorized Representative (LAR):** Person authorized to consent for subject.
- **Minimal Risk:** Harm ≤ daily life/clinical exam risks.
- **OHRP:** Office for Human Research Protections.
- **PHI:** Protected Health Information.
- **Protocol Deviation:** Departure from approved procedures.
- **Prisoner:** Incarcerated person under Subpart C protections.
- **Subpart D:** Federal regulations for research involving children.

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Appendix H. CITI Training Certification Form

I, _____ (print name), certify that I have completed NMJC-approved human-subjects research training (e.g., CITI Basic Course) on _____ (date). This certification is valid for three years.

- Course Modules Completed:
  ☐ History & Ethics
  ☐ Informed Consent
  ☐ Privacy & Confidentiality
  ☐ Vulnerable Populations
  ☐ Responsible Conduct of Research

Signature: _____ Date: _____
Supervisor/PI: _____ Date: _____