WRITTEN PROCEDURES: IRB OVERSIGHT OF EXEMPT RESEARCH

IRB Procedure Purpose: To outline the procedure for IRB reviewers to determine exempt status for research applications involving human subjects.

Document Purpose: Serves as the official written procedure for exempt research at DMACC and functions as a companion guide for IRB members when reviewing applications for exemption.

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Background

At Des Moines Area Community College (DMACC), all research involving human participants must be approved by DMACC's Institutional Review Board (IRB) in accordance with federal regulations.

IRB regulated human subjects research is defined as

"Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes." (45 CFR 46.102(d))

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Procedure: Exempt Status Review

At Des Moines Area Community College (DMACC), all research involving human subjects must be reviewed by the Institutional Review Board (IRB) to comply with federal regulations. Exempt research includes specific low-risk categories that do not require full IRB review but must still adhere to ethical standards. If a study involves no interaction, intervention, or identifiable data, it may be classified as "Not Human Subjects Research."

All IRB applications and associated documentation, including communications and decision letters, will be securely stored for a minimum of three years from the date of the final determination. After this period, if not previously closed, IRB approval for the study will automatically expire.

While exempt research typically does not require ongoing or continuing IRB review, the DMACC IRB reserves the right to impose additional oversight or request follow-up reviews if warranted by the nature of the study or the populations involved. Additional review will confirm that all research, regardless of exemption status, continues to uphold the highest standards for the protection of human subjects.

Review Timeline Requirements

The IRB aims to complete exempt status determinations within two weeks of receiving the application and review request. However, the committee may extend this timeframe as needed to allow for a comprehensive and careful review.

Criteria for Exempt Status

The following criteria must be considered:

Exemption Category Confirmation

Category 1: Educational settings and normal practices.
Category 2: Surveys, interviews, tests, or public observation with anonymity or minimal risk.
Category 3: Benign behavioral interventions with adult consent.
Category 4: Secondary research use of public or de-identified data.
Categories 5–8: Other specific categories as defined under 45 CFR 46.104(d).

General Eligibility

Minimal Risk: The research involves no more than minimal risk.
Exclusion Criteria: Automatically excluded populations (e.g., prisoners) and FDA-regulated studies. Automatically excluded: Exempt Categories 2 and 3 if the research collects identifiable information that could pose a risk if disclosed.

Subject Population

Equitable Selection: Subjects are selected fairly and appropriately.
Non-English Speakers: Exclusion must be scientifically justified.
Informed Consent (If Applicable)
No Interaction: No consent required if there is no subject interaction.
Interaction: Consent process includes purpose, procedures, voluntariness, and contact information.

Privacy & Confidentiality

Data Handling: Data is anonymous or de-identified.
Security Measures: Identifiable data is encrypted, password-protected, and stored securely.
Limited IRB Review: Required for identifiable data in Exempt Categories 2 and 3.

Research Personnel & Setting

Qualifications: Investigators are qualified and trained.
Setting: Guarantees safety and privacy for participants.

CITI Training

Certification: Principal investigator and all investigators have up-to-date CITI certificates.

IRB Actions

The following actions must be completed by the IRB:

Reviewer's Determination

Revisions: Requested revisions are sent to the coordinator who will communicate directly with the investigator.
Determination Options: Determinations can be approved, approved pending, deferred, disapproved, or tabled.
Documentation: Reviewer has documented the exemption category and rationale in the IRB system.
International Research: Local laws and cultural norms have been considered.
Data Retention: Appropriate data retention period and destruction plan are in place.
Limited IRB Review: Conducted if required (Exempt Categories 2 or 3 with identifiable data).
Exempt Status Confirmation: Research confirmed as exempt human subjects research—not 'Not Human Subjects Research'.

Reviewer Required Actions

Reviewers are expected to inform the IRB chair and coordinator of their determination within approximately two weeks of receiving the request to review the application. If additional time is needed to ensure a thorough review, reviewers should notify the chair. The final decision, along

with a one-paragraph description explaining the rationale and specifying the applicable exempt category, should be submitted via email to irb@dmacc.edu.

Role of the Coordinator

The coordinator is the sole person responsible for communication with the investigator throughout the application and decision process.

Role of the Chair

It is the responsibility of the IRB chair to maintain all documentation related to the application, correspondence, and final decision letter, and to make these records accessible to institutional officials beyond the IRB committee if requested. The chair is also responsible for overseeing any required future reviews and addressing instances of misconduct that may arise during the study or in the use of research data after the study concludes.

Overview of Exempt Status

Part 46—Protection of Human Subjects
Subpart A—Basic HHS Policy for Protection of Human Research Subjects
Section 46.104 Exempt Research
For detailed information: https://www.ecfr.gov/current/title-45/section-46.104
FAQs: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/index.html

Exempt research refers to specific categories of research involving human subjects that are considered to be of sufficiently low risk and therefore do not require full IRB review and approval. These categories are defined under 45 CFR 46.104 of the Common Rule. If no interaction, intervention, or identifiable data is involved, the study may fall under 'Not Human Subjects Research' instead.

Key Points about Exempt Research

Exempt Categories

Category 1: Educational Settings: Research conducted in established or commonly accepted educational settings involving normal educational practices.
Category 2: Educational Tests, Surveys, Interviews, or Observation: Research involving these methods, provided certain conditions are met, such as anonymity and minimal risk.
Category 3: Benign Behavioral Interventions: Research involving benign behavioral interventions with adult subjects who provide informed consent.
Category 4: Secondary Research: Use of identifiable private information or biospecimens, if certain criteria are met, such as the data being publicly available or the information being recorded in a way that subjects cannot be identified.

Category 5: Public Benefit or Service Programs: Research and demonstration projects designed to study, evaluate, improve, or examine public benefit or service programs. This includes projects conducted by or subject to the approval of federal agencies.
Category 6: Taste and Food Quality Evaluations: Research involving taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level found to be safe by the FDA.
Category 7: Storage of Identifiable Information or Biospecimens: Storage or maintenance of identifiable private information or biospecimens for secondary research use, provided broad consent is obtained and limited IRB review is conducted.
Category 8: Secondary Research Use of Identifiable Information or Biospecimens: Secondary research use of identifiable private information or biospecimens, if broad consent is obtained and limited IRB review is conducted.
These categories help promote research involving human subjects is conducted ethically while minimizing risk and administrative burden for low-risk studies.

Low Risk

Exempt research is considered low risk, meaning the potential for harm or discomfort to participants is minimal.

Determination Process

While principal investigators may initially assess whether their study qualifies as exempt, the DMACC IRB makes the final determination to promote accurate classification and appropriate review of non-exempt research.

Compliance

Even though exempt research does not require full IRB review, it must still comply with ethical standards and regulations to protect the rights and welfare of participants.

Role of the Reviewer

The role of an IRB reviewer in evaluating exempt research is crucial to ensuring the ethical conduct of studies involving human subjects. Reviewers are responsible for determining whether a proposed study meets the criteria for exemption as outlined in 45 CFR 46.104. This involves assessing the research's risk level, verifying that it falls within one of the specified exempt categories, and ensuring that the study complies with ethical standards and regulations. Reviewers must meticulously evaluate the research methodology, consent processes, and data handling practices to confirm that participants' rights and welfare are protected. Although exempt research does not require full IRB review, the accuracy and thoroughness of the exemption determination are vital to maintaining the integrity of the research process and safeguarding human subjects.

Reviewer Reminders and Tips

The section provides detailed guidelines and tips for IRB reviewers to ensure exempt research involving human subjects is conducted ethically and meets federal regulations.

General Eligibility

Purpose: Verify that the study qualifies for exemption from full IRB review under federal regulations.

What to Look For:

- ✓ Minimal risk means the likelihood and severity of harm are no greater than everyday activities.
- ✓ The study must fall under at least one of the federally recognized exemption categories.
- ✓ Privacy and data protection are addressed.
- ✓ Automatically excluded: Exempt Categories 2 and 3 if the research collects identifiable information that could pose a risk if disclosed.
- ✓ Automatically excluded: prisoners (with limited exceptions), FDA-regulated studies, unsupported broad consent.

Reviewer Tip: If the study doesn't clearly meet these requirements, escalate to expedited or full board review.

Exemption Category Confirmation

Purpose: Categorize the study under one of the 8 exemption types (45 CFR 46.104(d)).

What to Look For:

- ✓ Category 1: Educational settings and normal practices.
- ✓ Category 2: Surveys/tests/interviews/observations with anonymity or no harm risk.
- ✓ Category 3: Harmless, brief behavioral interventions with adult consent.
- ✓ Category 4: Use of existing data—public, de-identified, or HIPAA-compliant.
- ✓ Categories 5–8: Less common; confirm proper documentation.

Reviewer Tip: Choose the most specific category and document it.

Subject Population

Purpose: Validate that subjects are selected fairly and protected from undue burden.

- ✓ What to Look For:
- ✓ Subject group fits research questions.
- ✓ Vulnerable populations are only included if permitted.
- ✓ Justified exclusion of non-English speakers.

Reviewer Tip: Evaluate equity and inclusion.

Informed Consent
Purpose: Confirm participants are adequately informed even if formal consent (signed documentation) isn't required.

What to Look For:
✓ No subject interaction = no consent needed.
✓ If interaction occurs: Describe purpose, procedures, voluntariness, contact info.

Reviewer Tip: Verbal or implied consent may be enough.

Privacy & Confidentiality
Purpose: Ensure subjects' identities and data are protected.

What to Look For:
✓ Data is anonymous or de-identified.
✓ If identifiable: encrypted, password-protected, secured.
✓ Master list stored separately.

Reviewer Tip: Expediated of Full IRB Review required for identifiable data in Exempt Categories 2 and 3.

Research Personnel & Setting
Purpose: Confirm the team and setting are suitable.

What to Look For:
✓ Investigators are qualified and trained.
✓ Setting guarantees safety and privacy.

Reviewer Tip: Check for faculty supervision if a student is the PI.

CITI Training
Purpose: Confirm the investigators have completed and have up-to-date certificates.

What to Look For:
✓ Principal investigator has attached CITI certificates for all investigators.
✓ CITI certificates have not expired.

International Research
Purpose: Confirm international research meets local laws and cultural expectations.

What to Look For:
✓ Local laws, privacy expectations, and cultural norms must be considered.
✓ Appropriate safeguards are documented.

Data Retention Timeline
Purpose: Ensure that the data retention timeline is appropriate.

What to Look For:
✓ Security procedure for data during the study.
✓ Secure destruction of data is documented.
✓ Identifiable information destruction is handled with extra care.

Reviewer Tip: Plans for secure handling and destruction of data.

Reviewer's Determination
Purpose: Final judgment of whether exemption criteria are satisfied.

What to Look For:
✓ All boxes checked.
✓ No red flags.

Reviewer Tip: Document clearly. Request revisions if needed. If revisions are needed, the IRB coordinator will handle communication between the IRB and the investigator.

Reviewer Required Actions
Purpose: Record and submit the exemption determination.

What to Look For:
✓ Documented decision.
✓ Documented exempt category.
✓ One paragraph description of determination.
✓ Recommendation for additional monitoring or study.

Reviewer Tip: Determinations can be approve, approve pending, deferred, disapproval, tabled. Send documented decision to IRB chair, coordinator, and IRB@dmacc.edu.

IRB Reviewer Checklist for Exempt Research Applications

This section provides a comprehensive checklist for IRB reviewers to verify exempt research applications meet federal regulations and ethical standards.

General Eligibility

☐ The research involves no more than minimal risk.

☐ The research fits one or more of the eight exemption categories under 45 CFR 46.104(d).

☐ The study does not involve general exclusions (e.g., prisoners, FDA-regulated products, broad consent not supported by the institution).

☐ The PI has clearly described the study purpose, design, procedures, and setting.

Exemption Category Confirmation

☐ Category 1 – Educational Practices: Conducted in established educational settings and involves normal practices.

☐ Category 2 – Surveys, Interviews, Tests, or Public Observation: Meets conditions for anonymity or poses no harm if data disclosed.

☐ Category 3 – Benign Behavioral Interventions: Involves adults, brief, harmless, and with prospective consent.

☐ Category 4 – Secondary Research Use: Public data or de-identified data, or HIPAA-compliant usage of health data.

☐ Categories 5–8 – Other categories (e.g., food quality, public benefit programs) are appropriately justified.

Subject Population

☐ Subjects are selected equitably and appropriately for the study purpose.

☐ Vulnerable populations are included only when justified and permitted by exemption category.

☐ Exclusion of non-English speakers is scientifically justified.

Informed Consent

☐ No interaction with subjects (no consent required), OR:

☐ Consent process includes purpose, procedures, voluntariness, and contact info.

☐ Language is understandable and appropriate for the target population.

Privacy & Confidentiality

☐ Data is de-identified where possible.

☐ Identifiable data is stored securely (e.g., password-protected, locked storage).

☐ Master lists are stored separately from study data.

Privacy & Confidentiality Continued

☐ Only authorized personnel have access to data.

☐ Data retention and destruction plans are in place.

☐ Data confidentiality protections are reviewed and adequate.

Research Personnel & Setting

☐ Investigators and study staff are qualified and trained.

☐ The research setting protects participant privacy and is suitable for the procedures.

Reviewer's Determination

☐ All exemption criteria are met.

☐ Adequate safeguards for risk, privacy, and confidentiality are present.

☐ Consent process is appropriate.

☐ Study qualifies for Exempt Determination under federal regulations.

☐ Limited IRB Review has been conducted and documented.

Additional Checklist Items

☐ Reviewer has documented the exemption category and rationale in the IRB system.

☐ If research is international, local laws and cultural norms have been considered.

☐ Data retention period is appropriate, and destruction plan is in place.

☐ Limited IRB Review has been conducted if required (Exempt 2 or 3 with identifiable data).

☐ Research has been confirmed as exempt human subjects research—not 'Not Human Subjects Research'.

☐ Reviewer has submitted a recommendation to the IRB chair regarding the need for additional monitoring of the research.