Promoting Ethical Research

IRB Review of Research Proposals

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Presented by

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The purpose of the Molloy University Institutional Review Board(IRB)

…to respect and protect the rights of all human subjects invited to participate in research by faculty members, students, or other users of Molloy University facilities, regardless of where the research is conducted.

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Human Subjects Research

Involves a living individual about whom:

- data or biospecimens are obtained, used, studied, or analyzed through interaction, intervention,

or

- identifiable, private information is used, studied, analyzed, or generated.

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Examples of Human Subjects Research

- **Surveys:** Asking individuals about their opinions or behaviors.
- **Interviews:** Conducting conversations to gather personal experiences or data.
- **Medical Procedures:** Taking blood samples or biopsies for research purposes.
- **Behavioral Studies:** Observing and documenting the actions or interactions of individuals in a structured way.

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The Belmont Report

- **Respect for Persons**
  - Voluntary consent
  - Informed consent
  - Privacy and confidentiality
- **Beneficence**
  - Maximize the potential benefits and minimize the potential risks
- **Justice**
  - Relates to the fair and equitable distribution of the burdens and benefits (risk) within society.

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Learning Objectives

- IRBNet submission process
- IRB review

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When is IRB Approval Needed?

Research involving:

- Human subjects
- Sensitive data collection
- Identifiable private information

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Key Components of an IRB Proposal

Research Protocol

- Purpose, objectives, and significance

Informed Consent Forms

- Explanation of participant rights, risks, and benefits

Recruitment Strategies

- How participants will be recruited.

Data Collection and Analysis Plans

- Methods of data handling and analysis.

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Preparing an IRB Proposal

Gather required information

- Research team qualifications, study timeline, funding sources.

Detailed research design

- Methodology, participant demographics, compensation details.

Compliance with ethical standards

- Ensuring adherence to ethical guidelines

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Submission to IRBNet

- Upload CITI certifications to PI profile

- Complete the IRB application form
  - Classroom assignment, Action Research, Full, Exempt, Expedited application

- Upload the supporting documents
  - protocol, consent forms, recruitment flyers, site permission, etc.

MUIRB process

- Type of review is determined by:
  - Levels of **risk** to participants
  - Studies including **vulnerable populations**
    - Additional protections for children, pregnant women and fetuses, prisoners
  - Nature of research (survey vs intervention)
    - **Design**: nature of tasks, information (private/identifiable) or biospecimens collected from participants
  - Nature of **recruitment**
  - Process of **informed consent** (deception)

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Type of review

- **Exempt** (per, 45 CFR 46)
  - Reviewed by IRB chair/IRB member
  - Timeline: 2-4 weeks
  - Studies that meet federal exemption categories (i.e., low risk)
    - Exempt does not mean that PI is not obligated to follow ethical practices
      - IRB grants the exemption
  - Exemption categories (select):
    - Research on typical educational practices
    - Research includes interactions involving educational tests, survey procedures, observation of public behavior
    - Secondary research from publicly available databases
      - **Some of these categories may need limited review (e.g., participant privacy)**

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Type of review

- **Expedited** (per, 45 CFR 46)
  - Reviewed by IRB chair/IRB member
  - Timeline: 2-4 weeks
  - Studies that meet the criteria of minimal risk
    - Probability & magnitude of harm (or discomfort) in the study is not greater than those encountered in daily life
  - Expedited categories (select):
    - Clinical studies of drugs and medical devices
    - Collection of biospecimens in a non-invasive manner
    - Collection of data from voice, digital or image recordings

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Type of review

- **Full Board** (per, 45 CFR 46)
  - Reviewed by full IRB board
  - Timeline: 4-8 weeks
  - Studies can meet the following criteria:
    - Research poses more than minimal risk to human participants
    - Complex research design (e.g., intervention)
    - Participants may be vulnerable populations
    - Sensitive topic of study (e.g., addiction)

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Type of review

- **Classroom research assignment**
  - Reviewed by IRB chair/IRB member
  - Timeline: 2-4 weeks
  - Types: curriculum embedded (programmatic requirements); capstone projects; faculty sponsored research (UG/Graduate students)
  - IRB will review submissions and provide directive
    - Per the guidelines for MU classroom projects (see current IRBNet documents for PIs)

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IRB Review: Completeness & Compliance

- IRB is not concerned about the research topic
- Reviewers' task is to determine if the proposed study meets ethical and regulatory requirements
- Reason for revisions (not all inclusive):
  - The participant population is not appropriate for the study
  - The recruitment process may not be free of coercion
  - Several risks associated with the study (beyond minimal)
    - Risks outweigh potential benefits
  - Participant compensation is not fair and is coercive
  - Acceptable degree of anonymity and confidentiality is not maintained
  - Informed consent process is not ethically and legally acceptable

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Revisions

- Reviewers may request for changes or clarifications
  - PI will receive these requests in an email
  - IRBNet submission folder will be unlocked
  - PI can contact the reviewer
    - To understand the required modifications
    - Discuss ways in which compliance can be achieved
  - PI can submit revisions for further review

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Case Study 3- Simplified language

Example 2: Vague Description of Risks

> Any research has some risks, which may include things that could make you feel unwell, uncomfortable, or could harm you. You might have adverse effects (side effects) related to the study drug while taking part in the study. These effects may be mild or serious. In some cases, these effects might be long lasting, or permanent, and may even be life-threatening.

What's the problem?

In this example, the explanation of risks or discomforts needs to be more specific for it to be meaningful for participants.

For example, what exactly does "unwell" mean?

- If it means sleepy, dizzy, or experiencing double vision, what might that mean for a potential participant?
- If it means they could be unable to drive or operate machinery, it would be helpful to specify this since it could impact their everyday life.

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Case Study 3 – Simplified language

Use Active Voice

OASH | Office for Human Research Protections

Use active voice to simplify text and keep the tone conversational.

Original (Passive)	Rewrite (Active)
The sample will be collected.	A study team nurse will collect your sample.
A summary of the study's outcomes will be sent to the study participants.	We will send you a summary of the results.
Additional information will be communicated to you by a member of your study team.	A member of your study team will give you more information.
You will be asked questions about your health.	We will ask you questions about your health.

Screen 19 of 23

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Key Points

- Research and evidence-based practice studies involving human subjects are reviewed and approved by an IRB to ensure compliance with ethical standards and regulatory requirements.
- Voluntary informed consent from participants provides them with all necessary information to make a well-informed decision about their participation.
- Provisions to protect the privacy of subjects and maintain the confidentiality of their data must be included in the study protocol.
- Sound research designs and, when appropriate, best-practice procedures already being performed for diagnostic or treatment purposes minimize risks to subjects.

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Contact the Molloy University Institutional Review Board (IRB)

Kellenberg Hall 322

irb@molloy.edu

Request an appointment to discuss a submission

Include the IRBNet ID and title of the study submission on all communications with the IRB

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Members of the Molloy University IRB

Joanna Alcruz, PhD - School of Education & Human Services
Raymond Blanchard, PhD - School of Education & Human Services
Marcia Caton, PhD - The Barbara H. Hagan School of Nursing & Health Sciences
Audra Cerruto, PhD - School of Education and Human Services
Lorraine Emeghebo, EdD - The Barbara H. Hagan School of Nursing and Health Sciences
Debbie Langone, EdD - Executive Director for Instructional Technology & STEAM
Robert Marmo, PhD - Chief Planner Suffolk Probation
Ann Marie Nancy O'Donnell, MA - The Usher Syndrome Coalition
Gayle O'Keefe, MBA - School of Business
Sherry Radowitz, PhD - Ex-officio member
Heather Reens, PhD - The Barbara H. Hagan School of Nursing and Health Sciences
Kate Scotti, MS CCC-SLP, TSSLD - Speech Language Pathology in Motion
Ethel Ulrich, DNP – The Barbara H. Hagan School of Nursing and Health Sciences
Susan Vitale, PhD – The Barbara H. Hagan School of Nursing and Health Sciences

The full committee meets on the third Wednesday of each month.

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What are your questions?

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