Welcome to

Promoting Ethical Research II

Submitting an IRB Proposal

Spring 2025

Presented by

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&

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

…to safeguard and respect 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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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 distribution of risk within society

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Joanna Alcruz, PhD - School of Education & Human Services
John Carpente, PhD - School of Arts and Sciences
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
Janice Kelly, EdD - School of Arts and 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

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Members of the Molloy University IRB

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

Learning Objectives

- IRBNet submission process
- IRB review
- Case Studies

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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.

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IRBNet

Proposal Submission

Forms and Templates

Library Manager

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USER PROFILE LOGOUT

IRBNet

Welcome to IRBNet
Joyce Borelli

Help
My Projects
Create New Project
My Reminders

Other Tools
Forms and Templates

Project Information

Create a New Project

To create a new project, first provide the basic project information below. Once your project is created you may attach project documentation and share the project with other users.

Research Institution: * Molloy University, Rockville Centre, NY

Title: *

Local Principal Investigator: First Name:* Last Name:* Degree(s):

Keywords:

Sponsor:

You may specify an internal account number, billing identifier or reference number for this project.

Internal Reference Number:

Continue Cancel

* required fields

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Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Project History
Messages & Alerts

Other Tools
Forms and Templates

Designer

[2272904] Test Research Proposal

Package: 2272904-1 Work in progress (Not submitted)

Click to add a package description or notes.

Step 1: | Hide Form Libraries |

Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: Molloy University IRB, Rockville Centre, NY

Select a Document: 1. READ THIS FIRST !!!

Download

Step 2:

Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. | Learn more |

Documents in this Package:

There are no documents in this package.

There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |

Attach New Document (When should I do this?)

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ACTION RESEARCH : FACULTY APPLICATION FORM
ACTION RESEARCH : INSTRUCTOR INSTRUCTIONS FORM
ACTION RESEARCH APPLICATION FORM FOR STUDENTS
AMENDMENT APPLICATION TO A MOLLOY IRB APPROVED PROTOCOL
ANNUAL NON RESEARCH PROJECT REPORT FORM
APPLICATION FOR ONGOING CONTINUING REVIEW or FINAL REPORT
ASSENT GUIDELINES FOR RESEACHERS
ASSENT TO PARTICIPATE IN RESEARCH-ADOLESCENT 13-17
ASSENT TO PARTICIPATE-CHILD
Classroom Assignment Application Student_REVISED 11_06_2024.docx
Classroom Assignments Application Faculty Guidelines 11_06_2024.docx
EXPEDITED or EXEMPT RESEARCH ANNUAL REPORT
FERPA FORM
HIPAA FORM
HOW TO SHARE A PROJECT ON IRBNET.
HOW TO SUBMIT A MODIFICATION, AMENDMENT ,CONTINUING REVIEW , PROJECT CLOSURE FORM.
INFORMED CONSENT FOR ONLINE SURVEYS 2- SAMPLE
INFORMED CONSENT FOR ONLINE SURVEYS 1- SAMPLE_2024
INFORMED CONSENT FORM :TIPS ,PRONOUN USAGE, GENDER

Step 2:
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Documents

Document Ty
Abstract/S

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IRBNet™

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Share Project

[2272904-1] Test Research Proposal

You may share this project with other Researchers, Committee Members, Administrators and Sponsors. You may also send a complete copy of this project to a Principal Investigator at another site if this is a multi-site project. You may also transfer ownership of this project to another individual.

- **Share:** Use this option if you wish to share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this project with other members of your research team so that you may collaborate in the design and development of the project, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your project for review. You may provide any individual with **Full**, **Write** or **Read** access.
- **Multi-site:** Use this option only if your project is a multi-site project and you wish to send a complete and independent copy of this project to a Principal Investigator at another site. The local Principal Investigator will be able to obtain project documents from the lead site and may modify their copy of these documents (such as consent forms) to meet the requirements of their local Board. You will be able to monitor the progress of this project at every local site. The other local Principal Investigators will also be able to monitor the progress of this project at every local site (including your own).
- **Transfer:** Transfer your ownership of this project to another user. In doing so you will relinquish all access to this project and the designated user will be granted **Full** access.

USER PROFILE

IRBNet

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Sign Package

[2272904-1] Test Research Proposal

I Joyce Borelli, as [ ], certify that to the best of my knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.

Sign

To sign on behalf of another person, switch to **Designee Signature Mode**.

This package has not been signed.

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Submit Package

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IRBNet supports multiple models of review. Using the "Submit" feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

Please select a Board:

Search for an Organization [ ] Search Clear

☑ Only show My Default Boards

Select a Board *

- Molloy University IRB, Rockville Centre, NY
- Molloy University Grants and Sponsored Programs Office, Rockville Centre, NY

Continue Cancel

* required fields

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Tips for a Successful Submission

- Be thorough: Provide detailed information to avoid delays.
- Know the IRB's guidelines: Familiarize yourself with specific requirements.
- Seek feedback: Faculty advisor review and, or peer review before submission.
- Be responsive: Address IRB feedback promptly and thoroughly.

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IRB review

- Studies that meet the definition of research with human subjects are reviewed
  - Prior to beginning the study

- For IRB (per, 45 CFR 46)
  - Research: “systematic investigation including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge”**

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IRB review

- What is generalizable knowledge?
  - Knowledge gained from a study may be applied to populations outside of the specific study population
  - Knowledge can inform policy
  - Knowledge that is disseminated
    - publications, conference presentations (outside of the classroom), thesis/dissertation

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MUIRB process

- Post IRBNet submission, initial review determines
  - **Completeness of application**
    - Documentation
      - Study team will be alerted if documents are missing
  - **Type of review**
    - May be reassessed at any time during the review process

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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 studies

Case study 1 (from Ambrose & Yairi, 2002)

- A researcher wants to design a study to assess a theory of stuttering. The theory (Johnson, 1942) may be described as follows: “the diagnosis of stuttering is made by a lay person, usually a parent, which explains why stuttering runs in families”.
- The experiment includes four groups of children (22 children were orphans)
  - group 1A, five children **identified as stuttering** were told, “you do not stutter. Your speech is fine.”
  - group 1B, five children **identified as individuals who stutter** were told, “yes, your speech is as bad as people say.”
  - group IIA, six children, **who did not stutter**, were told that their speech was not normal at all, that they were beginning to stutter, and that they must correct this immediately.
  - group IIB, **six fluent (no stuttering) children**, similar in age to those above, were complimented on their nice enunciation.
- What type of review will this study qualify for and why? Do you identify any ethical dilemmas here?

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Case study 2

- A faculty member submits an IRB application to the IRB of their place of employment, a Mental Health Counseling Research facility. The Molloy University IRB is not notified. The study protocol is approved by the employment IRB and the investigator proceeds with the research.
- What is the problem? What appropriate steps should have been taken to avoid the problem?

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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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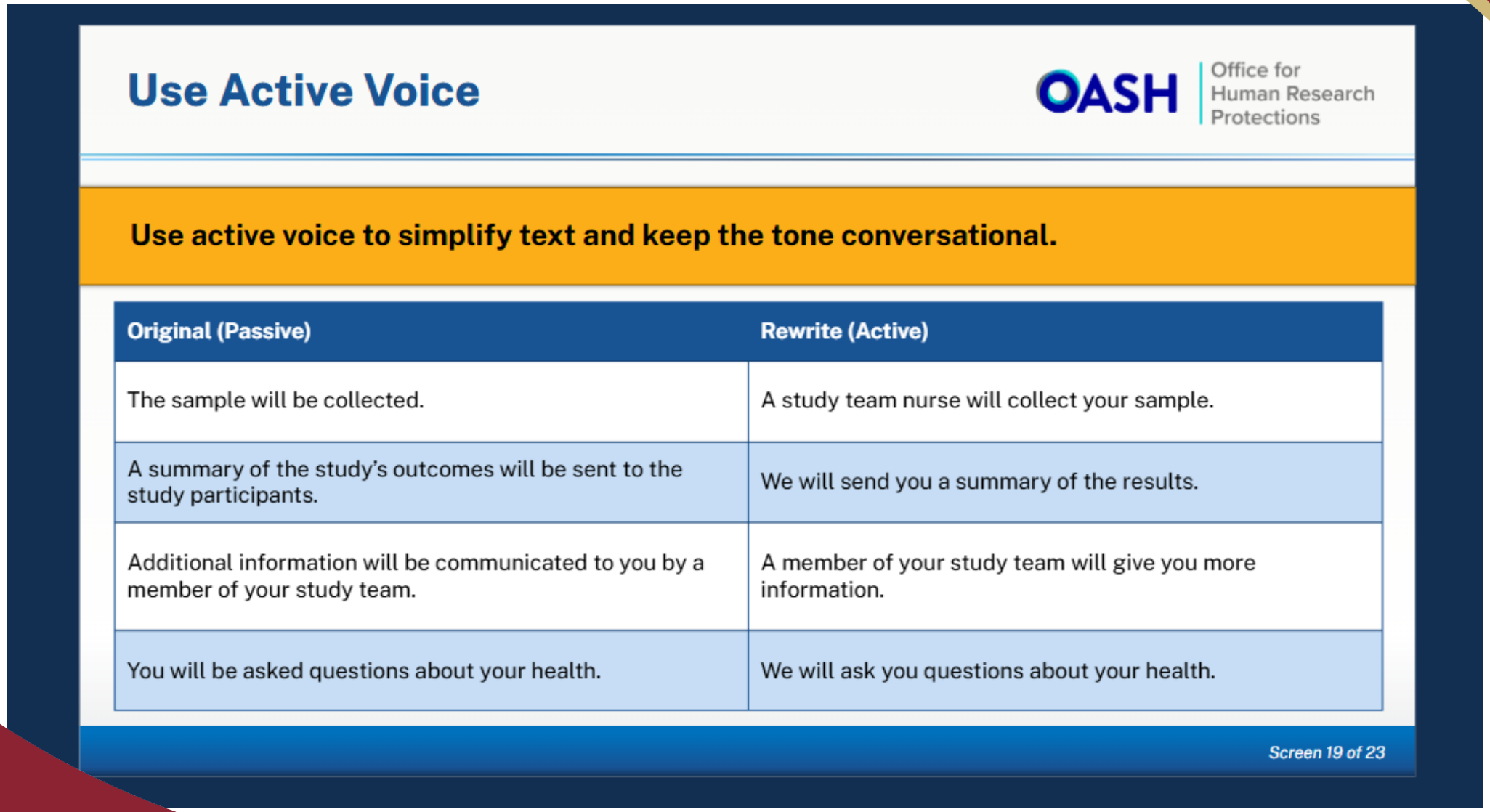
Case Study 3 – Simplified language



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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Conclusion

Key takeaways:

- Submitting an IRB proposal is crucial for ethical research involving human subjects.
- Understanding the process and requirements can streamline your submission.

Encouragement:

- Do not hesitate to contact the IRB for guidance.

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Contact the IRB

Institutional Review Board

Address: Kellenberg Hall 322

Email: irb@molloy.edu

Appointments are available by request.

Make sure to include your IRBNet protocol number and title on all communications with the IRB

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What are your questions?

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