## Welcome to

## Promoting Ethical Research Fall 2024 Presented by

## The Faculty Professional Center

**X** 

## The Office of Research, Scholarship, and Graduate Studies

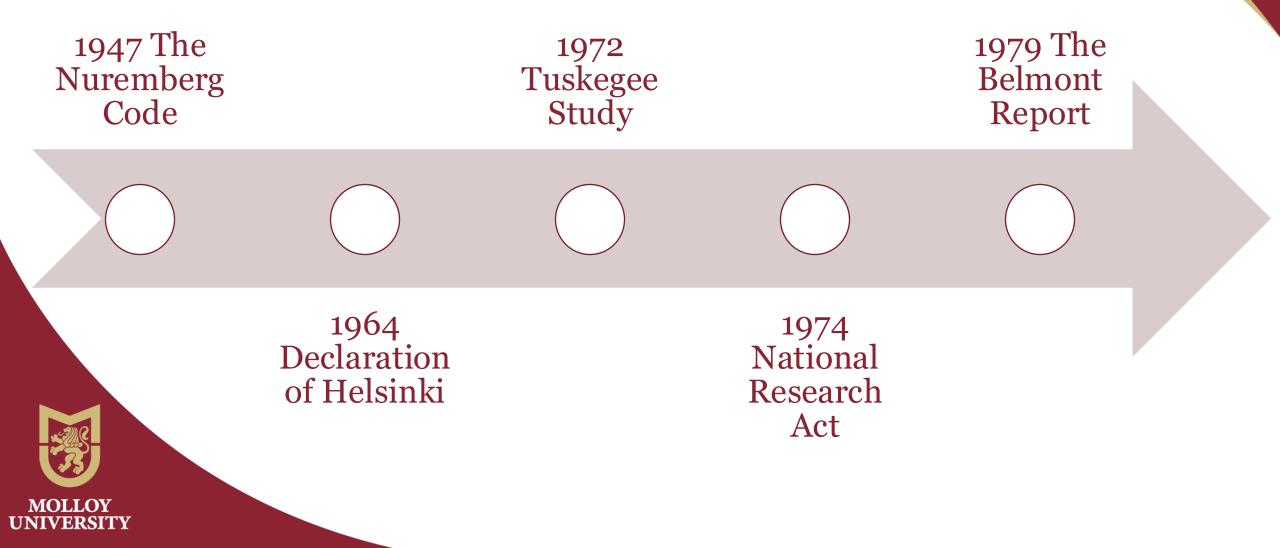


# Topics covered in this presentation:

- IRB review
- Comprehensive walkthrough of the IRB process
- IRBNet submission



## History of the Belmont Report



## **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

## 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.



## Members of the Molloy University IRB

**Ex-officio members:** Audrey Cohan, EdD and Sherry Radowitz, PhD **Chairperson:** Maureen Sanz, PhD

School of Arts & Sciences: John Carpente, PhD and Janice Kelly, EdD

School of Business: Gayle O'Keefe, MBA

School of Education & Human Services: Joanna Alcruz, PhD and Audra Cerruto, PhD

The Barbara H. Hagan School of Nursing & Health Sciences: Marcia Caton, PhD, Lorraine Emeghebo, EdD, Heather Reens, PhD, Ethel Ulrich, DNP, and Susan Vitale, PhD

### **Outside Community Members**

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 Kate Scotti, MS CCC-SLP, TSSLD - Speech Language Pathology in Motion



SUBMISSION DUE DATE	FULL BOARD MEETING DATE* Meeting Time: 3:30pm	<b>BOARD RESPONSE</b>
January 1, 2025	January 15, 2025	January 31, 2025
February 1, 2025	February 19, 2025	February 28, 2025
March 1, 2025	March 19, 2025	March 31, 2025
April 1, 2025	April 16, 2025	April 30, 2025
May 1, 2025	May 21, 2025	May 31, 2025

\* Proposals are reviewed during the summer months. Submissions that require Full Board review will be on the agenda for the September 17, 2025 IRB meeting.



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- Research that is more than minimal risk.
- Requires a majority vote by a quorum of the full IRB.
- The review process includes the criteria for IRB approval.
- Continuing review and relevant reporting of adverse events and benefits.
   Full Board
- Minimal risk research.
- The review process includes the criteria for IRB approval.
- Continuing review of changes and relevant reporting is required.
- Formal annual is not required unless determined so by the IRB.

### **Expedited Review**

**Review** 

- Minimal risk research.
- The review process includes the criteria for IRB approval.
- Continuing review of changes and relevant reporting is required.

## **Exempt Review**

• Formal annual is not required unless determined so by the IRB.

## **Before: Proposal Submission to the IRB**

- Consult the <u>Molloy University IRB webpage</u> for information regarding Human Subject Research and types of protocol determination as well as appropriate applications for the type and level of research activity submitted.
- Complete your CITI training.
- ALL people associated with the proposal to be submitted have documented appropriate Human Subjects Research (HSR) training (CITI Program training) in **BOTH** Responsible Conduct of Research (RCR) and Human Subjects Research (HSR).
  - Information regarding CITI Program training is on the <u>IRB website</u>.
- Create an <u>IRBNet account</u>.



## **Proposal Submission to the IRB**

- Obtain all required electronic signatures of the principal investigator (PI), the department chairperson or equivalent, Co-investigators and faculty advisor if it is a student submission on the application and in the IRBNet *Package Signatures* for PI and Co-investigators.
- Allow at least THREE weeks from the date of submission to the date of the IRB response regarding the proposal.
- Please respond promptly (within one week) if there are requested revisions to the proposal.



# **Proposal Submission to the IRB for students in an undergraduate class**

- If the proposal is submitted for students in an undergraduate class, the faculty member submits the proposal as the principal investigator and must have CITI certification.
  - Please clarify if the research involves individual or group work and use the appropriate form that can be found in the IRBNet library.
- For PhD, DNP, or EdD candidates, the student is the principal investigator and must submit a full proposal with the faculty mentor included as a co-investigator.



# **IRBNet**

**Proposal Submission** 

Forms and Templates

Library Manager





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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:* Degree(s):
Keywords:	
Sponsor:	
	You may specify an internal account number, billing identifier or reference number for this project. Continue Cancel
required fields	

USER PROFILE LOGOUT

**Project Information** 

### LOGOUI **USER PROFILE**

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Help

Designer

### Welcome to IRBNet Designer Joyce Borelli [2272904] Test Research Proposal Package: v 2272904-1 Work in progress (Not submitted) My Projects Create New Project 5 Click to add a package description or notes. Y My Reminders **Project Administration** Step 1: | Hide Form Libraries Project Overview Download blank forms, document templates and reference materials to assist you in assembling your document package. Select a Share this Project Molloy University IRB, Rockville Centre, NY V Library: Sign this Package Submit this Package Select a 1. READ THIS FIRST !!! Delete this Package Document: Download Send Project Mail Project History

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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

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My Projects	Package: v 2272904-1 Work in progress (Not submitted)		
Create New Project	Click to add a package description or notes.		
Y My Reminders			
Project Administration	Step 1:   Hide Form Libraries		
Project Overview	Download blank forms, document templates and reference materials to assist you in assembling your document package.		
Designer Share this Project	Select a Molloy University IRB, Rockville Centre, NY V		
Sign this Package	Library:		
Submit this Package	Select a 1. READ THIS FIRST !!!		
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Messages & Alerts	ACTION RESEARCH : FACULTY APPLICATION FORM		
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Other Tools Forms and Templates	maintaining v ACTION RESEARCH APPLICATION FORM FOR STUDENTS		
	AMENDMENT APPLICATION TO A MOLLOY IRB APPROVED PROTOCOL		
	ANNUAL NON RESEARCH PROJECT REPORT FORM		
	Document Ty APPLICATION FOR ONGOING CONTINUING REVIEW or FINAL REPORT		
	Abstract/S ASSENT GUIDELINES FOR RESEACHERS		
	ASSENT TO PARTICIPATE IN RESEARCH-ADOLESCENT 13-17		
	There are no 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		





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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.



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[2272904-1] Test Research Proposal

I Joyce Borelli, as v, 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.

**USER PROFILE** 

Sign Package

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### USER PROFILE



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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
		Molloy University IRB, Rockville Centre, NY Molloy University Grants and Sponsored Programs Office, Rockville Centre, NY
┥		
	Select a Board *	
1		-
		Continue Cancel
	* required fields	

## **IRB Review**

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to benefits, the knowledge that is expected to result.
- Selection of subjects is equitable.
- Consent document is clear in describing the essential elements.
- The consent process is described clearly and is appropriate
- There is a plan to ensure the safety of subjects during data collection, monitoring, and analysis.
- There are provisions to protect the privacy of subjects and to maintain the confidentiality of data.



# Contact Us Institutional Review Board Kellenberg Hall 322 Phone: 516 323-3405 Email: irb@molloy.edu Appointments are available by request. Please include your IRBNet protocol number and title on all

communications with the IRB



## Thank you for your participation!



