UMASS LOWELL	Application for Initial Review	
	Date Received	IRB Docket #

Use for newly proposed research								
Study Nickname:								
Study Title:								
Principal Investigator:								
PI Department:								
Date of CITI Training:		Degrees		Involved in Consent?	☐	Financial interest related to the research? Yes* ☐ No ☐		
Email Address:			**Phone #:**			**Cell:**		
Additional Contact:			**Phone #:**			**Cell:**		
Check here if you wish to be added to the UML IRB Listserv: ☐								
Check here if you wish to add all personnel to the UML IRB Listserv: ☐								

Names of all UML Personnel involved in the design, conduct, or reporting of the research					
Date of CITI Training	Name & Email Address	Degrees	Role in the research	Involved in consent?	Financial interest related to the research?
				☐	Yes ☐ No ☐
				☐	Yes ☐ No ☐
				☐	Yes ☐ No ☐
				☐	Yes ☐ No ☐
				☐	Yes ☐ No ☐
				☐	Yes ☐ No ☐
				☐	Yes ☐ No ☐
				☐	Yes ☐ No ☐
				☐	Yes ☐ No ☐
				☐	Yes ☐ No ☐

- "Immediate Family" means spouse, domestic partner, children, parents, spouse's parents, and dependents.
- "Financial Interest Related to the Research" means any of the following interests in the ***sponsor, product or service being tested, or competitor of the sponsor*** held by the individual or the individual's immediate family as defined above:
  - Ownership interest of any value including, but not limited to stocks and options, exclusive of interests in publicly-traded, diversified mutual funds.
  - Compensation of any amount including, but not limited to honoraria, consultant fees, royalties, or other income.

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- Proprietary interest of any value including, but not limited to patents, trademarks, copyrights, and licensing agreements.
- Board or executive relationship, regardless of compensation.

***If yes, you must complete the disclosure process by contacting Disclosures@uml.edu**

Funding Sources

Name of Funding Source	Grant Identifier

Additional Information

UML Location(s) where subjects/participants will be seen.	
Additional Departments involved in the study.	
Key Words	
Is this research required to be registered on ClinicalTrials.gov?	Yes ☐ No ☐
Consumer/Lay Summary of Study – limit to 3 succinct sentences/300 characters:	

Investigator Acknowledgment

The following check boxes must be checked before sending:

By checking below you are verifying that:

- **Yes** ☐ You have obtained the financial interest status ("Yes" or "No") for each member of the research staff.
- **Yes** ☐ You have obtained the agreement of each research staff to his/her role in the research.
- **Yes** ☐ You have obtained the agreement, if applicable, of any other department (outside of your own department) being asked to serve as a recruitment or study conduct site.
- **Yes** ☐ You will conduct this Human Research in accordance with requirements in the INVESTIGATOR MANUAL (HRP-103).
- **Yes** ☐ You have received appropriate approvals from your department chair or supervisor and it has been determined that all departmental requirements are met and that the investigator has adequate resources to conduct this Human Research in terms of time, facilities, staff, access to a subject population, and resources for care that subjects may need.

☐ By checking here, I attest that the information provided in this form is accurate.	Date:

Submit all documents to IRB@uml.edu

- FORM: Application for Initial Review (HRP-200), including as applicable:
  - Appendix A: External Site Approvals
  - Appendix B: Drugs and Device (include associated attachments, such as package insert, investigator brochure, or labeling, verification of IND/ IDE number)*
- Investigator Study Plan (See TEMPLATE (HRP-504) for instructions)
- All information intended to be seen or heard by subjects, including:(Advertisements and recruitment materials and changes to advertisements and recruitment materials must be IRB approved before their use)
  - Evaluation instruments and surveys
  - Advertisements (printed, audio, and video)
  - Recruitment materials and scripts
  - Consent documents
  - If consent will not be documented in writing, a script of information to be provided orally to subjects
  - Foreign language versions of the above

- Complete sponsor protocol (if applicable)
- Grant application, if any
- DHHS protocol and DHHS-approved sample consent document, if any

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Appendix A: External Sites Involved in the Research

Complete for each non-UML site where the investigator will oversee or conduct the research

Site name:			
Site PI name:			
Contact phone :		**Contact email:**	
Yes ☐ No ☐	Will the external site review the research?		
Yes ☐ No ☐	Will the external site rely on the UML IRB?		
Site name:			
Site PI name:			
Contact phone :		**Contact email:**	
Yes ☐ No ☐	Will the external site review the research?		
Yes ☐ No ☐	Will the external site rely on the UML IRB?		
Site name:			
Site PI name:			
Contact phone :		**Contact email:**	
Yes ☐ No ☐	Will the external site review the research?		
Yes ☐ No ☐	Will the external site rely on the UML IRB?		
Site name:			
Site PI name:			
Contact phone :		**Contact email:**	
Yes ☐ No ☐	Will the external site review the research?		
Yes ☐ No ☐	Will the external site rely on the UML IRB?		
Site name:			
Site PI name:			
Contact phone :		**Contact email:**	
Yes ☐ No ☐	Will the external site review the research?		
Yes ☐ No ☐	Will the external site rely on the UML IRB?		