

INTRODUCTION TO THE UMES INSTITUTIONAL REVIEW BOARD PROCESS

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What is Human Subjects Research?

Research - “A systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (Protection of Human Subjects 2018)

Human subject – “A living individual about whom an investigator conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.” (Protection of Human Subjects 2018)
 - Identifiable private information – “Identifiable private information is private information for which the identity of the subjects is or may readily be ascertained by the investigator or associates with the information.” (Protection of Human Subjects 2018)

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Authority of the IRB

- Review proposed Human Subjects Research
 - Require application submission
 - Require modifications to secure approval
- Approve human subjects research
 - IRB approval must be given prior to any research activity - no retroactive approvals.
 - The institution may decide that IRB-approved research may not be conducted.
 - If an IRB has disapproved the research, the institution may not override the IRB decision.
- Oversee human subjects research
 - Conduct continuing reviews
 - Suspend or terminate approval
 - Observe, or have a third party observe, the consent process and the research procedures

Roles of Faculty & Students Conducting HSR

Faculty Role in HSR

Be familiar with the requirements of human subjects research

Possess CITI certificates – Investigator and RCR for Human Subjects Research

Guide students through the IRB application process – proofread the application prior to submission.

Submit the application to the IRB.

Inform student when they can initiate their research by providing them with a copy of the IRB approval notice.

Discuss research ethics with students.

Continue communications with the IRB – questions, apply for amendments, report issues, continuation

Keep records for at least 3 years after project termination

Student Role in HSR

Be familiar with the requirements of human subjects research

Possess CITI certificates – Student and RCR for Human Subjects Research

Complete the IRB application under the guidance of the faculty investigator.

Receive a copy of the IRB approval notice from faculty investigator.

Maintain communication with faculty investigator: Report unexpected issues, ask questions

Maintain communication with the IRB: Report unexpected issues, ask questions

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Types of IRB Review

Limited Review - minimal risk projects that fall into one of eight categories that are “exempt” categories

- Minimal risk - probability and magnitude of harm or discomfort anticipated in the research are not greater, per se, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations

Expedited Review - minimal risk projects that fall into one of nine categories and of which a breach of confidentiality is the primary risk.

- Confidentiality - treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission

Convened Review - projects that involve more than minimal risk and or studies using vulnerable populations

- Vulnerable Populations: psychiatric, cognitive, or developmental disorders; impaired decision-making capacity; pregnant women, fetuses, and neonates; prisoners; children

Limited IRB Review

Categories are exempt from the other provisions of the regulations at 45 CFR 46.

Category 1: Research conducted in established or commonly accepted educational settings.

Category 2: Research that only includes interactions involving education tests, survey procedures, interview procedures or observation of public behavior.

Category 3: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses.

Category 4: Secondary research for which consent is not required.

Category 5: Research and demonstration projects that are conducted or supported by a Federal department or agency.

Category 6: Taste and food quality evaluation and consumer acceptance studies.

Category 7: Storage or maintenance for secondary research for which broad consent is required.

Category 8: Secondary research for which broad consent is required.

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Timeline Approximation

CITI Training	Write IRB Application	IRB Review	Revisions	IRB Review	Review by other entities involved
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1 wk

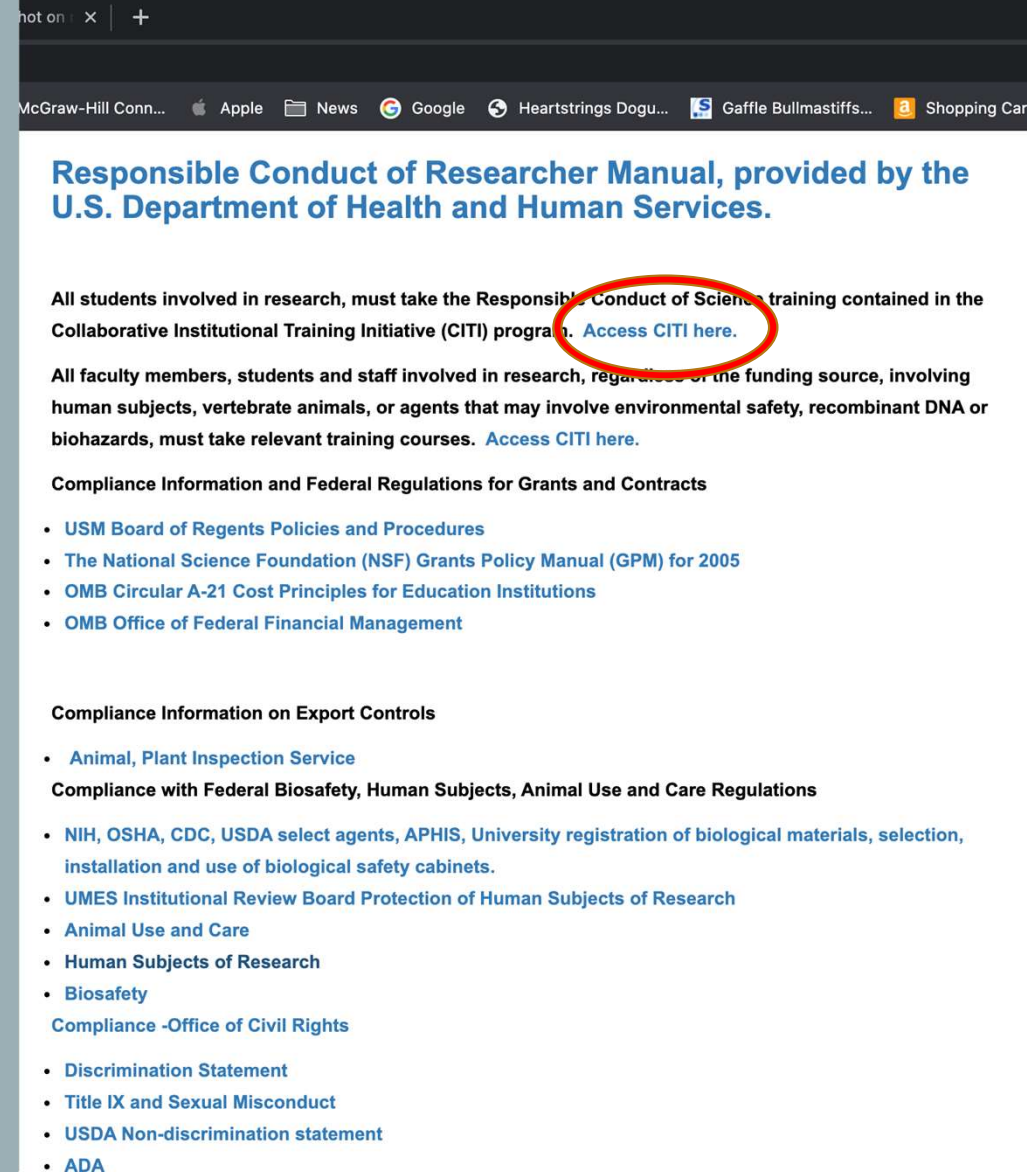
Note: School systems may require two months or more

CITI Training

<https://www.umes.edu/OSRP/>

Scroll down the page and click **ACCESS CITI HERE**

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Responsible Conduct of Researcher Manual, provided by the U.S. Department of Health and Human Services.

All students involved in research, must take the Responsible Conduct of Science training contained in the Collaborative Institutional Training Initiative (CITI) program. [Access CITI here.](#)

All faculty members, students and staff involved in research, regardless of the funding source, involving human subjects, vertebrate animals, or agents that may involve environmental safety, recombinant DNA or biohazards, must take relevant training courses. [Access CITI here.](#)

Compliance Information and Federal Regulations for Grants and Contracts

- [USM Board of Regents Policies and Procedures](#)
- [The National Science Foundation \(NSF\) Grants Policy Manual \(GPM\) for 2005](#)
- [OMB Circular A-21 Cost Principles for Education Institutions](#)
- [OMB Office of Federal Financial Management](#)

Compliance Information on Export Controls

- [Animal, Plant Inspection Service](#)

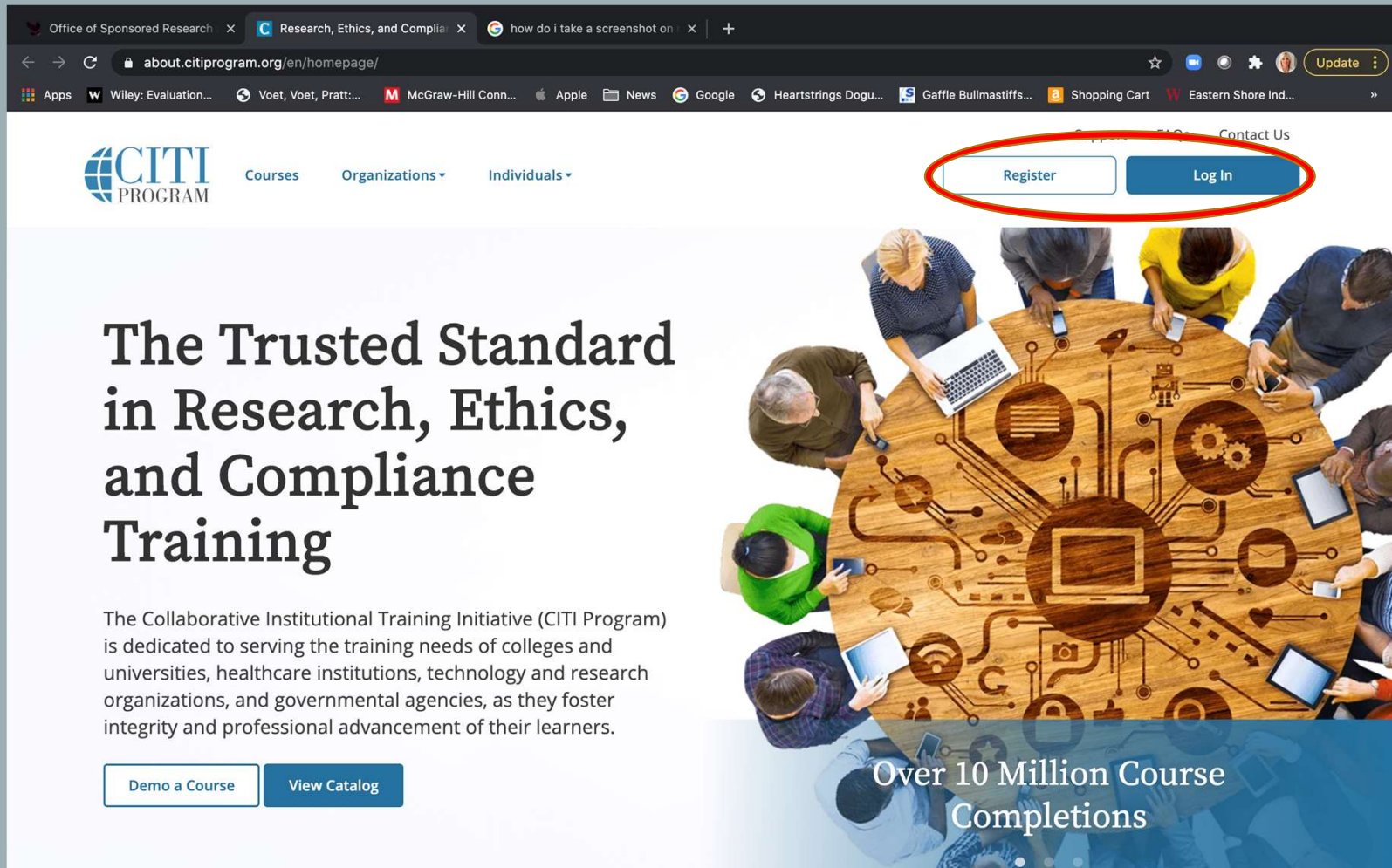
Compliance with Federal Biosafety, Human Subjects, Animal Use and Care Regulations

- [NIH, OSHA, CDC, USDA select agents, APHIS, University registration of biological materials, selection, installation and use of biological safety cabinets.](#)
- [UMES Institutional Review Board Protection of Human Subjects of Research](#)
- [Animal Use and Care](#)
- [Human Subjects of Research](#)
- [Biosafety](#)

Compliance -Office of Civil Rights

- [Discrimination Statement](#)
- [Title IX and Sexual Misconduct](#)
- [USDA Non-discrimination statement](#)
- [ADA](#)

Register for CITI or Login



The screenshot shows the CITI Program website homepage. The browser's address bar displays `about.citiprogram.org/en/homepage/`. The navigation menu includes the CITI PROGRAM logo, [Courses](#), [Organizations](#), and [Individuals](#). The [Register](#) and [Log In](#) buttons are circled in red. The main heading reads "The Trusted Standard in Research, Ethics, and Compliance Training". Below this, a paragraph states: "The Collaborative Institutional Training Initiative (CITI Program) is dedicated to serving the training needs of colleges and universities, healthcare institutions, technology and research organizations, and governmental agencies, as they foster integrity and professional advancement of their learners." At the bottom left, there are buttons for [Demo a Course](#) and [View Catalog](#). On the right, a large graphic of people around a table with tech icons is overlaid with the text "Over 10 Million Course Completions".

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about.citiprogram.org/en/homepage/

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CITI PROGRAM Courses Organizations Individuals Register Log In Contact Us

The Trusted Standard in Research, Ethics, and Compliance Training

The Collaborative Institutional Training Initiative (CITI Program) is dedicated to serving the training needs of colleges and universities, healthcare institutions, technology and research organizations, and governmental agencies, as they foster integrity and professional advancement of their learners.

[Demo a Course](#) [View Catalog](#)

Over 10 Million Course Completions

Select **View Courses** next to University of Maryland Eastern Shore to share your certifications: Please send me the certificate, not the link

Office of Sponsored Research

Research, Ethics, and Compliance

CITI - Collaborative Institutional

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citiprogram.org/members/index.cfm?pageID=50

Update

Apps

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Institutional Courses

Institutional Courses are available to learners who have an affiliation with one or more subscribing institutions. If an institution with which you are affiliated is not listed, you may want to [add an affiliation](#). If you are no longer associated with a listed institution, you may want to [remove an affiliation](#).

University of Maryland Eastern Shore

View Courses

Would you like to affiliate with another Institution?

Add Affiliation

Would you like to remove an existing affiliation?

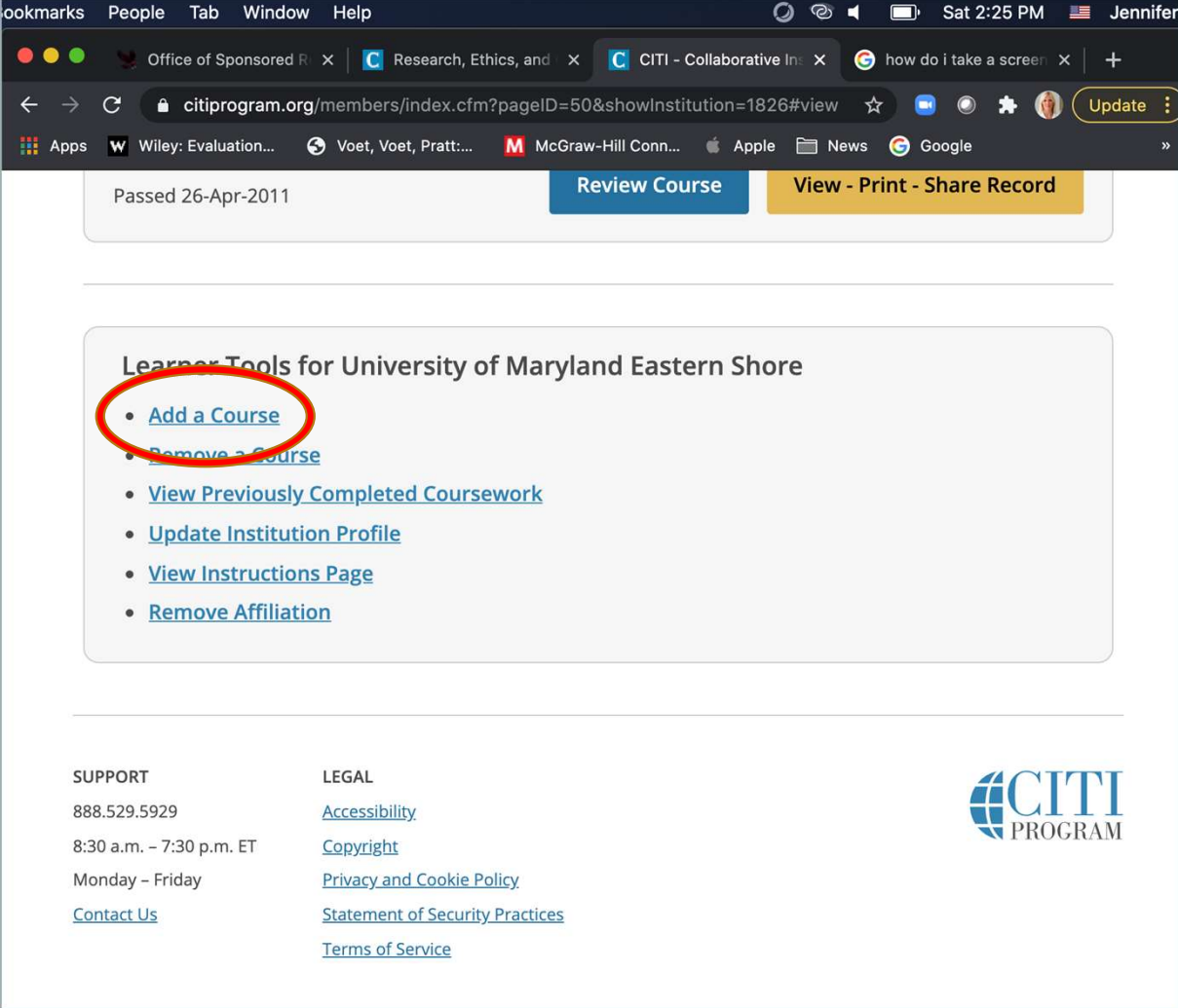
Remove Affiliation

Independent Learner

Register as an independent learner to purchase course content. Before you purchase a course, please make sure you do not already have access to that course through an Institutional affiliation. Please note that refunds are not available for courses purchased as an Independent Learner.

Register as an Independent Learner

Scroll to the bottom of the page and select **ADD A COURSE**



The screenshot shows a web browser window with the URL citiprogram.org/members/index.cfm?pageID=50&showInstitution=1826#view. The page displays a status bar at the top indicating "Passed 26-Apr-2011" and two buttons: "Review Course" and "View - Print - Share Record". Below this, a section titled "Learner Tools for University of Maryland Eastern Shore" contains a list of links. The first link, "Add a Course", is circled in red. Other links in the list include "Remove a Course", "View Previously Completed Coursework", "Update Institution Profile", "View Instructions Page", and "Remove Affiliation". At the bottom of the page, there are two columns of links: "SUPPORT" (888.529.5929, 8:30 a.m. – 7:30 p.m. ET, Monday – Friday, Contact Us) and "LEGAL" (Accessibility, Copyright, Privacy and Cookie Policy, Statement of Security Practices, Terms of Service). The CITI PROGRAM logo is located in the bottom right corner.

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Passed 26-Apr-2011 Review Course View - Print - Share Record

Learner Tools for University of Maryland Eastern Shore

- [Add a Course](#)
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LEGAL
[Accessibility](#)
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[Statement of Security Practices](#)
[Terms of Service](#)



Question 1

Human Subjects Research

Please choose one learner group below based on your role and the type of human subjects activities you will conduct. You will be enrolled in the Basic Course for that group.

- ☐ Biomedical Research Investigators: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Biomedical research with human subjects.
- ☐ Social & Behavioral Research Investigators: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social and Behavioral research with human subjects.
- ☐ IRB Members: This Basic Course is appropriate for IRB or Ethics Committee members.
- ☐ Students conducting no more than minimal risk research
- ☐ Research with data or laboratory specimens- ONLY: No direct contact with human subjects.
- ☐ IACUC
- ☐ IBC Members
- ☐ None of the above

Question 2

Responsible Conduct of Research

To take RCR training, please select your learner group below:

- ☐ Research Investigator
- ☐ Research Staff
- ☒ RCR for Human Subjects
- ☐ RCR for Animal Welfare
- ☐ RCR for Administrators
- ☐ RCR for Engineers
- ☐ None of the above

Question 3

Biosafety Training

To take the Biosafety Training, select "Enroll me in Biosafety Training" below:

- ☐ Enroll me in Biosafety Training
- ☒ Not at this time.

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Question 4

Laboratory Animal Welfare

Do you conduct studies that use Lab animals?

1. If YES, then you must complete the Basic course and the appropriate species specific modules.
2. If you are an IACUC Member you should complete the "Essentials for IACUC Members".
3. Choose the appropriate species specific electives according to your research interests.

- ☐ Animal Use & Care
- ☐ If you are an IACUC Member you are required to complete the "Essentials for IACUC Members" course now.
- ☐ If you are planning to do aseptic surgery on animals, you may want to complete the "Aseptic Surgery" course now. Your Institution may require this.
- ☐ Antibody Production
- ☐ Using Animal Subjects in Research
- ☐ Working With Animals In Biomedical Research - Refresher Course

Submit

Do not make a selection



UMES INSTITUTIONAL REVIEW BOARD APPLICATION FOR INITIAL REVIEW OF
HUMAN SUBJECTS RESEARCH
November 2019

Name of Principal Investigator (PI) _____ Phone _____
(Faculty/Staff)

Department of PI _____

Email of PI _____

Campus Address of PI _____

Name of Co-Investigator _____ Phone _____
(Faculty/Staff)

Email of Co-Investigator _____

Student Investigator(s): Student(s), Fellow, Post-Doctoral Fellow

Name _____ Phone _____ Student ID # _____

UMES Sponsor for Non-UMES Investigators

Name and position _____

Department Address _____

Phone _____

Email _____

_____ Inclusion of all investigators' RCR and Human Subjects Research CITI certificates and
IRB approvals from other institutions (if applicable)

Project Title _____

Project Duration _____

Funding Agency _____

Please suggest whether this research may be exempt from a full IRB review by indicating all of
the relevant exemption categories. Your notation is simply a suggestion to the
IRB. _____

Principal Investigator _____ Date _____
Signature

Co-Investigator _____ Date _____
Signature

Student Investigator _____ Date _____
Signature

Student Investigator _____ Date _____
Signature

UMES Sponsor _____ Date _____
Signature

All IRB applications **MUST** be sent to me from the PI

- Please respond to the email chain that is established

Names and credentials should appear on the application
as you want them to appear on your approval notice

Everyone affiliated with UMES should list their UMES
email address

Everyone affiliated with an institution should list their
institutional email address

Check the line to denote that CITI certificates for
everyone on the application are included.

- CITI certificates must be included

Details, Spelling & Grammar

UNIVERSITY OF MARYLAND EASTERN SHORE INSTITUTIONAL REVIEW BOARD APPLICATION INSTRUCTIONS

1. Research Design/Methods

Include a brief description of the research and its purpose.

a. Is the approach appropriate and valid?

- ~200 words
- Purpose of the research
- Approach

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2. Subject Selection

a. Who are the subjects?

b. How will they be recruited? If you plan to advertise for subjects, include a copy of the notice.

c. From where will they be recruited?

d. Are the subjects being selected for any specific characteristics, e.g., age, sex, race, ethnic origin, religion, social or economic qualifications?

e. Provide assurance that there is equitable selection in terms of age, sex, race, ethnic origin, religion, social and or economic qualifications. If there is not equitable selection, provide a justification.

- Who are the ideal subjects? Why are they ideal?
- If you plan to email the subjects, how will you obtain their email addresses?
- Provide a draft of recruitment email, telephone conversation, flyer in your application.
- Where will you recruit – do you need permission to recruit at that location?

3. Procedures

- a. What precisely will be done to the subjects? Explain in detail your methods and procedures in terms of what will be done to the subjects.
- b. Where will the study be conducted? If not on campus, please explain the nature of your cooperative arrangement with those in charge of the research site and also attach the appropriate Human Subjects Research Approval forms from the cooperative site, if applicable.

- Details, details, details!
- If you plan to use an online survey platform, please specify which one you will use.
- Research at other locations requires approvals, general IRB Authorization Agreements

4. Risks/Anticipated Benefit Analysis

Care must be taken to minimize the risks subjects are exposed to by participating in the research project.

- a. What are the risks to the subjects?
- b. How did you attempt to minimize the risks to the subjects?
- c. What are the direct and indirect benefits of this research?
- d. Are benefits distributed fairly among populations?

- It is your responsibility to state these risks no matter how small.
- If you think there are no risks associated with your research, make a statement to support this claim.
- Don't forget to address C and D

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5. Privacy/Confidentiality

Adequate provisions must be made to protect the privacy of subjects and to maintain confidentiality of identifiable information.

- a. Explain how procedures are in place to assure confidentiality of subjects' identification and information collected.
- b. Explain how procedures protect subjects' privacy.

Confidentiality - treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission

- Informed Consent
- Assent

Privacy - having control over the extent, timing, and circumstances of sharing oneself.

INFORMED CONSENT

Project Title

Statement of Age of Subject (parental consent needed for minors AND assent from minors)

I state that I am over 18 years of age, in good physical and mental health, and wish to participate in the research being conducted by (state the PI's name) at the University of Maryland Eastern Shore in the Department of (Department PI is affiliated with).

Purpose Succinctly state the purpose of the research project. The purpose must be conveyed in language that is understandable by the research subject.

Procedure(s) State what the subject is expected to do to participate in the study.

Confidentiality Simply explain how privacy and confidentiality will be respected.

Risks Explain the risks associated with participation in research.

Benefits (Direct or Indirect) Explain the benefits, direct or indirect, to the participant and to the broader population.

Freedom to Withdraw and Ask Questions

I understand that I can ask questions at any time during my participation and that I can withdraw from the study at any time without penalty.

Where Medical Care is Available

In the event of injury resulting from participation in this study, I understand that immediate medical treatment is available nearby at Peninsula Regional Medical Center. However, I understand that the University of Maryland Eastern Shore does not provide any medical or hospitalization insurance coverage for participants in the research study nor will the University of Maryland Eastern Shore provide any compensation for any injury sustained as a result of participation in this research study except as required by law.

Conclusion

You are making a decision whether or not you will participate in this study. If you give consent, you are agreeing to participate based on your reading and understanding of this form.

If you have questions regarding the study, please speak with (PI's name), the principal investigator, who can be reached at (PI's phone number).

If you have questions regarding your rights as a research subject, please contact the Chair of the Institutional Review Board at the University of Maryland Eastern Shore, Dr. Jennifer Bobenko by calling 410-651-7945 (office), 443-614-9226 (cell) or via email at JLHearne@umes.edu.

Each page of the Informed Consent must have a line for printed name, date and signature.

Printed Name & Date

Signature

Please use this document as your template.

Project Title must match your IRB application page.

It is critical that you address how you will obtain informed consent/assent prior to conducting research.

Informed Consent is provided by an adult.

Assent must be obtained from minors in addition to Consent from their legal guardian.

- Minors cannot sign an assent form
 - print name
 - date
 - check a box to acknowledge understanding

If your document is more than 1 page, the subject must sign both pages.

You must be able to provide a copy of the signed form to the subjects.

7. Research Plan for Collection, Storage and Analysis of Data

- a. Include a description of how data will be collected from subjects. If you plan to use a questionnaire or handout, include a copy of the questionnaire or handout.
- b. Include a description of how the data will be stored.
- c. Include a description of how the data will be analyzed.
- d. Indicate who will have access to the data.
- e. Indicate how long the data will be stored.
- f. Indicate when data will be destroyed and the method of its destruction.

- Data cannot be stored by only by the student, the PI must have access to the data.
 - Hard copy, files in a shared drive, online survey platform account
 - Data should be stored by the PI for at least 3 years post completion.
- Include the survey or intended interview questions with your application.

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8. Conflict of Interest

- a. Describe any potential conflicts of interest, individual or institutional, including how such a conflict would affect the level of risk to the study participants. Please consult the University of Maryland policy on conflict of interest as defined by the University of Maryland Policies and Procedures III-1.11 and can be viewed at:
<https://www.usmd.edu/regents/bylaws/SectionIII/III111.html>
- b. If a conflict of interest is probable or inevitable, provide a management plan to reduce bias in the research.

9. HIPAA Compliance

- a. Does your research include the collection of protected health information (PHI)?
- b. If the data to be collected meets the definition of identifiable PHI and are being used for purposes that fall within HIPAA's definition of research, an explicit written authorization (consent) from the data subject for research use is required, unless: a) the research involves only minimal risk to the subject; b) the data is used solely for activities preparatory to research; c) only deceased individual's information is used in the research; d) it is grandfathered research. Include a copy of the authorization form. Attach a copy of the form, if required.

It is acceptable to have a COI provided you have a plan to handle it. Common COIs include student-professor relationships, pharmacist-patient relationships.

What happens when ...

Investigators from other universities are involved?

IRB AA

Investigators from other non-university institutions with IRBS are involved?

IRB AA

Investigators that are not associated with a university or institution with RIB are involved?

Individual AA

When you conduct international research?

Site Permission Letter

Memo of Cultural Appropriateness

Letter of Unregulated Activities

Questions, ask an IRB member...

Jennifer C. Bobenko, PhD JLHearne@umes.edu

Dennis Klima, Department of Physical Therapy, Co-Chairperson

Hoai-an Truong, School of Pharmacy

Madhumi Mitra, Department of Natural Sciences

Donna Satterlee, Department of Human Ecology

Garland Hayward, Community Member

Gertrude Hairston, ex-officio

Joseph Pitula, ex-officio

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Interesting History

- Nuremberg Code of 1947 - "the voluntary consent of the human subject is absolutely essential"
- Helsinki Declaration of 1964 – protocols should be reviewed by an independent committee prior to initiation
- 1971 Guidelines – issued by U.S. Department of Health, Education, and Welfare Codes for the conduct of social and behavioral research
- 1974 National Research Act - created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
 - Identified the basic ethical principles that underlie the conduct of biomedical and behavioral research involving human subjects
 - Developed guidelines to assure ethical principles are employed
- 1979 Belmont Report - published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: Respect for Persons, Beneficence, Justice
- 1981 HHS codified the Policy for the Protection of Human Subjects (45 CFR 46).
 - Subpart A of these regulations "Common Rule" - basic foundation for protecting human research subjects
- 2000 Office of Human Research Protections was founded as the regulatory arm of the DHHS
- 2017 Common Rule was revised to strengthen protections for human subjects
 - IRB operations, informed consent, exemptions
- 2018 Common Rule revised to exclude:
 - Scholarly and journalistic activities
 - Public health surveillance activities
 - Collection and analysis of information, biospecimens, or records by or for a criminal justice agency
 - Authorized federal intelligence and defense activities