OFFICE OF
RESEARCH
COMPLIANCE
CENTRAL MICHIGAN UNIVERSITY

New Faculty Orientation – 2023

Research Compliance

Message from the Director

The Office of Research Compliance is made up of several sections that support a culture of research integrity with university policies and federal regulations for the conduct of research. The Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), and Institutional Review Board (IRB) staff are available to assist in guiding you in conducting your research within the established norms of CMU and federal regulations.

We are here to get your research up and going as smoothly as possible. My staff along with the committee chairs are available for consultation if you have any questions concerning your research. Please feel free to contact me directly or visit our office for assistance. Stop by to say hello and put a face to the compliance staff.

Wishing you the best for the 2023-2024 academic year.

Belinda

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Research Compliance Web Site

Materials and information about the various oversight committees are posted on the Research Compliance web pages, which are updated frequently to keep you informed of current developments and new guidance.

Applications to conduct research involving human beings, animal subjects, biohazardous substances, recombinant or synthetic nucleic acid molecules are completed online in IRBManager. https://cmich.my.irbmanager.com/

If you have any questions about the accuracy or currency of information presented on the Research Compliance web pages, please contact our team at ComplianceQuestions@cmich.edu.

CITI Training

Required training in various areas of research compliance can be taken online through the Collaborative Institutional Training Initiative (CITI). Investigators who have taken equivalent training at other institutions can transfer their current training credentials by affiliating to CMU. For further information, please contact our team at:

- Human Subjects Research: cmuirb@cmich.edu
- Animal Research: IACUC_Admin@cmich.edu
- Recombinant Nucleic Acid Molecules and Biohazardous Research: IBC@cmich.edu

Note: When registering with CITI, select the correct CMU site you are closely associated with. The sites are:

- Central Michigan University (Mt. Pleasant campus)
- Central Michigan University -Saginaw
- Central Michigan University- Detroit

Registration at CITI

1. Go to https://www.citiprogram.org/
2. Select "Register" under the "Create an account" utilizing your CMU global ID/password. Use your CMU email access and credentials to utilize the "Single Sign-On credentials" (SSO).
3. Enter Organization/Select Affiliation as Central Michigan University
4. Answer a series of questions during enrollment that will direct you to a curriculum or "Learner Group" (You will be able to update your learner group later if you need to complete courses in more than one subject by selecting "Add a course or update your Learner Group".)

5. Once registered you can use single sign on (SSO)

Note: Additional instructions for registering and using CITI can be found in the Guide to getting started.

Transferring CITI Training Credentials

1. After logging into your CITI account, select the link to "Add an Institutional Affiliation".
2. Enter the Organization/Select Affiliation as Central Michigan University (CMU).
3. Answer the member information questions and enroll in the course(s) for CMU.
4. Enroll in the same stage of the course (Basic/Refresher) for a transfer to occur.

Required Courses for Investigators Conducting Human, Animal, and Biohazardous Research

Human Subjects Research (HSR): CITI Program's HSR series covers current regulatory and ethical aspects of human subjects research. There are two basic tracks: Biomedical (Biomed) and Social-Behavioral-Educational (SBE); enroll in the one that is closest to the kind of research you will be conducting. HSR training must be renewed every 3 years.

Research using protected health information (PHI): Investigators conducting research that will collect PHI from research subjects or from medical records must demonstrate understanding of their obligations under the Health Insurance Portability and Accountability Act (HIPAA) through completion of the CITI Health Information Privacy and Security (HIPS) for Clinical Investigators and HIPAA courses.

Animal Care and Use (ACU): ACU modules cover general principles of ethical care and use of animals in research, training, and testing. Additional modules focus on the care and use of particular species.

Biosafety and Biosecurity (BSS): BSS content covers the principles of biosafety and biosecurity, including safe use and containment of recombinant molecules and biohazardous agents. Required for all researchers working above BSL1/RG1, follow the link for more information on risk groups and containment.

Required Course in Financial Conflicts of Interest (COI) for all PHS Grantees

CITI Program's COI course covers the revised U.S. Public Health Service (PHS) regulations associated with financial conflicts of interest and an investigator's responsibilities related to disclosure of "Significant Financial Interests."

Required Courses in Responsible Conduct of Research (RCR)

Many CMU Colleges have tailored the elements of their courses in RCR. Taking the RCR course for your college satisfies National Institutes of Health (NIH), the National Science

Foundation (NSF), and the U.S. Department of Agriculture (USDA) requirements for grantees and trainees.

Responsible Conduct of Research: CITI Program's RCR series consists of a basic course, complemented with a set of additional modules of interest, and a refresher course. Both courses contain modules that cover core norms, principles, regulations, and rules governing the practice of research. The NIH, the NSF, and USDA require certain categories of researchers to receive RCR training. Please note, RCR modules are not an acceptable substitute for HSR, ACU or BSS training requirements.

Additional Courses that may be Required

Good Clinical Practice: Covers ICH GCP E6 and FDA Regulations as well as other required and optional topics related to clinical research.
Introduction to Export Compliance: This is a new offering providing export compliance information for this important topic. There is also a simple introduction to Export Controls on the Research Compliance website.

Other Training Requirements

The Office of Laboratory and Field Safety offers a variety of project-specific training, a good place to get started is with Safety Training Form of the chemical hygiene plan. The form serves as a checklist that principal investigators/laboratory supervisors must complete for each new laboratory worker and is a useful guide for new investigators.

Bloodborne Pathogens Training: This annual training is required for individuals with exposure to sharps, blood, and other potentially infectious materials. Meets the training requirements of MIOSHA Part 554.

Lab Safety Training: This training is required for individuals who work with hazardous chemicals in a laboratory setting. Meets the training requirements of MIOSHA Part 431.

Hazard Communication/Global Harmonized System: This annual training is required for non-laboratory workers who work with chemicals. Meets the training requirements of MIOSHA Part 430.

Radiation Training - Bone Densitometer: This annual training is required for individuals who operate the DXA bone densitometer.

Facility Access Training: Some facilities at CMU (e.g. animal vivaria, BSL2) require facility specific training (e.g. orientation and tour, appropriate PPE, safety practices) prior to being granted access. To complete this training please contact the IACUC/IBC Coordinator at IACUC_Admin@cmich.edu or IBC@cmich.edu .

Institutional Review Board (IRB)

CMU's Office of Research Compliance oversees two IRBs, Mount Pleasant Campus IRB and Children's Hospital of Michigan- Pediatric IRB (CHM located in Detroit). When selecting an application for IRB review, verify that you are selecting the correct IRB location. The applications request different information for each location.

MP Chair	Rachael Nelson	X2695	nelso1rk@cmich.edu
Coordinator	Deb Geasler	X6401	stane1dm@cmich.edu
CMU-CHM Chair	Melissa Gregory	1-313-745-5604	grego3mj@cmich.edu
Coordinator	Deb Geasler	X6401	stane1dm@cmich.edu

Who can submit to the IRB: Only faculty members can serve as Principal Investigators.

IRBManager: All applications to the IRB are submitted through IRBManager, which can be accessed by single sign on (SSO) using your CMU global ID/password. A log-in option is also available for non-CMU collaborators at other institutions who may also register within the system for access to project materials. Instructional guidance documents regarding the IRBManager system are posted on the ORC web page.

When to submit: Applications to conduct research involving human subjects that are eligible for exemption or review by expedited procedures are processed on a rolling basis. Consult the MP IRB Meeting Schedule or the CMU-CHM Meeting Schedule for meeting and subsequent submission deadline dates for applications that require review at convened meetings (full board review).
CMU CHM investigators must first engage with the University Pediatricians Clinical Research Institute staff prior to submitting to the IRB. For more information, contact Jason Czachor at czach1j@cmich.edu

Plan ahead: Investigators planning time-sensitive activities such as grant applications and joint submissions with colleagues at other institutions, which may require their own IRBs to review an application, are advised to plan accordingly. Students planning to submit applications to conduct thesis or dissertation research are advised to submit applications at least one semester before planned data collection.

Seek advice: Investigators who are new to the world of IRB are encouraged to consult with the IRB Chair or Coordinator to discuss which type of submission might be suitable (and easiest!). Simple changes in approach can often make a protocol eligible for a quicker review process.

Review and approval times: The IRB tries to render decisions about exempt determinations and expedited reviews within 21 days of submission. Recent experience indicates that protocols reviewed at convened meetings usually require at least **2 cycles** to

be approved. Given the schedule of meetings and the 3-week requirement for submission in advance of a meeting, protocols require **at least 8 weeks** to be reviewed and approved. Factors such as an incomplete submissions, missing training documentations or materials, investigator response time for revisions or clarifications can lengthen approval time.

Guidance Documents*:* A library of guidance documents on various topics to assist investigators in completing applications is available on the ORC website. Suggestions for new documents are welcome.

Forms: Please make sure you are using the most recent versions of consent templates. Templates can be found under the Useful Links feature on your IRBManager dashboard or by a hyperlink embedded in various application forms. Using old versions of forms may delay the review process due to missing or inaccurate information.

The CMU IRB became accredited by the *Association for the Accreditation of Human Research Protection Programs (AAHRPP)* in 2017 then was granted re-accreditation in 2020. The primary purpose of AAHRPP accreditation is to strengthen protections for research participants. CMU voluntarily sought AAHRPP accreditation to build the infrastructure at CMU for their human subject protection program. AAHRPP-accredited organizations work together to promote innovative practices and establish benchmarks so there is consistency within the human subject protection programs world-wide. Displaying the earned gold seal identifies to outside organizations that CMU IRBs have a streamlined, efficient operation they can trust to work with.

Institutional Animal Care and Use Committee (IACUC)

Chair	Jon Kelty	x1381	kelty1jd@cmich.edu
Attending Veterinarian	Rob Werner	906-322-2243	werne2r@cmich.edu
Coordinator	Jennifer Marrs	X7313	marrs1j@cmich.edu

IRBManager: All protocol submissions to the IACUC are submitted through IRBManager, which can be accessed by single sign on (SSO) using your CMU global ID/password. A log-in option is also available for non-CMU collaborators at other institutions who may also register within the system for access to project materials. Instructional guidance documents regarding the IRBManager system are posted on the ORC web page.

Seek advice: Investigators who are new to CMU are encouraged to contact the IACUC Coordinator to become familiar with committee policies and procedures, such as the protocol review process, training expectations, or navigating the IRBManager system. Consulting with the university's Attending Veterinarian when developing a study may shorten the time between submitting a proposal and receiving final approval.

When to submit: Applications to use animals in research, teaching, or outreach; protocol amendment requests; personnel addition forms; and other IACUC forms may be submitted at any time.

Review and approval times: The time from submission to final approval averages 5 weeks. Factors such as incomplete submissions, delay in providing a response to committee feedback, or unfulfilled training requirements will prolong the review process.

Forms: The most recent versions of all IACUC forms can be found in IRBManager. All forms are in electronic format.

Occupational Health and Safety Program - Animal Research, Biohazardous Research

Investigators planning to conduct research involving animals must participate in the Animal Research Occupational Health Program.

For additional information, please contact IACUC Coordinator or the Office of Laboratory and Field Safety at LabFieldSafety@cmich.edu.

Some researchers working with BSL2 biohazards are required to participate in Occupational Health Programs. For more information, contact the Office of Laboratory and Field Safety.

Institutional Biosafety Committee (IBC)

Chair	Greg Colores	X3412	color1gm@cmich.edu
Coordinator	Jennifer Marrs	X7313	marrs1j@cmich.edu

IRBManager: All applications to the IBC are submitted through IRBManager, which can be accessed by single sign on (SSO) using your CMU global ID/password. A log-in option is also available for non-CMU collaborators at other institutions who may also register within the system for access to project materials. Instructional guidance documents regarding the IRBManager system are posted on the ORC web page.

Seek advice: Investigators who are new to CMU are encouraged to contact the IBC Coordinator to become familiar with committee policies and procedures, such as the application review process, training expectations, or navigating the IRBManager system. Consulting with the University's IBC Chair and Office of Laboratory and Field Safety when developing a study may shorten the time between submitting a proposal and receiving final approval.

When to submit: Applications to conduct research using biohazardous materials, application amendment requests, personnel addition forms, and other IBC forms may be submitted at any time.

Review and approval times: Registrations requiring full committee approval prior to commencement are reviewed at regularly scheduled or *ad hoc* convened meetings. The time from submission to final approval averages 4 weeks. Factors such as incomplete submissions, delay in providing a response to committee feedback, or unfulfilled training requirements will prolong the review process.

Forms: The most recent versions of all IBC forms can be found in IRBManager. All forms are in electronic format.

For any clinical research questions regarding recombinant or synthetic nucleic acid molecules, contact our team at IBC@cmich.edu or cmuirb@cmich.edu.

Export Controls

Export of certain items and information to foreign countries or to non-US persons (including non-US persons in the US) is controlled by regulations administered by the Departments of State, Commerce, and Treasury. Almost none of the research and educational activities at CMU are subject to export control regulations. However, investigators should be aware of certain situations in which an activity or an item may be covered under the regulations such as:

- traveling to certain countries.
- purchasing foreign-made equipment.
- sending equipment, samples or data to colleagues in foreign countries.
- hiring non-US persons to work on research projects.
- accepting restrictive clauses in research contracts.
- and foreign influences on research.

Additional information on our website provides a basic introduction to the subject.

The Office of Research Compliance can assist investigators in analyzing these situations. An Export Control Review Form may be submitted to the office for review of a particular situation and is available on the export website. For further information, contact Export@cmich.edu.

Controlled Substances in Research

Federal and state laws governing use of controlled substances in research place primary responsibility for maintaining a current license and use and disposal records on individual investigators. This web page contains links to useful forms and guidance documents. For further information, contact Compliancequestions@cmich.edu.

Reporting Concerns

Concerns about the conduct of research, particularly concerns about research involving human beings, animal subjects, use of recombinant molecules or biohazards, should be reported to the Office of Research Compliance at ResearchConcern@cmich.edu or confidentially via our on-line portal. Concerns can also be reported anonymously to Central Michigan University Internal Audits via the Ethics Hotline.

Research Compliance Team

Name	Position	Phone	Email	Office
Belinda Adamson	Director	3477	adams1bs@cmich.edu	Foust 104
Kristin DeMuro	Assistant Director	3748	kristin.demuro@cmich.edu	Foust 108
Deb Geasler	IRB Coordinator	6401	deb.geasler@cmich.edu	Foust 104
Jennifer Marrs	IACUC/IBC Coordinator	7313	marrs1j@cmich.edu	Foust 104

For general questions, they can be submitted to each section's mailbox:

- Human Subjects Research: cmuirb@cmich.edu
- Animal Research: IACUC_Admin@cmich.edu
- Recombinant Nucleic Acid Molecules and Biohazardous Research: IBC@cmich.edu
- Export Controls: Export@cmich.edu
- General Inquiries: ComplianceQuestions@cmich.edu

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