Research Compliance: Ethics and Protections for Research Subjects

Janelle Taylor, Coordinator of Graduate Student and Research Affairs

Graduate Studies and Research

Research Ethics?

- In general terms, "research ethics" is simply good citizenship applied to professional life
- Four basic tenants
  - HONESTY –convey information truthfully and honoring commitments
  - ACCURACY –report findings precisely and taking care to avoid errors
  - EFFICIENCY –using resources wisely and avoiding waste
  - OBJECTIVITY –letting the facts speak for themselves and avoiding improper bias

9 Rules of Research Ethics

- 1. Be honest
- 2. Be fair
- 3. Do no harm
- 4. Know and follow the rules
- 5. Bad rules should be changed, not broken
- 6. Be a good citizen
- 7. When in doubt, ask questions
- 8. Listen to your conscience
- 9. If you suspect unethical behavior, proceed cautiously

NMU Scientific Misconduct Policy

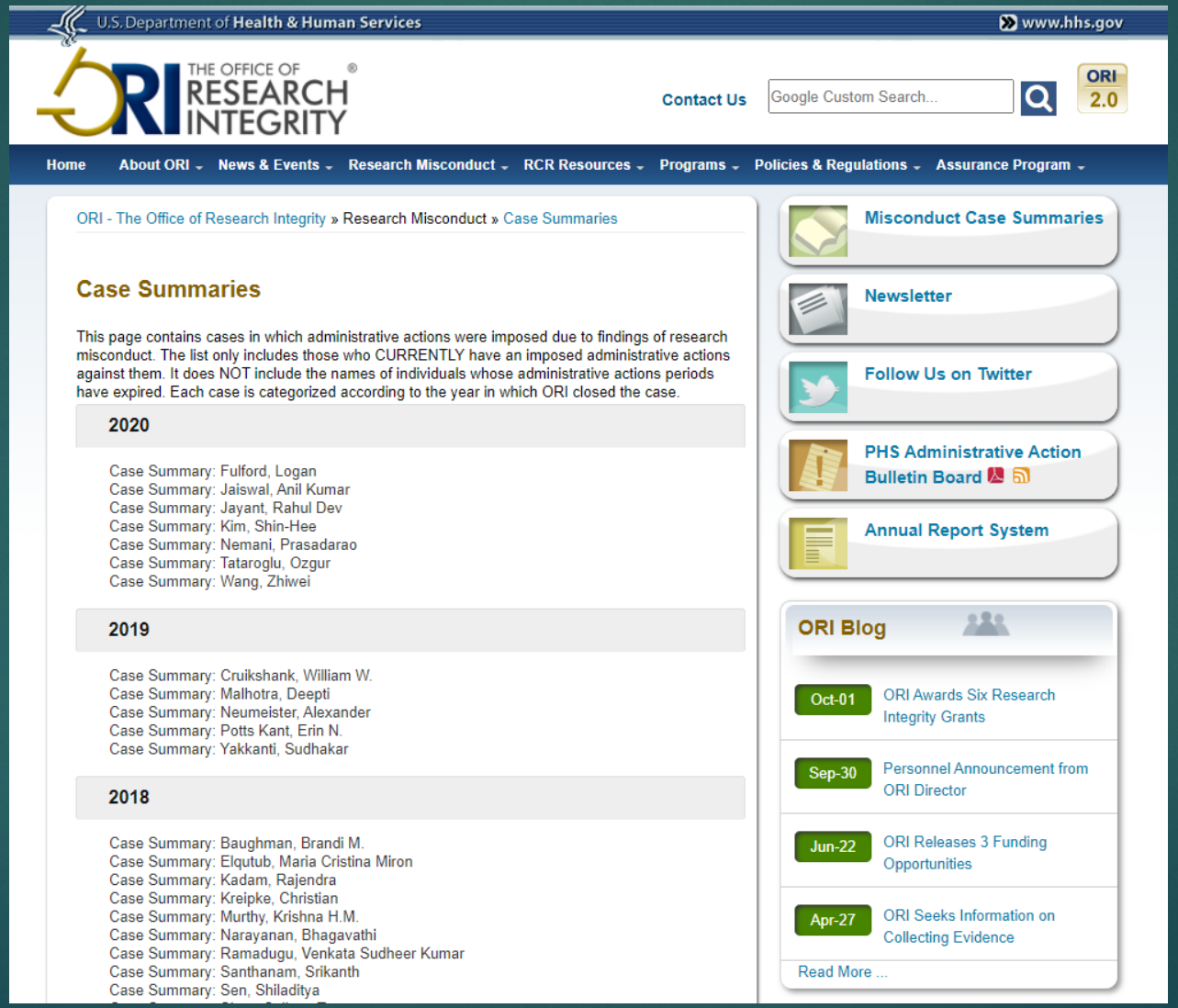
- https://www.nmu.edu/grantsandcontracts/scientific-misconduct

- "Misconduct in science" or "misconduct" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

- Researchers are responsible for seeking human or animal subject board approval BEFORE beginning any research.

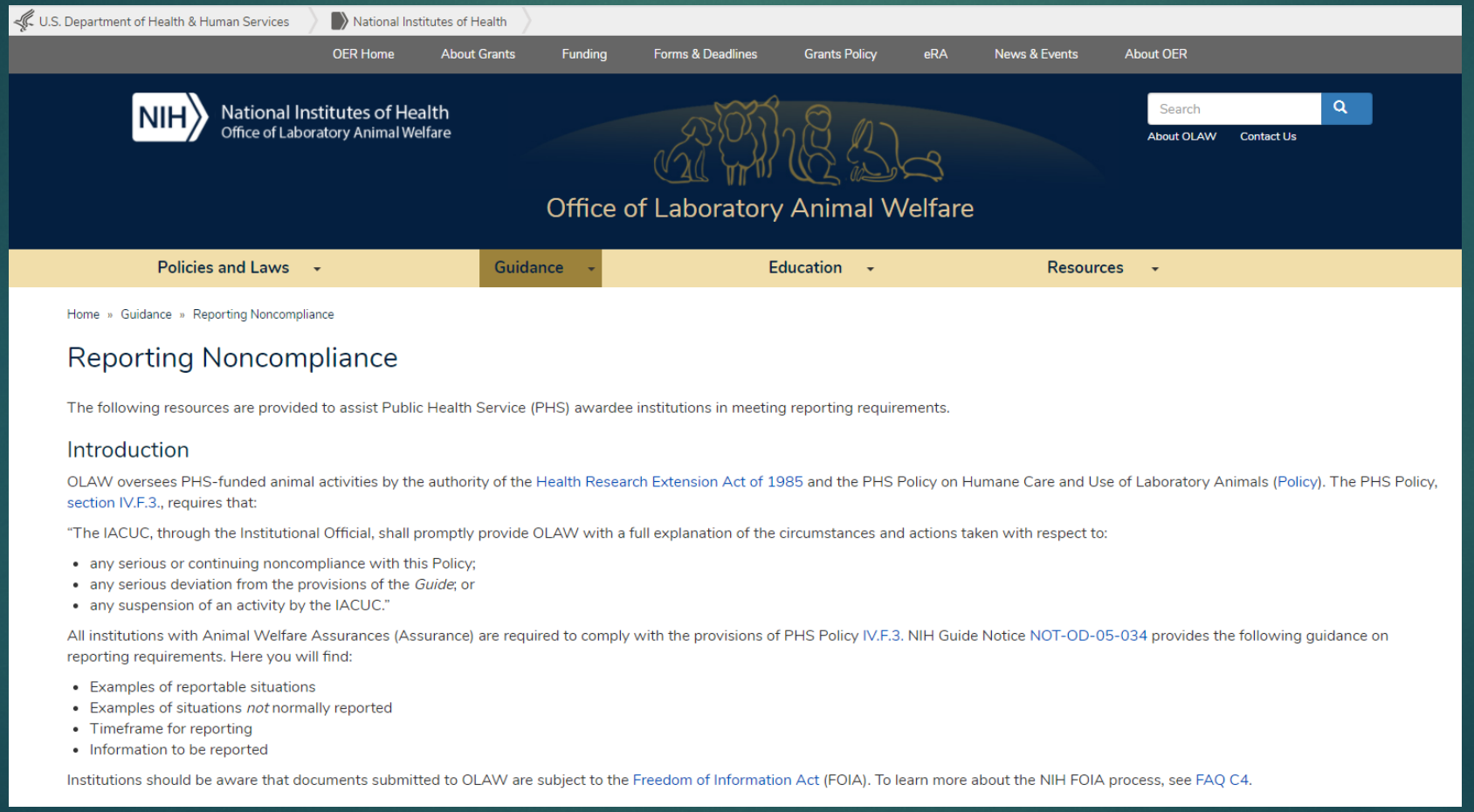
- Faculty, staff and students of Northern Michigan University have the right and responsibility to create, seek and state knowledge freely and openly and to strive for academic excellence. Honesty in the conduct of academic research is fundamental to its integrity and credibility and to the maintenance of public trust in the university.

Human subject research is overseen by the U.S. Department of Health and Human Services Office of Research Integrity



https://ori.hhs.gov/content/case_summary

Animal Subject protection is overseen by the National Institute of Health Office of Laboratory Animal Welfare (OLAW)



https://olaw.nih.gov/guidance/reporting-noncompliance.htm

Reasons for Scientific Misconduct

- Conflict of Interest: situation in which financial or personal considerations may compromise a researcher's judgement

- Pressure to have results
- Pressure to have the results that they hypothesized
- Want research to support the way you wanted your research to go
- For grant funding
- Getting into grad school
- Getting promoted
- General prestige
- Fear of failure

Home / The Nutshell

OSU Professor Falsified Data on Eight Papers, Resigns

Ching-Shih Chen's research involved anticancer therapeutics that were being tested in clinical trials.

Catherine Offord
Apr 2, 2018

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The investigation into Chen's work was launched in 2016 after OSU received anonymous allegations of six instances of data falsification in papers published between 2010 and 2014, according to OSU student newspaper, *The Lantern*. Seizure of Chen's hard drive led to the discovery of multiple manipulated images, and helped take the number of allegations up to 21.
https://www.the-scientist.com/the-nutshell/osu-professor-falsified-data-on-eight-papers-resigns-29849

He Jiankui was convicted of violating a government ban by carrying out his own experiments on human embryos, to try to give them protection against HIV.
He was globally condemned when he announced his experiments, and the birth of twin babies, last November.
As well as the prison sentence, He was fined three million yuan ($430,000; £328,000).
The court also handed lower sentences to two men, Zhang Renli and Qin Jinzhou, for conspiring with He to carry out the experiments.
A court in Shenzhen said the men had acted "in the pursuit of personal fame and gain", and had seriously "disrupted medical order", Xinhua news agency reported.
"They've crossed the bottom line of ethics in scientific research and medical ethics," the court added.
https://www.bbc.com/news/world-asia-china-50944461

China jails 'gene-edited babies' scientist for three years

30 December 2019 Share

He Jiankui sparked an international backlash with his experiment last year

A scientist in China who said he had created the world's first gene-edited babies has been jailed for three years.

- Calls for researchers involved to be fired
- IACUC board being evaluated for effectiveness
- Call to return all federal grant money
- Possibility of past research being invalidated

NOTRE DAME LAB VIOLATED ANIMAL WELFARE LAWS IN STUDY ON MICE

Researchers at the University of Notre Dame violated federal animal welfare laws last year by mistreating mice during lab studies, according to documents the school filed with a federal agency.

Posted: May 21, 2020 11:32 AM
Posted By: Associated Press

SOUTH BEND, Ind. (AP) — Researchers at the University of Notre Dame violated federal animal welfare laws last year by mistreating mice during lab studies, according to documents the school filed with a federal agency.

The university self-reported the violations to the federal Office of Laboratory Animal Welfare and suspended the lab's operations last August because of "serious deviation" from animal treatment guidelines, the documents say.

The documents, which are letters and reports university officials sent to the federal agency, were obtained by the animal advocacy group Stop Animal Exploitation Now through a Freedom of Information Act request to the federal agency. The group released the documents to news media outlets, the South Bend Tribune reported Wednesday.

Notre Dame's vice president of research, Robert Bernhard, detailed the violations of animal welfare policy in an August 2019 letter sent to the federal agency.

On Aug. 9, 2019, veterinary staff at the Freimann Life Sciences Center saw two mice in a lab that had missing limbs and another pair with their "bowels exteriorized" after surgery, with sutures and clips missing. Ten mice had tumors larger than the allowable two centimeters.

All the mice were euthanized after they "likely experienced unrelieved pain or distress," Bernhard's letter says.

University researchers had injected the mice with breast cancer cells to study tumors.

An internal investigation found that lenient oversight and lack of communication contributed to the violations, according to a letter the university later sent to the federal agency.

The university's Institutional Animal Care and Use Committee, which oversees animal research, concluded that one person was responsible for a "significant number" of the violations, which also included intentionally hitting a mouse on a table. That person was removed from working with animals but remains in the lab, according to the documents.

The animal advocacy group has requested the university fire those involved in the study and its federal grant money to return, Executive Director Michael Budkie said.

A university spokesman told the South Bend Tribune that officials promptly addressed the violations when they were informed of them and followed all reporting protocols.

Scripps Research Institute to Pay $10M for Improper Use of NIH Grants

POSTED BY KEN STONE ON SEPTEMBER 11, 2020 IN TECH | 5484 VIEWS | 4 COMMENTS | LEAVE A COMMENT

Share This Article:

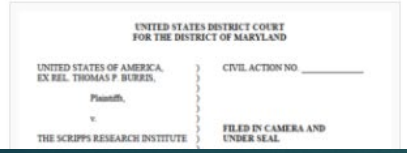
Former TSRI employee and whistleblower Thomas Burris, who worked at the Florida campus (shown), will be paid $1.75 million, the government says. TSRI photos

By Ken Stone

In the wake of a whistleblower suit, **The Scripps Research Institute** has agreed to pay $10 million to settle claims it improperly charged **NIH-funded research grants** for time spent by researchers on nongrant-related activities, the **government announced Friday**.

The renowned nonprofit biomedical research institute with campuses in La Jolla and Jupiter, Florida, is accused of using the grants on banned activities including writing new grant applications.

The money also allegedly was used for teaching and other administrative activities, the Department of Justice said.



UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA, EX REL. THOMAS P. BURRIS,
Plaintiffs,
v.
THE SCRIPPS RESEARCH INSTITUTE

CIVIL ACTION NO. _____

FILED IN CAMERA AND UNDER SEAL

"The NIH has finite resources to support important research across the nation," said Acting Assistant Attorney General Jeffrey Clark for the Department of Justice's Civil Division. "Today's settlement demonstrates our commitment to protect those resources by ensuring

Burris, now at **St. Louis College of Pharmacy**, worked from September 2008 through December 2013 at Scripps Florida, serving as a tenured professor of the Department of Molecular Therapeutics and also, from 2009 through 2013, as a professor of the Department of Metabolism and Aging.

During those years, the DOJ said, Burris was caught up in a high-pressure system that led to the alleged fraud — forcing staffers to secure 100% of their salary via grants. (He names more than 40 others in the same position, mostly at the La Jolla campus.)

Burris had eight federal research grant projects totaling over $10 million, while also preparing and submitting at least 18 new grants/resubmissions that were never awarded, the government says.

"During this period, [Burris] estimates that he spent between 20%-50% of his working time on grant proposal activity," the DOJ said. "Further, he estimates that other faculty and research staff spent a significant amount of their time assisting him in preparing the grant applications."

Thus, the DOJ said, Scripps knowingly overcharged the eight awarded grants for Burris' salary by 20%-50% for his time and a portion of the other researchers' time spent on activity not related to those grants — writing and compiling the data for 18 other grant applications or resubmissions.

https://timesofsandiego.com/tech/2020/09/11/scripps-research-institute-to-pay-10m-over-improper-use-of-nih-grants/

Reporting Misconduct

- Unsure if something is research misconduct?
  - Talk to people you trust, like your lab director, advisor, or department head. They might be able to help you understand the situation and chose the appropriate course of action.

- Reporting misconduct: The institutional official at NMU is Dr. Lisa Shade Eckert, Dean of Graduate Studies and Research. Reports of research misconduct should be directed to her.

Avoiding Research Misconduct

- Discuss authorship with all research collaborators at the outset of a project so everyone involved understands who will be listed as an author, and the expectations regarding the use of the data by those involved in the research.
- Ask questions about questionable results.
- Set reasonable expectations about the time it will take to collect the necessary data.
- Maintain thorough and complete research records.
- Respect the research process.
- Do not stray from the protocol without obtaining the necessary approvals.
- Communicate any actual or perceived problems with the research. Most research misconduct allegations are the product of communication difficulties between researchers.
- Carefully and accurately report the research. Be specific about methods and procedures used and the data obtained.
- Thoroughly review all papers where you are listed as an author.
- Attend Responsible Conduct of Research workshops.
- Obtain the proper authorizations for human and animal subject research.

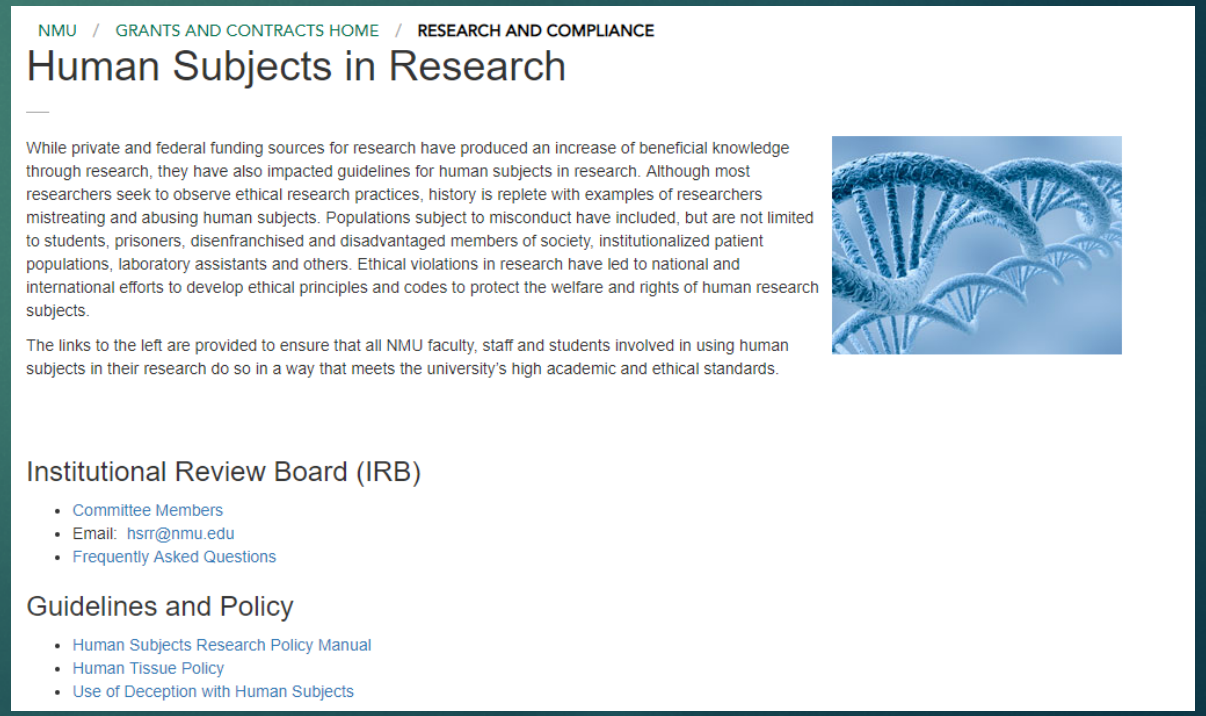
https://rci.ucmerced.edu/research-misconduct

Human Subjects in Research

Who Reviews Human Subject Research?

- All research entities (universities, survey groups, research labs, hospitals, etc.) have an institutional review board, commonly called the IRB, that reviews human subject research

- The IRB committee is made up of NMU faculty members and community members



What is Human Subjects Research?

- Research is defined as: a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- A human subject is defined as: an individual about whom an investigator conducting research obtains 1) data through intervention or interaction with an individual, or 2) private identifiable information

- What does Human Subject Research look like?
  - When you are doing a thesis
  - When you are writing a paper to be published
  - When you are collecting data
    - Surveys
    - Trials
    - Interviews
    - Interventions

What is Human Subject Research: the details

- Studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand the beliefs, customs, and practices, not only of those individuals, but also of the community or group to which they belong… The purpose and design of such studies or activities is to reveal something about the community or group – that is, to develop generalizable knowledge. Because the purpose of such studies or activities is not to limit the inquiry to knowledge about the particular individuals being observed, the protections provided by the requirements of 45 CFR part 46, such as the requirement to minimize any harm to the specific individuals from which the information was collected, are appropriate.
  - From: Office for Human Subjects Research Protections, hhs.gov

Submitting your Project Proposal for Review

- Who should be involved:
  - Your faculty advisor for the project. As a student, you MUST have a faculty advisor for any human subjects research project.
- Where to submit:
  - Email your proposal to hsrr@nmu.edu. Be sure to include your faculty advisor on your email and check for any department regulations (some departments want department heads included as well)
  - Include the IRB application, any supporting documents for your research, and the report of CITI completion for all researchers on the project
- Use word documents and PDFs whenever possible. Other formats can be difficult to send to reviewing committee members.
- Once approved: remember to use your IRB approval number on EVERYTHING
  - IRB approval numbers at NMU look like : HS18-1457

Use the Website!

- The NMU IRB offers templates and samples for many types of documents you may need to submit with your IRB. Use them!
- COVID note:

Application and Forms

- Human Subjects Research Application
- Human Subjects Project Renewal Form
- Human Subjects Project Modification Form
- Human Subjects Project Completion
- Human Subjects Adverse Event Form
- Application for Mass Email Distribution

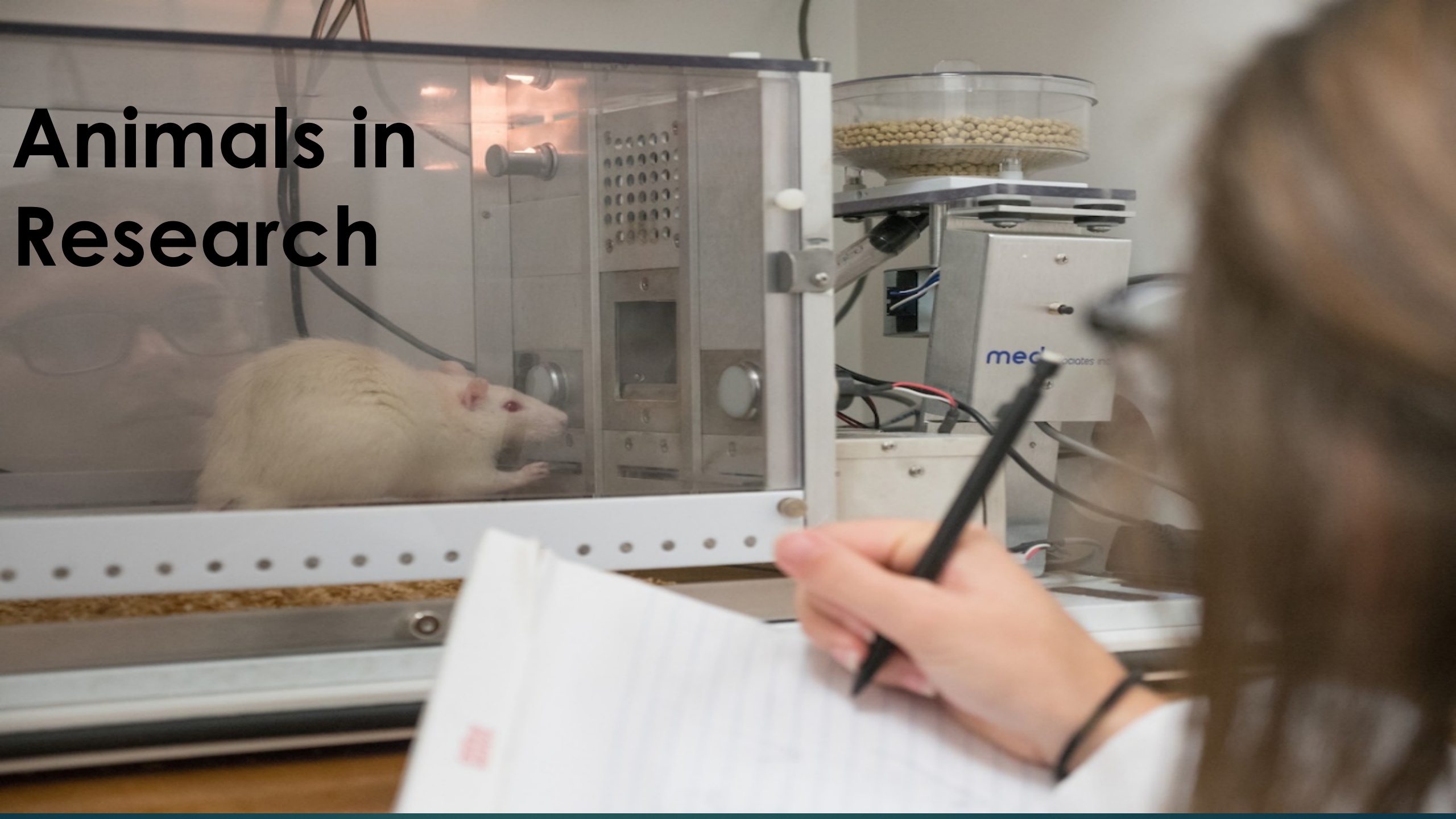
Consent Form Templates and Examples

- Adult Consent Form
  - Informed Consent Form Example
- Phone Interview Consent Form
- Informed Consent Form with Recording Example
- Anonymous Consent Form
- Child Assent Form (Age 7+)
- Child Assent Form (Age 7 and under)
- Parent-Guardian Consent Form
- Consent Form for Adults Unable to Provide Legal Consent
- Broad Consent Form
- COVID-19 Research Participant Agreement and Release
- COVID-19 Researcher Agreement and Release

Categories of Human Subject Research Review

- Limited: For basic level research. The IRB committee chair or designated representative reviews the project proposal and either approves or suggests changes.
- Expedited: This process takes roughly two weeks. The project proposal is sent to two or three committee members who review it and either suggests changes or approve.
- Full/Convened: This is the longest and most intense review process. It can take up to month. For full reviews, the IRB committee meets with the researcher/s and asks questions and seeks clarification of the project. The committee will either approve or suggests changes.

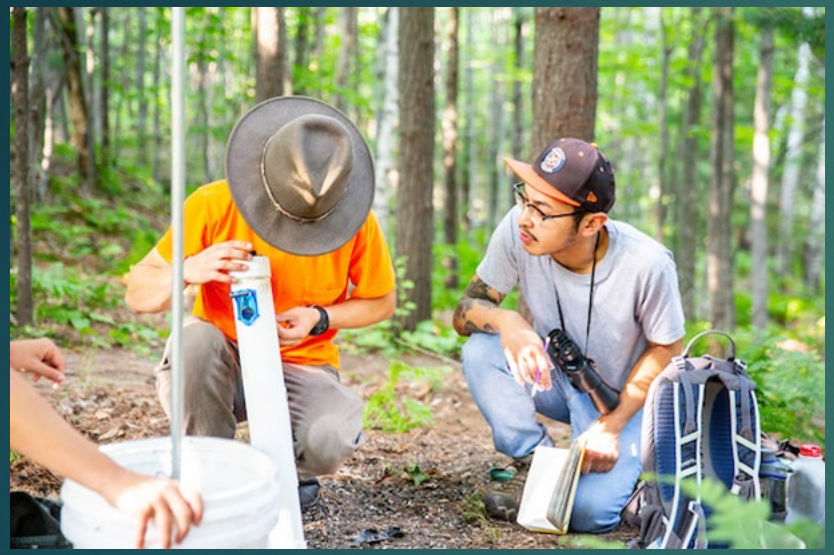
Animals in Research



Who Reviews Animal Research?

- The Institutional Animal Care and Use Committee (IACUC)
- Every institution that interacts with animals as part of research is required to have a committee that reviews and approves the studies.
- The IACUC is a committee of faculty and community members who are trained in animal research standards and laws. The IACUC committee is required to have: scientist members, non-scientist members, members who are not affiliated with the institution, a veterinarian, and an institutional official.

When Do I Need IACUC Approval?



- Any time you are doing research that involves or can impact animals
- It is the policy of Northern Michigan University to establish and maintain proper measures to ensure the appropriate care and use of animals involved in research, research training and biological testing activities conducted or supported by NMU.
- As a student, you will ALWAYS work closely with a faculty researcher on any animal research project. They are the Principal Investigator (PI) on the project.

What is the Animal Research Approval Process?

Approval takes time! Plan for it!

- Types of Review:
  - Exempt: any individual wishing to involve animals in anything on campus must fill out a form with their intentions, even if you do not think that the committee needs to oversee it.
    - Example: Therapy dogs in the library for exam week
  - Designated Member Review: Members of the committee review the research proposal and ask for adjustments and clarification, or approve. This process usually takes from 2 weeks to a month.
  - Full Committee Review: The IACUC committee meets to discuss the research with the Principal Investigator. They also ask for clarification, adjustments, or approve the project. This process usually takes a month or more.
- The type of review required is determined by the IACUC board.

CITI – Collaborative Institutional Training Initiative

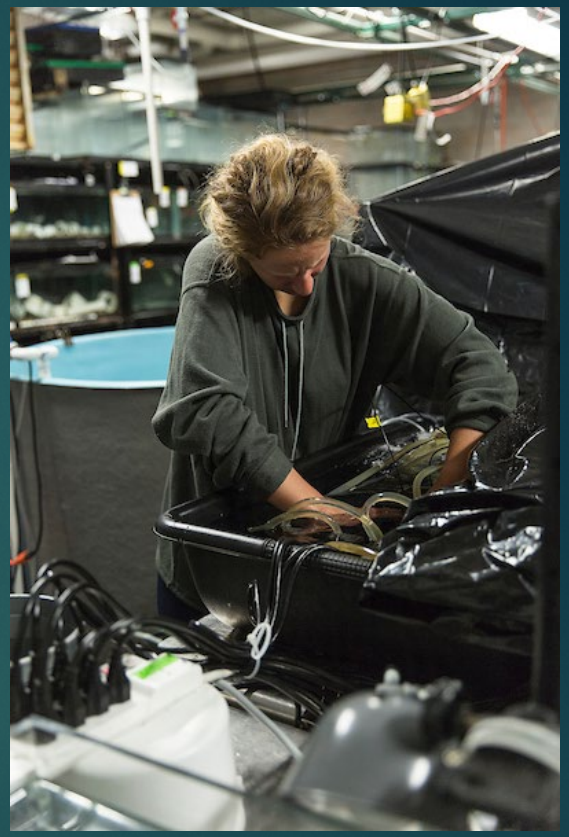
- CITI is an online training program that NMU subscribes to on behalf of its students, faculty, and staff involved in research.
- CITI provides training for researchers about the laws, rules, and ethics of both human and animal research
- You must create a CITI account with your Northern email to access the training

CITI Requirements

CITI Training expires after 4 years

- Everyone is required to complete CITI training before engaging in research at NMU

- Trainings are listed in modules (sets of smaller courses) that you must complete in order to get a certification of completion
  - Select your research type when signing up to access modules that pertain to you
  - Students are required to complete the 'Students in Research' module
  - Other additional modules may be required by your project advisor based on your project type
    - For example, for a project with children subjects you will additionally take 'Children in Research', or a birdwatching project members will take 'Wildlife in Research'



Responsibility

- You work with a faculty mentor, but that does not mean that you have no responsibility for following research conduct rules.

- If you are working on a research project that requires approvals from the IRB or IACUC, you must be named on the research protocol (the application for the project that has been approved by the research board).
- Know your protocol.
  - If you are named on a human or animal subject protocol (either as an individual project or part of a lab) you should have access to the protocol covering that work. This will inform you of the approved processes and procedures associated with that project.

- If you feel that something is not right, TELL someone.
  - Talk to the PI or faculty project advisor
  - Talk to the head of the lab or department
  - If you don't feel heard or comfortable talking to them, talk to the Office of Graduate Studies and Research

Important Links

- NEW NMU Research Website: a portal for all things research: https://www.nmu.edu/research/
- NMU Animal Subjects Page: https://www.nmu.edu/grantsandcontracts/animal-subjects
- NMU Human Subjects Page: https://www.nmu.edu/grantsandcontracts/human-subjects-research
- CITI Website: https://about.citiprogram.org/en/homepage/

- Contact the IRB: hsrr@nmu.edu
- Contact the IACUC: iacuc@nmu.edu
  - Feel free to ask questions!

Note your research project status in your thesis!

Questions?

- Janelle Taylor
  - jantaylo@nmu.edu
  - 906-227-1407

- This powerpoint will be available online at NMU > Graduate Education > Students > Workshops