EASTERN MICHIGAN UNIVERSITY

The IRB Process

The Office of Research Compliance

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Sonia Chawla, Associate Vice President for Academic Research and Regulatory Compliance

Agenda

Intro to Research Ethics

What is IRB?

Human Subject Compliance Training Requirement

Submitting your IRB Application

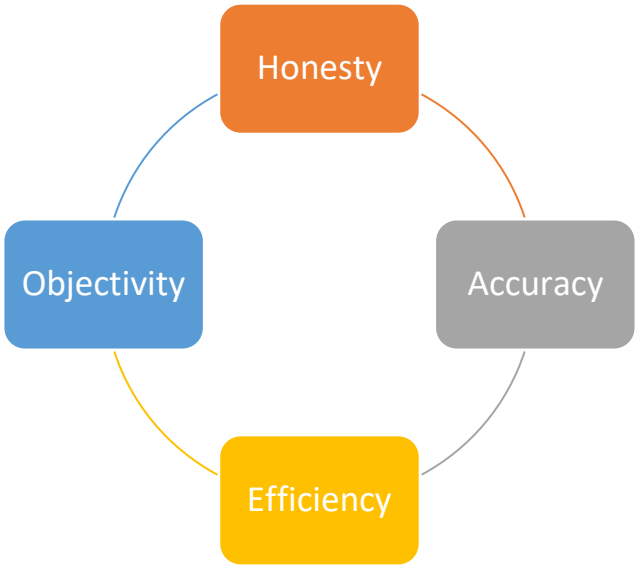
What happens after you submit

Continuing Review

Questions welcome anytime

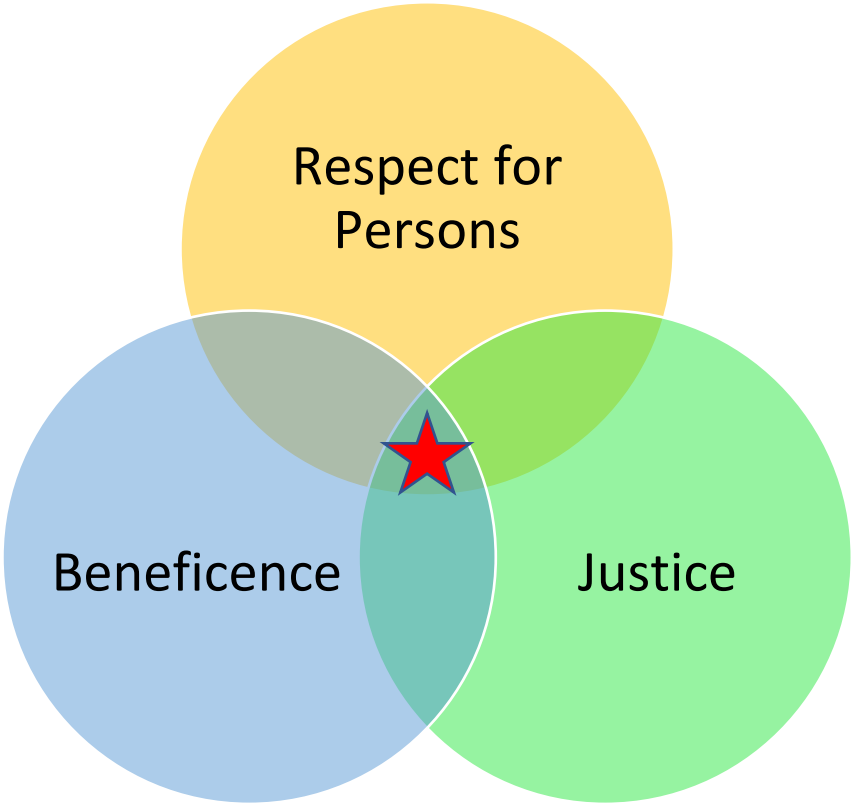
What do we mean by research ethics?

- Research conducted with integrity



- Acknowledge when we cannot achieve complete honesty, accuracy, efficiency, or objectivity due to our human limitations

Ethical Framework for Human Subject Research: Belmont Principles



What is an IRB?

- Charged with protecting rights of human subjects in research
- Diverse backgrounds and areas of expertise
- All institutions receiving federal funding for research must have an IRB
- **An IRB is NOT a scientific merit committee**

Do you need IRB review?

- **Research**
  - *A systematic investigation designed to develop or contribute to generalizable knowledge*

- **Human subjects**
  - *Living individuals about whom an investigator conducting research:*
    - *Obtains information or biospecimens through intervention or interaction and uses, studies, or analyzes the information or biospecimens; OR*
    - *Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.*

Does your Study Require IRB Approval?

If your study matches the definition of research and the definition of human subjects, then it needs IRB review.

Key components of human subject research are identifiable and generalizable information.

Human Subject Training

Before you can start an IRB application, you must pass a Human Subject compliance training course with 80% score.

EMU has our own compliance training on Canvas! Please complete this form to enroll in one or more of the online classes.

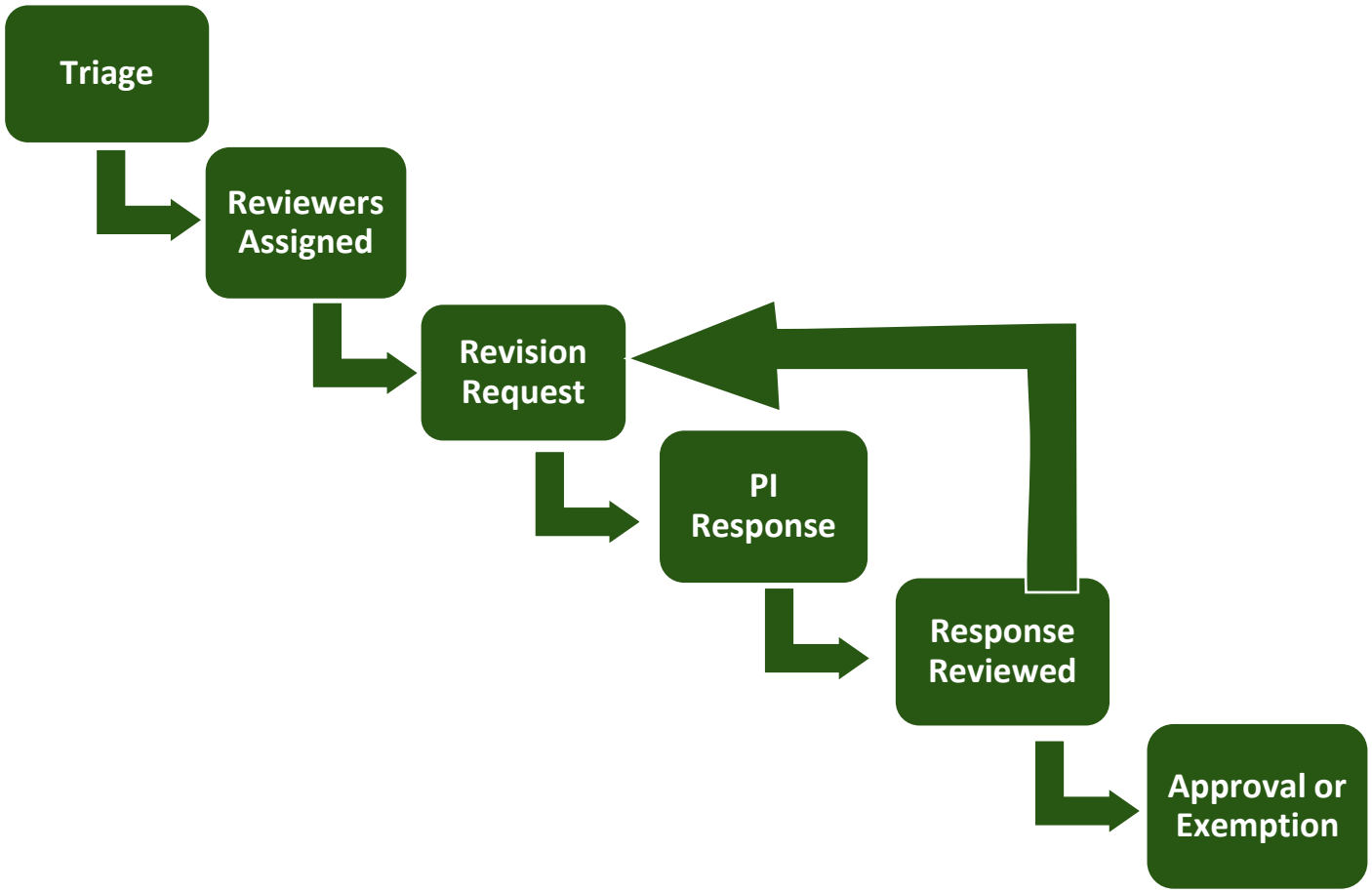
Certification is valid for 3 years after the completion date.

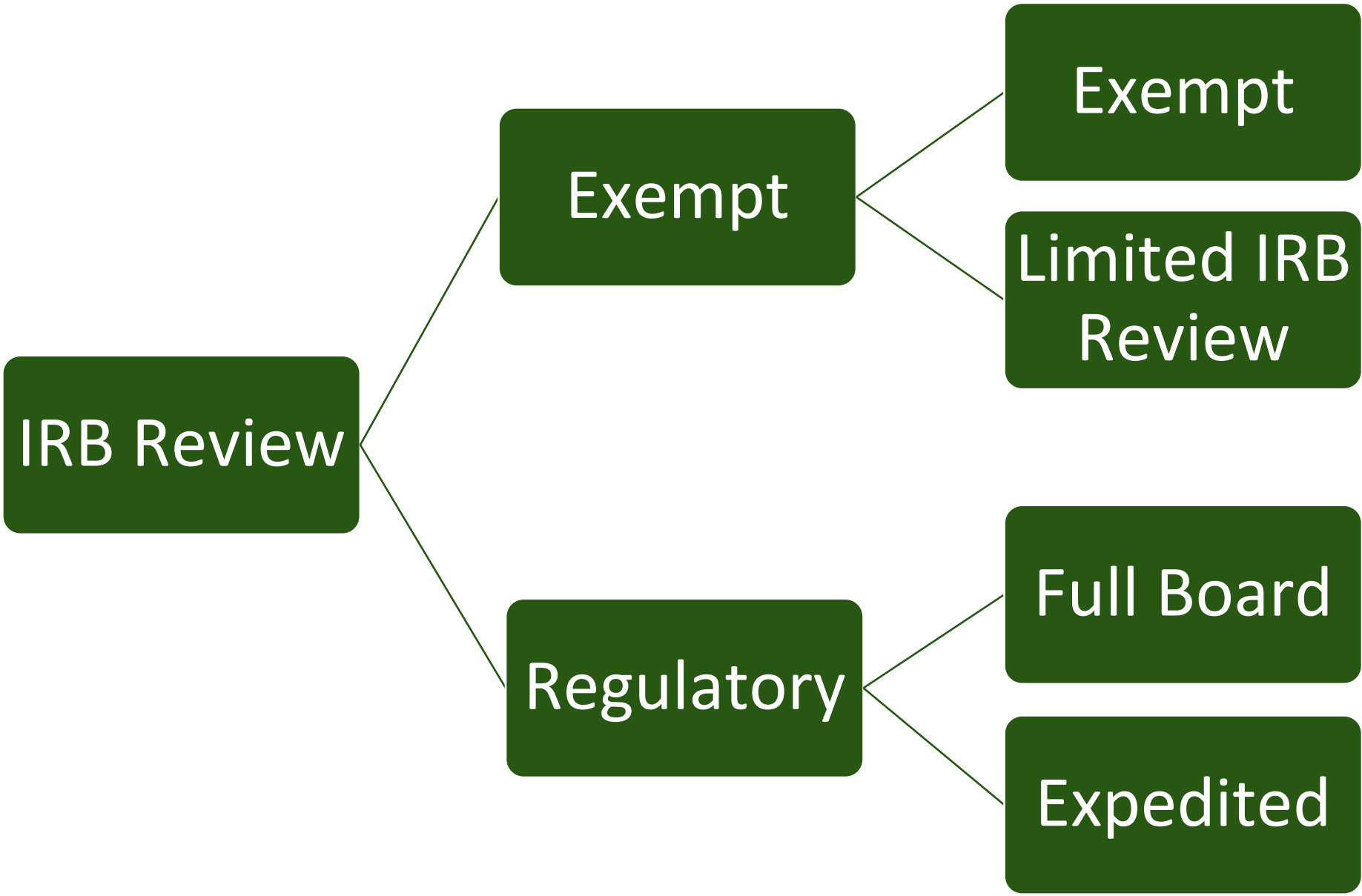
IRB Applications

- **Applications submitted online via Cayuse IRB**
  - Students have to request access by submitting this form.
  - Instructions on Research Compliance website (www.emich.edu/research/compliance/human-subjects)
  - Let's take a look at the IRB application!

- **Supplemental documents must be uploaded:**
  - Consent/assent forms (we have a Consent template!)
  - Recruitment materials
  - Assessments/interview or focus group questions/questionnaires, etc.
  - Online human subject training certificate and Faculty Advisor

IRB review


Triage
Reviewers Assigned
Revision Request
PI Response
Response Reviewed
Approval or Exemption

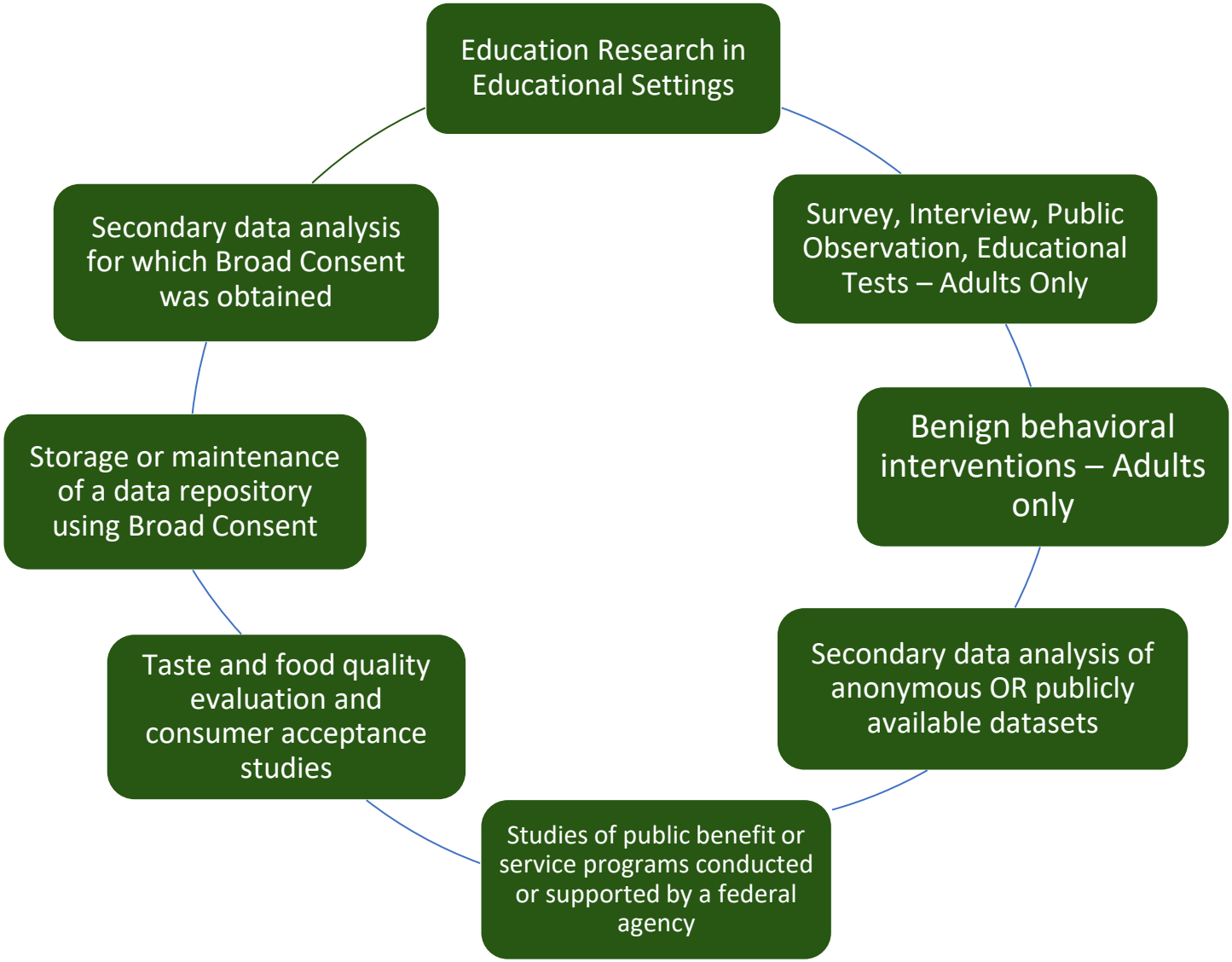

IRB Review
Exempt
Exempt
Limited IRB Review
Regulatory
Full Board
Expedited

Exempt Review

- Not subject to regulatory criteria

- Must follow EMU policy
  - Clear description of study procedures in application and consent
  - Minimize coercion in recruitment procedures
  - Respectful treatment of human subjects
  - Reasonable consent process

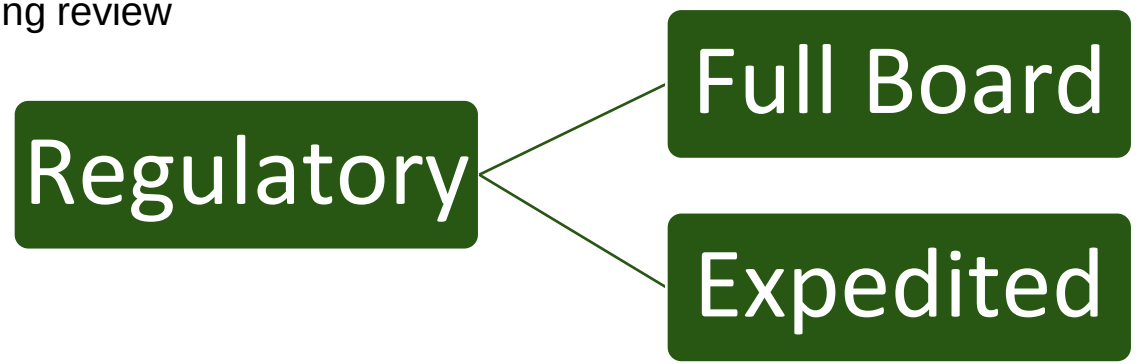
Categories for Exempt review



Risk in SBER

- Most studies in social/behavioral/educational research are “not greater than minimal risk”
  - *harm or discomfort anticipated is not greater than that ordinarily encountered in daily life or during routine physical or psychological exams or tests*

- Regulatory perspective
  - Full board review vs. Expedited review
    - Expedited: no continuing review



Regulatory Criteria for Approval

- Respect for Persons
  - Informed consent process
  - How is consent documented?
  - How are privacy and confidentiality protected?
- Beneficence
  - Are risks minimized?
  - Are risks reasonable given the potential benefits, if any?
  - How are data monitored for changes in risk?
- Justice
  - Is eligibility equitable?
  - Additional protections for vulnerable populations

Expedited Categories

- Studies involving non-investigational drugs or medical devices
- Collection of small blood samples
- Prospective, noninvasive collection of biological specimens
- Collection of data through noninvasive clinical procedures, excluding x-rays or microwaves
- Research involving materials collected for non-research purposes
- Voice, video, digital, or image recordings collected for research purposes
- Research on individual or group characteristics or behavior **or** research using survey, interview, oral history, focus group, program evaluation, human factors evaluation

Approval and Monitoring

- Research may not begin until IRB approval obtained
- Must maintain contact with IRB during course of research
  - Continuing Review – Full board protocols only
  - Modification Requests
  - Event Reporting

How to Contact the EMU UHSRC

- Phone: 734 487 3091
- Email: human.subjects@emich.edu
- Office: 200 Boone Hall
- Website: http://www.emich.edu/research/compliance/human-subjects/

Questions?