EASTERN
MICHIGAN UNIVERSITY

Demystifying the IRB Process for Research on Teaching and Learning

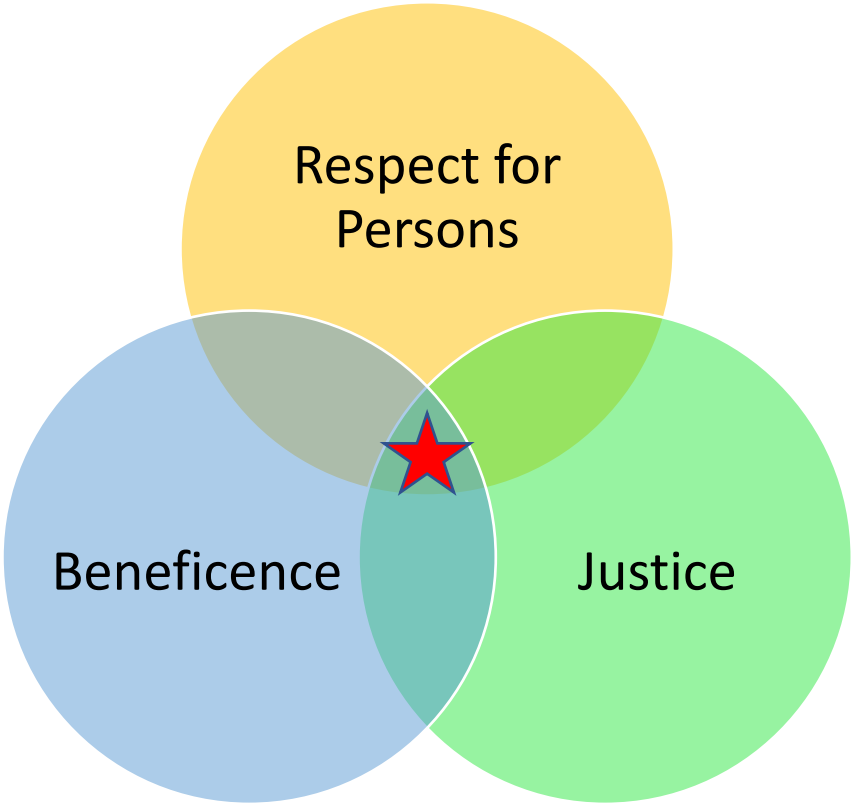
Sonia Chawla, PhD
Director, Office of Research Compliance
Eastern Michigan University

Human Subject Research

- 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 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*

Ethical Framework for Human Subject Research: Belmont Principles



The IRB

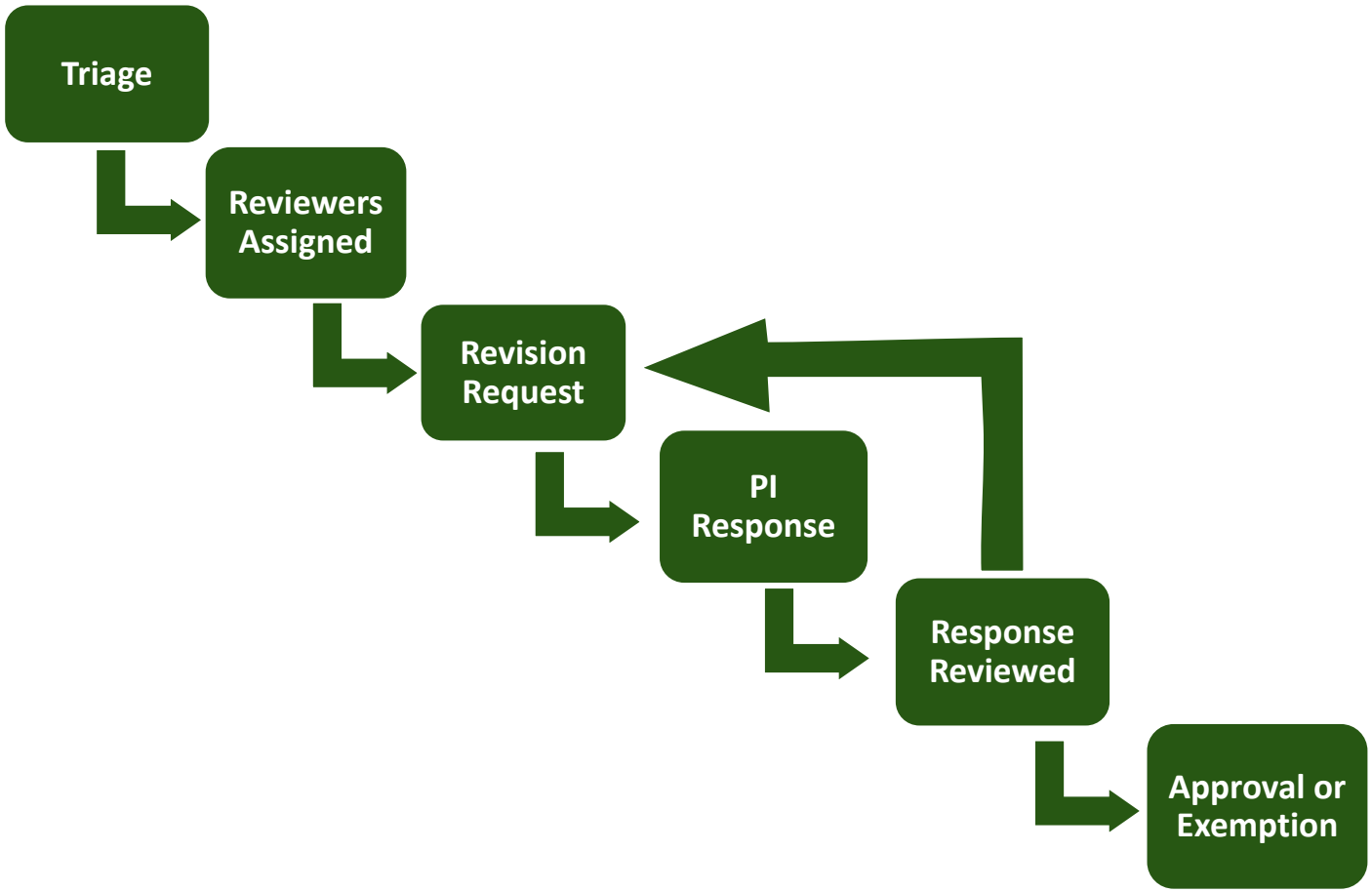
- Charged with protecting rights of human subjects in research
- Independent
- Diverse backgrounds and areas of expertise
- All institutions receiving federal funding for research must have an IRB
- **An IRB is NOT a scientific merit committee**

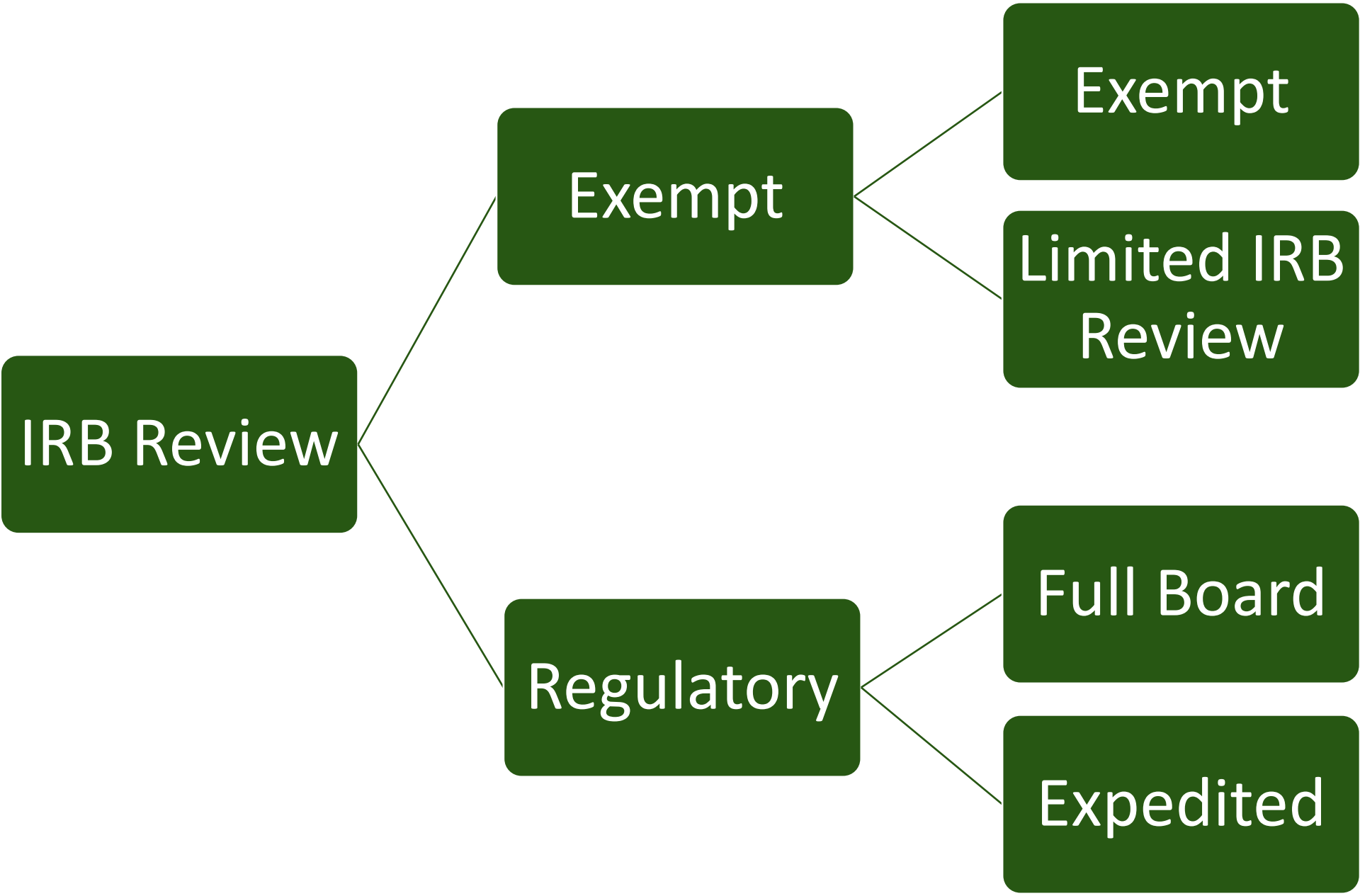
IRB Applications

- Applications submitted online via Cayuse IRB
  - Instructions on Research Compliance website (www.emich.edu/research/compliance/human-subjects)

- Supplemental documents must be uploaded:
  - Consent/assent forms
  - Recruitment materials
  - Assessments/interview or focus group questions/questionnaires, etc.
  - Documentation of human subject protection training

IRB review


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

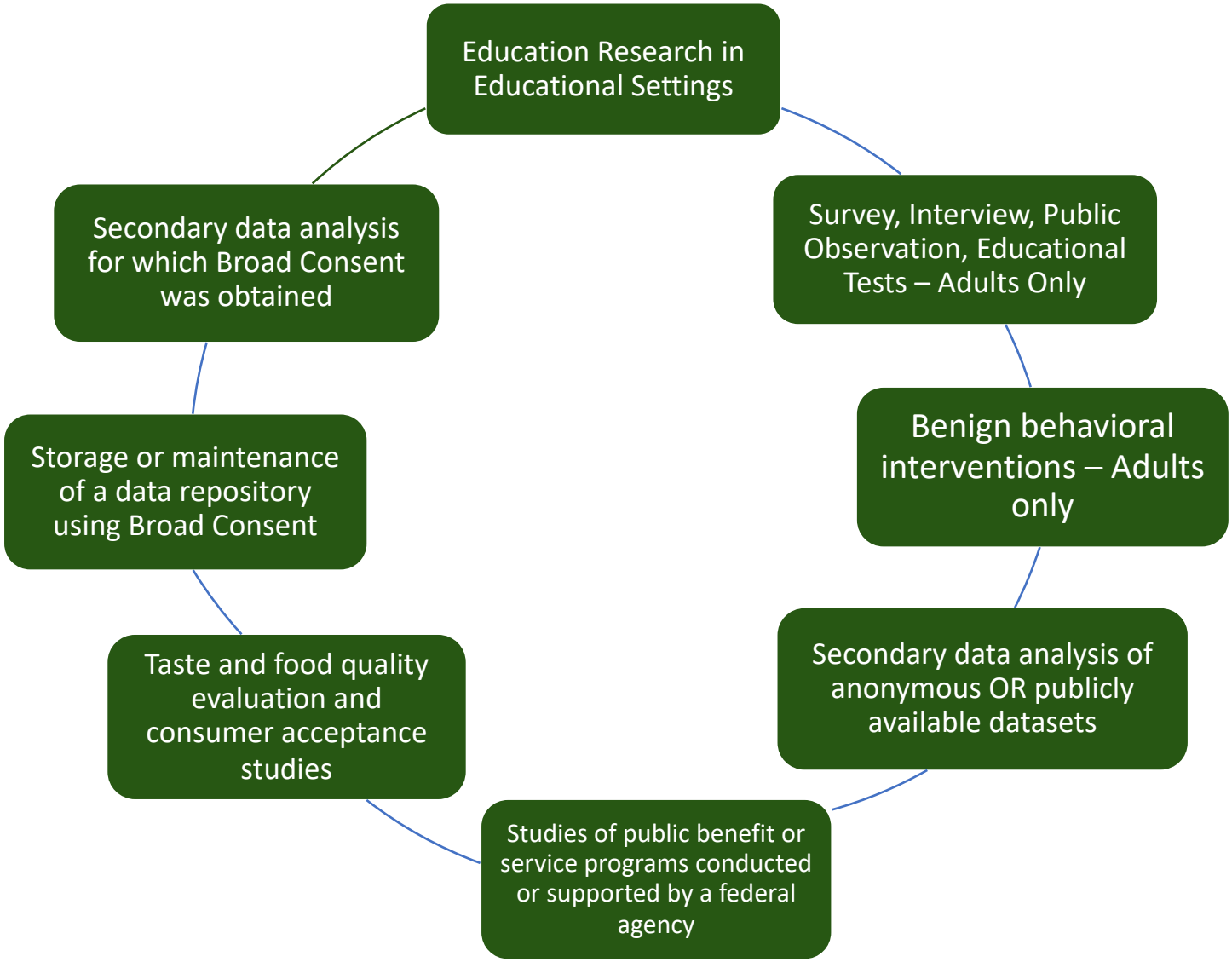

IRB Review
Exempt
Exempt
Limited IRB Review
Regulatory
Full Board
Expedited

Exempt Review

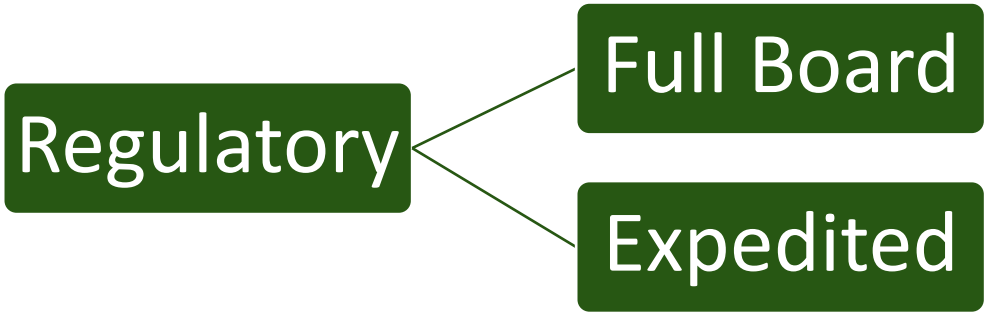
- Not subject to regulatory criteria
  - No annual renewal

- 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



Regulatory Reviews



- Full Board Review
  - This is the default
  - Approval lasts 365 days; annual re-review is required
- Expedited Review
  - Studies must **not be greater than minimal risk,** and all study procedures must fall into at least one of nine categories
  - Studies are reviewed by one or a few IRB members and not the entire committee
  - Approval is indefinite
- Definition of **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*

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, or quality assurance methods

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

Addressing Risks Specific to SoTL

- Students as subjects
  - May be susceptible to undue influence
  - Have a co-investigator recruit and consent students

- Dual role of instructor/investigator
  - *Appearance* of a conflict of interest
  - Have the co-investigator keep consent forms until after grades have been submitted

- ”Therapeutic misconception”
  - Overlap in what constitutes teaching and research
  - Clearly disentangle what is required as a part of the course and what is exclusive to the research in the IRB application and the consent form

Confidentiality of Student Data

- If using assignments as research data:
  - Use a de-identified copy of the assignments
  - Store the research data separately from the course assignments

- Data from the educational record (FERPA)
  - Release of or access to identifiable data in the student record **requires** signed consent
  - Release of **de-identified** data does not require signed consent
  - Contact school FERPA administrator with questions
    - EMU registrar
  - You may **not** use your professional access to Banner or school records for research purposes. This is a FERPA violation.

Data Identifiability

Identifiable

Contain values or variables that, on their own, identify subjects. Direct identifiers include:

- Name
- Social Security Number
- Video recordings
- EMU EID number
- Email address
- Home address

Coded

Data can be coded, which means that, while the data set does not contain any direct identifiers, the data set contains a study ID number that is linked, in a separate file, to direct identifiers.

The study ID serves as a code for re-identifying subjects via the key (i.e., a separate file linking study ID numbers with direct identifiers). Coded data are indirectly identifiable.

De-Identified

Data cannot be indirectly identifiable, which means that the data set does not contain direct or indirect identifiers.

In addition, individual values, fields, or variables within the data set must not be able to be combined to re-identify subjects.

Approval and Monitoring

- Research may not begin until IRB approval obtained
- Must maintain contact with IRB during course of research
  - Continuing Review
  - 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/