Committee on the Use of Human Subjects in Research

IRB Training

August 25, 2026

What is the IRB?

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

Committee on the Use of Human Subjects in Research - Membership	
Tilo Roy- Chair Teddi Deka (Psychology) Jim Okapal (Social Science and Humanities) Amit Verma (Business)	Sharyl Trout (External Member) Kristen Walton (Biology) Tammie Conley (Nursing) LeAnn Whitman (Social Work)

What Constitutes Human Subjects Research and What Research Needs to Be Reviewed?

Human subject means a living individual about whom an investigator conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

The Common Rule

What is the Common Rule? (VA.Gov)

The Common Rule is a short name for “The Federal Policy for the Protection of Human Subjects” and was adopted by a number of federal agencies in 1991.

The Common Rule:

- Describes the types of research subject to regulation
- Defines key terms such as research, human subject and minimal risk
- Requires a written assurance of compliance with the common rule
- Sets forth requirements for an Institutional Review Board’s (IRB) membership, authority, review procedures, records and criteria for approval
- Lists the general requirements for informed consent

Types of Review

Exempt

- “designed to study, evaluate, improve, or otherwise examine public benefit or service programs..” (HHS)
- Still needs to go through MoWest IRB

Expedited

- Reviewed by at least 1 member of the IRB
- 3-year expiration date
- Annual Check-ins

Full Board

- Reviewed by voting quorum of the IRB
- 1-year expiration date
- Annual Reports

Documents You Will Need

Training Certificates

Informed Consent

Survey(s)

Recruiting Materials (flyers, ads, etc.)

Informed Consent

“Key Information” to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the individual’s participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the participant

Informed Consent

- A description of any benefits to the participant or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained

Informed Consent

- An explanation of whom to contact for answers to pertinent questions about the research and participant's rights, and whom to contact in the event of a research-related injury to the participant
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the individual may discontinue participation at any time without penalty or loss of benefits, to which he/she is otherwise entitled

Exempt Research Categories

Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

Exempt categories continued…

1. Research with Educational Settings (Category 1):
    - Research conducted in established or commonly accepted educational settings involving normal educational practices.
    - Examples include studying teaching methods, classroom management, or the effectiveness of different instructional materials.
2. Educational Tests, Surveys, Interviews, and Observations (Category 2):
    - Research involving educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or public behavior observations.
    - The research must not involve sensitive topics or have the potential to place subjects at risk.
    - Examples include anonymous surveys about student opinions, interviews about learning strategies, or observing classroom behavior.

Exempt categories continued…

3. Benign Behavioral Interventions (Category 3):
    - Research involving brief, harmless, and non-intrusive interventions that are not likely to cause harm.
    - Examples include playing online games, solving puzzles under various conditions, or having subjects make simple decisions.
4. Secondary Research (Category 4):
    - Secondary research uses of identifiable private information or identifiable biospecimens.
    - This includes accessing and analyzing existing data or biospecimens for research purposes.
    - Restrictions apply regarding the availability of consent for the original data collection and the potential risk of re-identification.
    - 5. Public Benefit and Service Program Evaluations (Category 5):

Exempt categories continued…

5. Public Benefit and Service Program Evaluations (Category 5):
    - Research and demonstration projects designed to study public benefit or service programs.
    - These projects must be conducted or approved by a federal department or agency.
6. Taste and Food Quality Evaluations (Category 6):
    - Research involving taste and food quality evaluations and consumer acceptance studies.
    - This includes studies on food products, additives, and agricultural chemicals, provided they meet certain safety criteria.

Expedited Review

- Be of minimal risk to the subjects
- Must not involve prisoners or mentally impaired persons
- The expedited review procedure is not permitted when identification of the subjects and/or their responses would reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Expedited Review Categories

1. Clinical studies of drugs and medical devices only when the following conditions are met:
    - Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    - Research on medical devices for which an investigational device exemption is not required, **OR** the medical device is cleared/approved for marketing and is being used in accordance with its cleared/approved labeling.

Expedited Review Categories Cont.

2. Prospective collection of biological specimens for research purposes by noninvasive means, (through procedures not involving general anesthesia or sedation) that are routinely employed in clinical practice, excluding procedures involving x-rays or microwaves

a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

b. From other adults and children (persons under 18 years old) considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

Expedited Review Categories Cont.

3. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

4. Collection of data from voice, video, digital, or image recordings made for research purposes.

5. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Full Review

If the proposed research does not qualify for Exempt or Expedited Review as defined above, it will be subject to a Full Review. In addition, if the proposed research involves any of the following, it will be subject to Full Review.

- Children under the age of 18
- Prisoners
- Homeless population
- Pregnant women

Full Review Continued

- Individuals with impaired decision-making capacity
- Economically or educationally disadvantaged persons
- Procedures that might cause physical harm.
- Procedures that might cause significant psychological/emotional distress.
- Collection of information about highly sensitive topics.
- Collection of information about illegal behavior.
- Collection of information that could seriously harm the participant legally, socially, financially etc. if other people could identify them.
- Protocols requiring Full Review are vetted by the entire IRB and discussed at a convened meeting.

IRB Protocol Management System

MoWest's IRBWebsite: https://www.missouriwestern.edu/humansubsresearch/

Training Certification Requirements (please download and save the certificates)

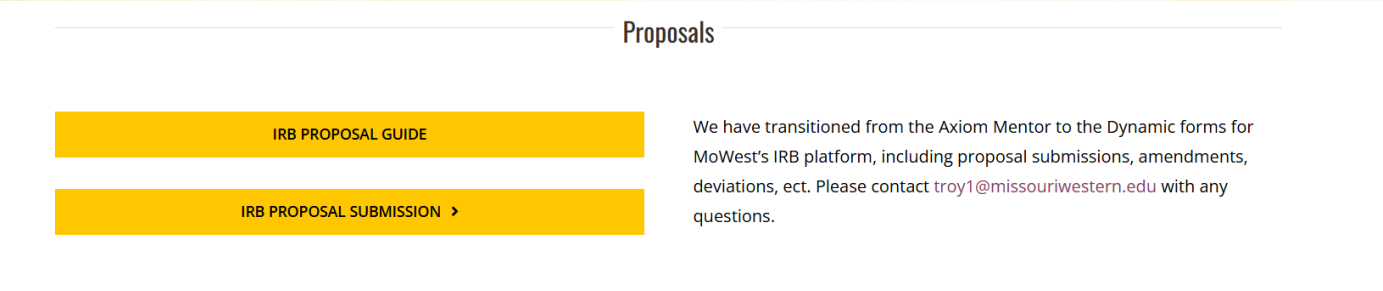
- Lesson 1: When HHS Regulations Apply
- Lesson 2: What is Human Subjects Research?
- Renew every 3 years

Accessing the Protocol Management System – Please see the next few slides!

How to access the proposal submission dynamic form?

Two options!

1. From MoWest's IRB webpage (click on the IRB proposal submission tab):



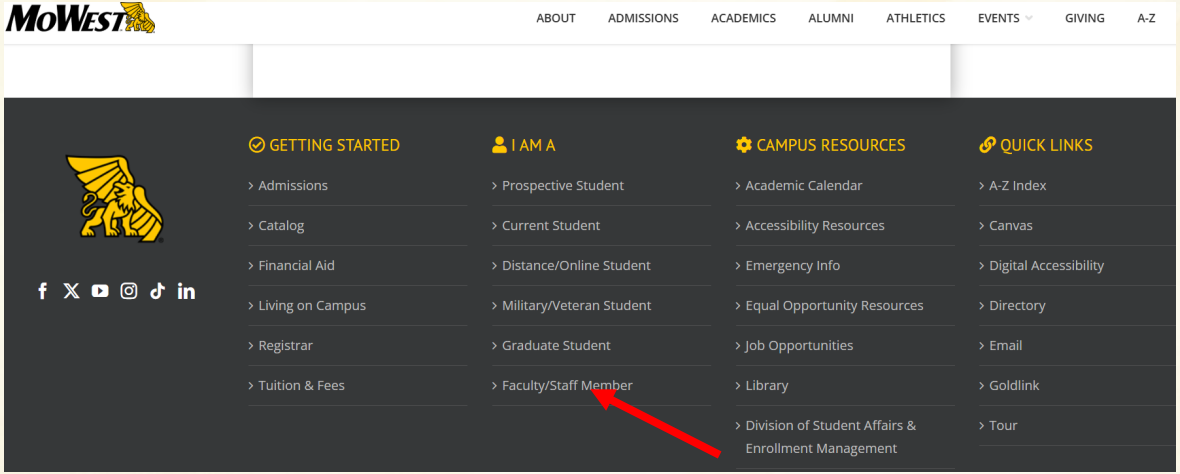
2. From the employee forms A-Z link:

FORM NAME	DEPARTMENT
HSA Payroll Deduction Form	Human Resources
Incomplete Grade Contract Form	Academic Affairs
Initiate New or Increase Existing Course Fee Form	Academic Affairs
IRB – Adverse Event Form	Institutional Review Board
IRB – Amendment Form	Institutional Review Board
IRB – Proposal Form	Institutional Review Board

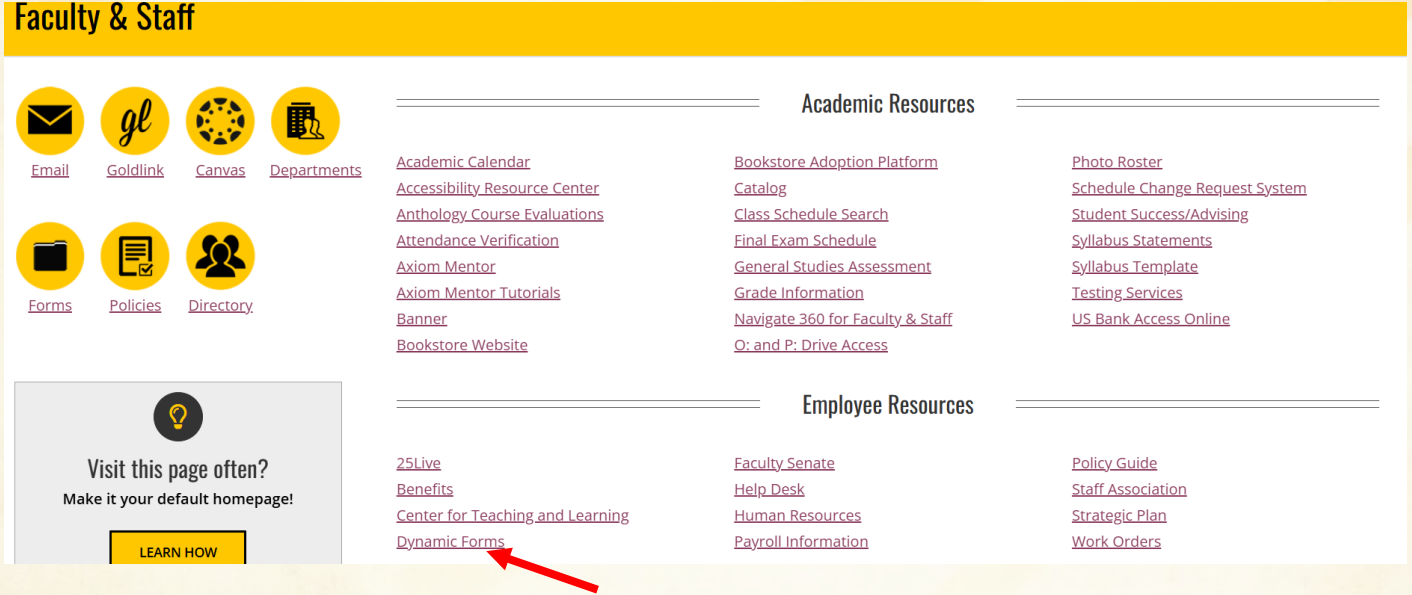
The proposal submission form is timed (45 mins!), so please remember to hit the save button at the bottom periodically!

Here is how to retrieve your saved form:

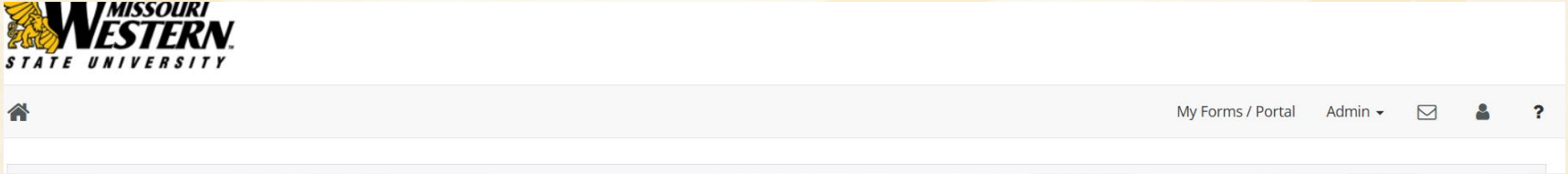
1. Please go to the bottom of MoWest's page and click on "Faculty/Staff member"



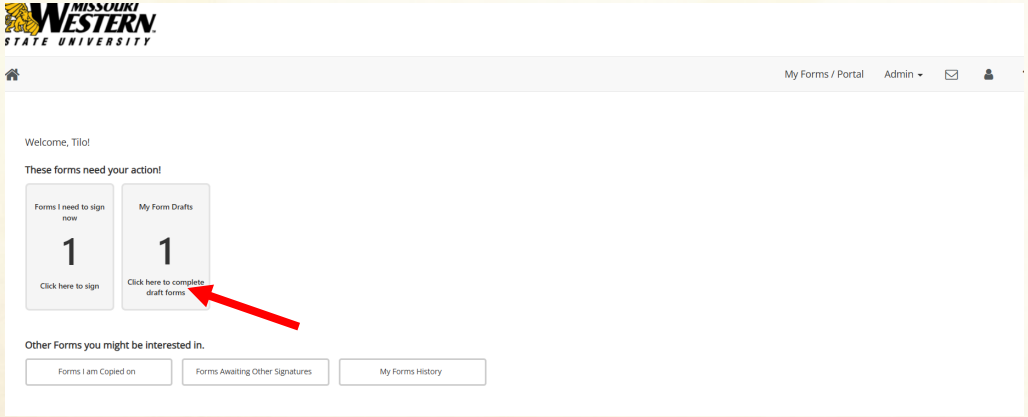
2. Click on “Dynamic forms”



3. Click on “My forms/portal”



4. Your saved form will show up here as a draft:



Questions?

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Frequently Asked Questions