Institutional Review Board (IRB) Overview

UM Extension

11/17/23

UNIVERSITY OF MARYLAND FEARLESSLY FORWARD

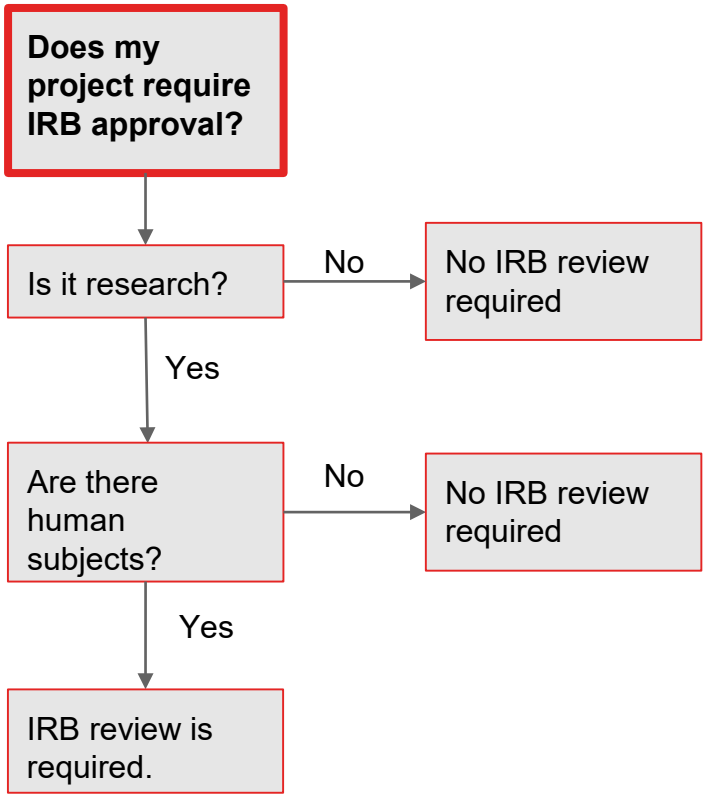
IRB Overview

What is the IRB?

- IRB: Institutional Review Board
  - Independent committee to assure the protection of the rights and welfare of human subjects in research.
- What do they do?
  - Review research to ensure there are adequate protections for human subjects by assessing the risk-benefit ratio
  - Research should have a favorable risk-benefit ratio
- Who is part of it?
  - Chair and Members (faculty, students, staff, community members) appointed by the VPR
- What rules/regulations do they follow?
  - Federal regulations (45 CFR 46), USM Policy, IRB Standard Operating Procedures, and State and Local laws

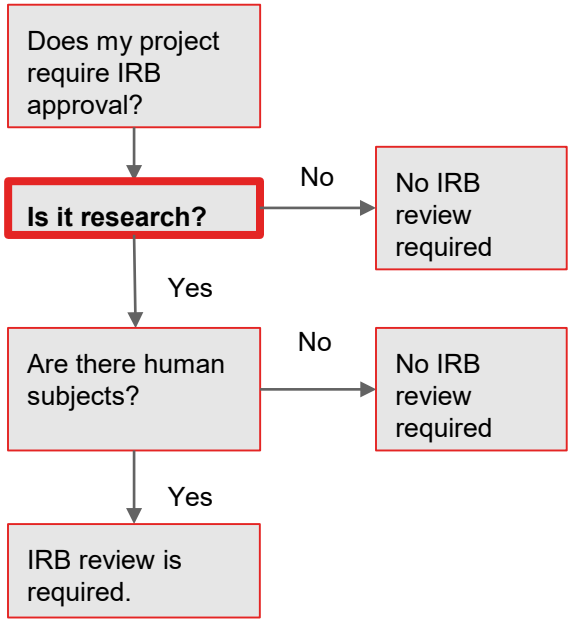
What requires IRB approval?

- Anything that meets the definition of human subject research (HSR) per the regulations (45 CFR 46)
  - First ask: Is it research?
  - If it is research, ask: Are there human subjects?
    - If yes to both, IRB review is required



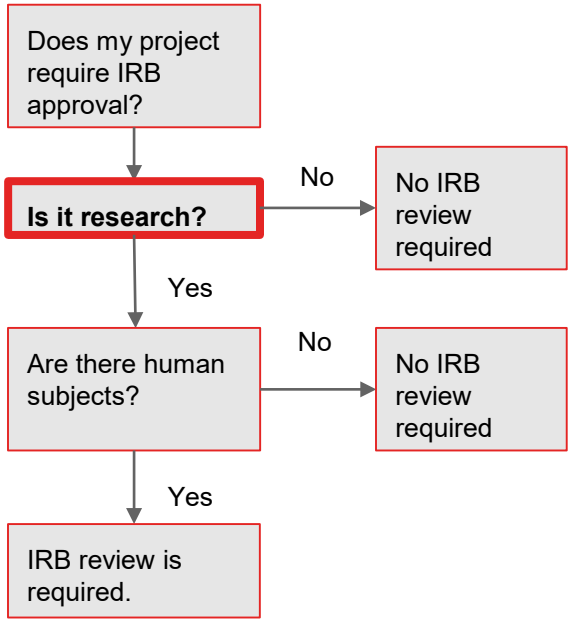
Is it research?

- **Research**: a systematic investigation such as research development, testing, and evaluation, designed to contribute to generalizable knowledge (e.g. via publication or presentation, including conference presentations)
  - Systematic investigation refers to a methodical approach likely (but not always) involving a hypothesis, research question, and plan to systematically collect and analyze data



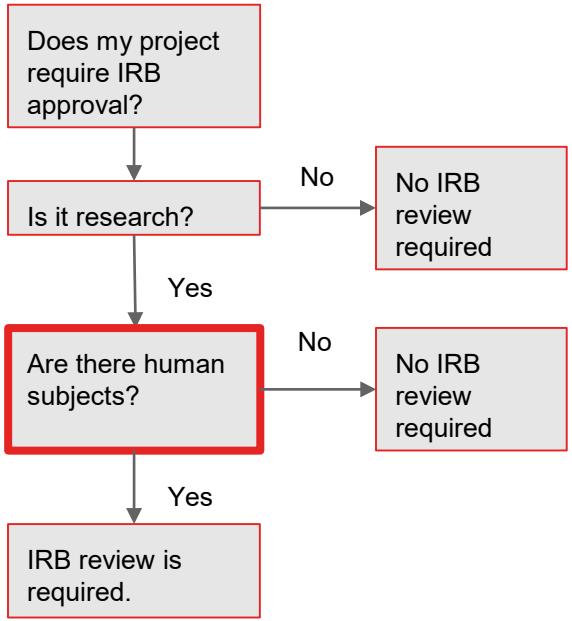
NOT Research

- Scholarly and journalistic activities (e.g. oral history, journalism, biography, case studies)
  - **IF** they focus on an individual's experience and/or documenting events and lives - does not contribute to generalizable knowledge
- Quality assurance/quality improvement and program evaluation activities
  - **IF** no intent to generalize findings outside of the project
- Pilot data
  - **IF** it will not be included in a publication/presentation
  - Focus on refining materials/procedures - does not contribute to generalizable knowledge



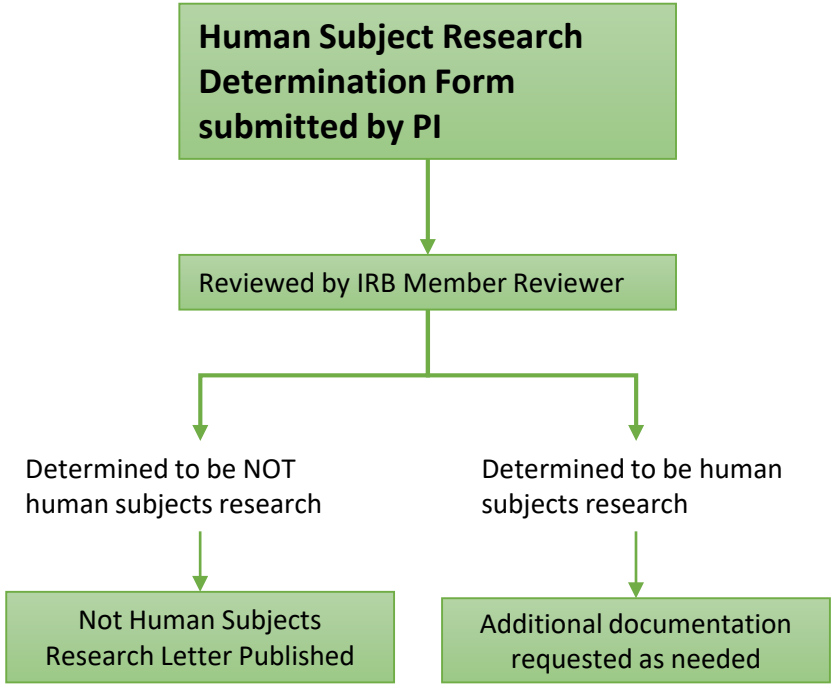
Are there human subjects?

- **Human subject**: a living individual 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.



What if I am still not sure?

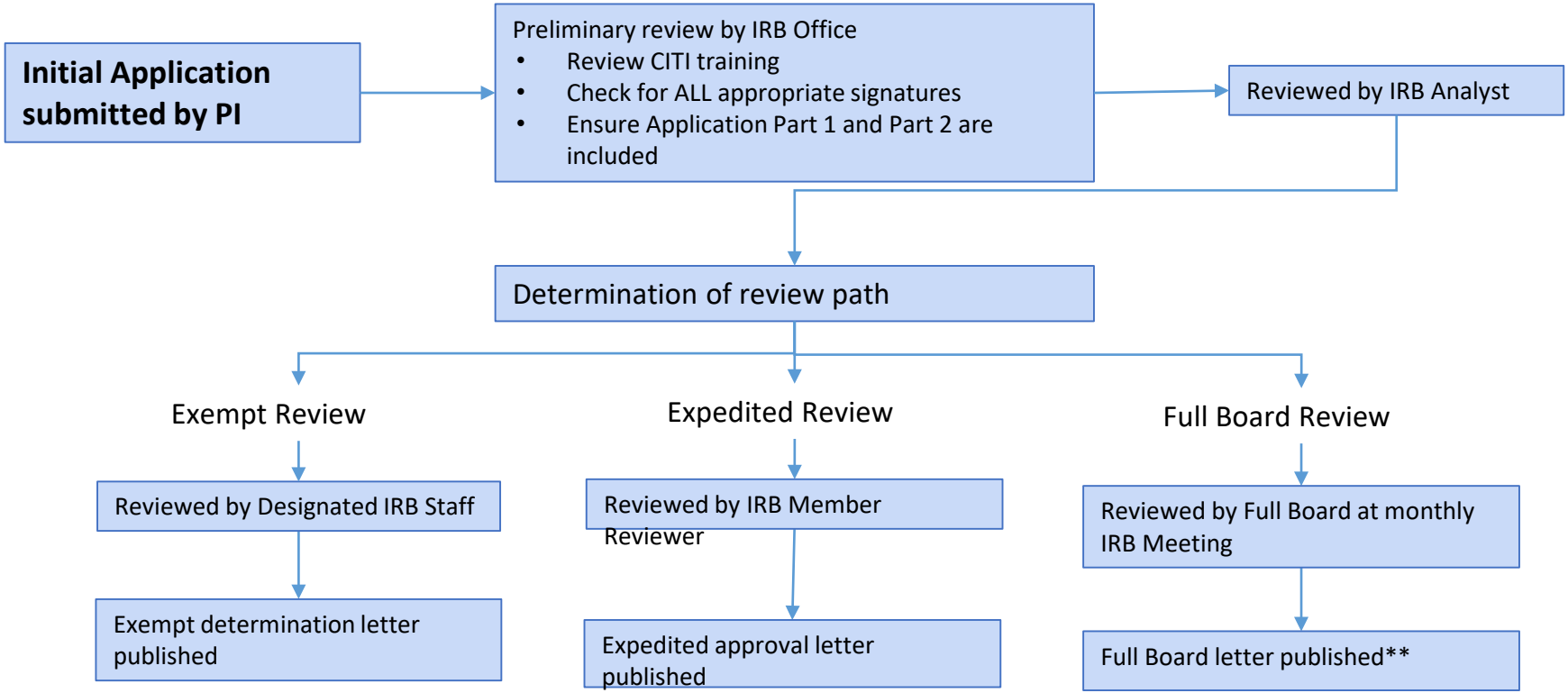
- If you are not sure, submit a Human Subject Research Determination Form for an official determination



What are the review paths?

- Not Human Subjects Research
  - Official determination from the IRB Office, usually resulting from submission of a Human Subject Research Determination Form
- Exempt
  - Project is exempt from the regulations at 45 CFR 46, but is required to adhere to USM Policy, IRB Standard Operating Procedures, and State and Local laws
  - Must fit into one or more of eight categories
  - Examples: anonymous surveys/interviews, passive observation of public behavior without collection of identifiable information, some secondary data analysis
- Expedited
  - Must be **minimal risk** and fit into one of nine federally-defined categories (surveys, interviews, exercise, blood draws, specimen collection), includes most research with children
  - **Minimal risk**: the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or a routine physical or psychological examination/test
- Full Board
  - Research presenting greater than minimal risk and/or does not fit into an Expedited category
  - Examples: DEXA scans, upsetting stimuli, drug/device trials

Determination of Review Path



UNIVERSITY OF MARYLAND FEARLESSLY FORWARD

**The full board letter depends on the determination of the Committee. The Committee may approve the project, approve the project with conditions, table the project based on modifications, or disapprove the project.

How to Submit an Application: Pro Tips

Before You Submit

- CITI Training Certificates for all Investigators
  - Includes: PI, Co-PIs who will interact with human subjects and/or their identifiable data
  - Course Title: Social and Behavioral Basic/Refresher or Biomedical Research Basic/Refresher
- Initial Application Part 1
  - Complete using “Start a Wizard” function in IRBNet
- Initial Application Part 2
  - Use the Part 2 Instructions!
- Department Liaison Signature
- Principal Investigator Signature

Click “Submit this Package” when all elements are completed

Initial Application Part 1

Part 1

- Principal Investigator
- Co-Investigators
  - Anyone who will interact with human subjects and/or their identifiable data
- Funding (if you have it)
- Review Path: this is only a requested review path!
  - The IRB makes the final determination
- Answer the questions to the best of your ability as they apply to your study

Initial Application Part 2

- Write in layperson terms.
- References are **not** necessary.
- The Part 2 Completion guide is your friend!

Abstract (Section 1)

- Describe the purpose of the research and strategies used to protect human subjects.
- ~200 words.
- Don’t overdo it.

Subject Selection (Section 2)

- 2a. *how* you obtain access to your participants, *how* you contact them, and *how* participants sign up.
  - Flyers? Announcements? Listservs?
  - **Social Media**: what platform and whose accounts.
  - **Snowball sampling**: preferable to ask participants to share your study, do not get personally identifiable information (PII).
- 2b. *who* will be enrolled
  - **ALWAYS** state 18 years of age or older, unless minors will be recruited.
- 2c. *why* this group
- 2d. *how many*
  - Should be the **maximum** number of participants for the **entire** study
  - Do **NOT** provide a **minimum**.
- 2e. *why* that number of participants

Procedures (Section 3)

- State what participants will be asked to do, start to finish
- Commonly missed details:
  - Time commitment
  - Where the study will take place
  - Tasks - we want to know what participants will be doing from start to finish
  - Topics covered in surveys, including demographics.
  - How data will be recorded by investigators
    - Paper survey, audio or video recording
    - **IF** recording, state whether it is required for participation
  - Compensation: mode and conditions.
  - Research participation separate from program participation

Risks (Section 4)

- State the potential risks to participants and describe how you plan to minimize these risks
  - If there are no risks, state there are "**no known risks**."
- Common risks:
  - Potential breach of **confidentiality** (unless not collecting PII)
  - Discomfort or embarrassment
  - Frustration or boredom
- Minimization strategies:
  - Through confidentiality measures described in Part 2 Section 6
  - Skip uncomfortable questions
  - Stop participating at any time
- Do **NOT** list every possible risk one might encounter - consider probability and magnitude

Benefits (Section 5)

- State known **direct** or **potential** benefits
  - Direct benefit: a guaranteed benefit to participants (rare)
  - Potential benefit: a benefit that ***may*** help participants or happen due to findings of research
- Generally, “no direct benefits.”
- Most common benefits:
  - Potential generalizable knowledge - briefly describe
  - Potential new skill for participants or new knowledge
- Do **NOT**:
  - List compensation as a benefit.
  - Overestimate the benefits.

Confidentiality (Section 6)

- State what procedures are in place to protect the participants and their data
- **Data storage**: *where*.
- **Access to PII**: *who*.
  - Note: recordings are considered PII
- **Destruction (of PII)**: *when* and *how*.
- **Key**: will there be a key linking study data to identifiable information?
  - If so, it should be stored securely and separately from study data

Consent Process (Section 7)

- How participants will consent
  - Examples: verbally, by clicking a button, by signing their name digitally or physically
- Where.
  - How will their privacy be protected during consent process?
- When.
  - At the end of a program? After completing an eligibility survey?
- Provide a copy of form

Note: Privacy ≠ Confidentiality
Privacy: protects the participant
Confidentiality: protects the data

Parental Consent/Child Assent

- State how parental consent and minor assent will be obtained and documented
  - For children under 12, use verbal assent
  - For children 12+, use written assent
  - Language must be age-appropriate
- Use the Parental Consent Template
  - Write for the parents: Your child is invited to participate…

Waiver of Consent Documentation

- Participants will not sign their name (physically or digitally) to consent
  - Examples: verbal consent or checking a box
- Address how project meets at least one of the following criteria in Part 2 Section 7:
  - Minimal risk + procedures do not normally require a signed consent form
  - Only link between subject and research would be the informed consent form - up to participants to sign or not sign
  - Participants are part of a distinct cultural group in which signing forms is not the norm

Waiver of Consent Documentation

This research meets the criteria for a waiver of consent documentation for the phone interview parts of the study in the following ways:

-This research presents no more than minimal risk of harm to subjects because the risks are limited to breach of confidentiality and a recorded phone interview about demographics and one's linguistic background does not normally require written consent outside of research.

Full Waiver/Alteration of Consent

- **Alteration**: investigators will use deception
- **Full waiver**: there will be no consent process at all
  - Applicable to waiving parental consent
- Address each of the five points:
  - Minimal risk
  - Not practical to conduct study without waiver/alteration
  - If using PII, research cannot be practicably conducted without identifiable information
  - Rights and welfare not affected
  - Participants will receive additional information after participation (if appropriate)

Program Evaluation Projects

- Participation in the program without participation in the research
- Focus on the “research” in the IRB submission
  - Activities where data is collected from participants to be analyzed for generalizable purposes
  - Example: Section 2a should be how potential participants are informed of the opportunity to participate in the survey/interview portion, not the program itself
- Provide some context for the program in Part 2 Section 1

Other Materials

Other Materials to Submit

- Recruitment materials
- Consent Forms
  - Use Consent Form template and Completion Guide
- Survey/interview questions

Recruitment materials

What to include:

- It is for research/a study
- PI name, affiliation (UMD), contact information
- Purpose of research (brief)
- Time commitment
- Eligibility criteria
- Compensation
- If any recording will be used, what type and whether it is required for participation
- If in-person, state where

Sample Advertisements

Want to earn some CA$H???

to participate in hearing research

You will receive $12 per hour for your participation!

For more information, please contact:

The Hearing Lab
(301) 405-7454

Sample Advertisements

Participants needed!

$12 per hour for 16 hours total

Participate on UMD's campus! Complete an audiometry test, pitch sensitivity test for signal detection analysis!

For more information, contact:
The Hearing Lab
301-405-7454

Sample Advertisements

Paid Volunteers Needed

to participate in hearing research

You will receive $12 per hour for your participation!

Who? Persons 18 - 35 years old with normal hearing
Persons 65 – 85 years old with either normal hearing or hearing impairment

American English must be your first language.

Where? The Hearing Science Lab, 0119 LeFrak Hall

What does the research involve? You will be seated in a sound booth and will listen to sentences, tones, or noise bursts. You will be asked to push a button when you hear a particular sound, repeat the words or sentences you hear, or watch a video while we record your brainwaves to the sounds presented.

How long will it take? 16 hours, total, scheduled in sessions of 1-2 hours.

For more information, please contact:

The Hearing Lab
(301) 405-7454

Consent Form Template Tips

- **Footer**
  - Update the footer with YOUR project's IRBNet ID
- **Project Title**
  - Match what is in IRBNet
- **Procedures**
  - Description of what participants will be asked to do and the time commitment
- **Risks, Benefits + Confidentiality**
  - Be consistent with Part 2
- **Medical Treatment**
  - Remove unless greater than minimal risk
- **Statement of Consent + Signature and Date**
  - Modify to reflect method of consent (digital signature, verbal agreement)

Online consent

- **Multiple formats**: continuing with the survey, clicking “I agree,” checking a box, clicking “Next.”
- However, it requires an abridged version of the same points required in the consent form:
  - **PI**, institutional affiliation, and their contact information
  - **Purpose** of the study
  - Brief description of **procedures** (i.e., time, topics addressed)
  - **Risks** and how they will be mitigated
  - **Benefits**
  - **Confidentiality** measures (i.e., will identifiable information be collected? If so, will responses be kept confidential?)
  - **Participant rights** (i.e., participation is voluntary, can withdraw without penalty or loss of benefits)
  - This project has been reviewed by the University of Maryland I**nstitutional Review Board** (irb@umd.edu; Package Number XXXXXXX-X).
  - **Statement of consent**. For example, "By [clicking ‘I agree’], you indicate that you are at least 18 years of age; you have read this consent form or have had it read to you; your questions have been answered to your satisfaction and you voluntarily agree to participate in this research study. You may print/download/save a copy of this consent form."

Need help?

Get in touch with the IRB Office:
irb@umd.edu or 301-405-4212
Location: 1204 Marie Mount Hall

UNIVERSITY OF MARYLAND FEARLESSLY FORWARD

Thank you!

UNIVERSITY OF MARYLAND FEARLESSLY FORWARD