Human Research Protection Program

Institutional Review Board

Policies and Procedures

What is the IRB?

IRB: independent committee to assure the protection of the rights and welfare of human subjects in research.

- Adequate Protections based on a favorable risk : benefit analysis of the research
- Chair and Members appointed by VPR (Designated Institutional Official)
  - Diverse in expertise, affiliation, representation (prisoner rep, LGBTQ, students)
- Guided by Federal regulations [45CFR46], USM Policy, IRB SOP, State & Local laws

Human Subject Research Definition

Human subject (45CFR46.102(e)(1): 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.

Research (45CFR46.102(l): means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

- Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.
- The following activities are not considered research: scholarly and journalistic activities (oral history, journalism, biography, historical scholarship, etc). Public health surveillance activities (authorized by a public health authority). Collection of information for purposes of criminal investigation. Operational activities in the support of intelligence, homeland security, or other national security missions.

Federalwide Assurance & Engagement

- **FWA**: Agreement to adopt 45CFR46 in order to apply for and receive federal research funding.
  - UMD IRB applies 45CFR46 to all HSR regardless of funding source
- **Engagement**: An institution becomes engaged in HSR when its agents (faculty, students, staff):
  - Interact with living individuals for research purposes; or
  - Obtain individually identifiable private information for research purposes
- **Reliance Agreement**: Two or more institutions engaged in HSR
  - Allows one institution to be the IRB of record for the life of the study
  - Benefits: Reduce admin burden, eliminate confusion, streamline
  - SMART IRB – eases challenges w/multisite research

Prior to Project Submission

- **ORA – Prior to IRB Approval Form**
  - Allow PI to access award funds prior to obtaining IRB Approval.
  - Begin pre-HSR work (hiring, supplies, space, etc.)

- **Award w/Human Subject Research**
  - Must submit a project through IRBNet and have it approved prior to beginning HSR
  - Project may have more than one funding source
  - "118 Letter" - NSF/NIH may require if HSR activities not beginning right away. Contact IRB Office.

- **Award w/o Human Subject Research**
  - Does not require IRB Review, but if unsure, contact IRB to discuss
    - ***There is no retroactive IRB Approval!***
    - ***Do not make decision w/o IRB Office consultation***

Criteria for Approval

1) Risk Minimized

- **What are the risks of participation in the study?**
- **How are the risks minimized?**
- **Are procedures consistent with sound research design?**

2) Risks reasonable in Relation to Benefits

- **What are the anticipated benefits of the study?**
- **Are the potential risks reasonable in relation to the potential benefits?**

3) Subject Selection is Equitable

- **How is subject selection equitable?**
- **Are vulnerable populations included?**

4) Informed Consent will be Sought

- **Will informed consent be sought from each subject?**
- **Will a Legally Authorized Representative be approached for consent?**
- **Parental Consent and Assent Processes?**

Criteria for Approval

5) Informed Consent will be Documented

- **How is the consent process documented?**
- **Is a waiver or alteration of this requirement requested and justified?**

6) Data Monitoring Plan (when appropriate)

- **What is the monitoring plan for this protocol?**
- **How is it appropriate in relation to the potential risks?**

7) Confidentiality and Privacy Provisions are appropriate

- **What are the measures to ensure that privacy and confidentiality are protected?**

8) Vulnerable Populations

- **What vulnerable populations are recruited for this protocol?**
- **What measures are in place to protect these populations?**

FDA Criteria for Approval: 21 CFR 56.111

Review Paths

- **Minimal Risk**
  - The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests
- **Human Subject Research Determination Form**
  - Program evaluation, oral history, secondary data sets, etc.
  - Provides official determination from IRB Office.
  - Submit this form if you are fairly certain your project is not HSR.
    - Be very clear if the work is intended to contribute to generalizable knowledge and if you are working with human subjects.
    - This is not required to be submitted prior to a "normal" IRB Application. It is a tool to document when activities are not considered HSR.
- **Exempt**
  - 45CFR46.101 – Project meets one or more of six categories. Not required to meet the regulatory requirements in the remainder of 45CFR46.
  - Restrictions on populations and restricted use data sets
- **Expedited**
  - 45CFR46.110 – 9 categories (surveys, interviews, exercise, blood draws, specimen collection, etc.)
- **Full Board**
  - Research presenting greater than minimal risk (DEXA scans, upsetting stimuli, drug/device trials)

Review Process

- **Admin pre-review**
  - Signatures (PI/Advisor/Liaison) & CITI Training checks
- **Pre-review**
  - Analyst review
  - Modifications sent
  - Review Path determined and category suggested
- **IRB Chair or IRB Member review and approval**
  - Additional mods requested (possibly)
  - Scientific merit/integrity review (procedures consistent w/sound research design)
  - Approval granted by IRB Chair/Member and processed by IRB Office staff
  - Approval letter published in IRBNet. Notification email sent to staff shared on IRBNet application.
- **Full Board Review**
  - Pre-review and agenda assignment
  - Contact reviewers to ensure availability and no conflicts
  - Feedback due in two days prior to meeting. Analyst reviews feedback for glaring issues. Try to avoid tabling.

Review Process
Special Considerations

- **Vulnerable Populations & Protections**
  - **Children/Minors**
    - Parental consent/Waiver
    - Background checks
    - Recommend: Two research team members present w/minor
  - **Prisoners**
    - Risk of retribution
    - Risks must be commensurate w/those accepted by non-prisoners
  - **Pregnant Women/Fetus**
  - **Students**
    - Power dynamic/authority/grades
  - **Military**
    - Power dynamic/authority
  - **Cognitively Impaired**
    - Legally Authorized Representative
    - Witness
    - Evaluation to Sign Consent

Application Forms

Consent Form & Waivers

- Parental Consent Template
  - 7 and younger: verbal consent in language understandable to child
  - 7 – 12yo: verbal consent w/information sheet
  - 13 -17yo: signed consent; separate form or on parental consent form
- FMRI Template – Specific safety language
- Waiver [45CFR46.117(c)]/Alteration [45CFR46.116(f)(3)] Criteria
  - No more than minimal risk and involves no procedures for which written consent is normally required outside of the research context
  - Waiver will not adversely affect rights and welfare of subjects
  - Research could not be practicably conducted w/o waiver OR activities
  - Subjects provided with additional info after participation whenever appropriate
  - Cultural concerns

Amendment Form

Submit when proposing changes to approved application.

Continuing Review Form

- If human subject research will continue beyond initial approval period, submit CR prior to expiration date in order to maintain IRB Approval.
- Expedited protocols are no longer required to submit a CR, unless the IRB determines it is justified due to funding requirements, oversight concerns, population, research activities etc. The approval letter will reflect if a CR is required.

Protocol Review Notes

PI can be Graduate Student

- Faculty Advisor must be on project and have CITI Training

International Research

- OHRP Compilation in Part 2 Completion Instructions
- Check for specific regulations in that country
- Include translated consent forms
- Include approval letters

Timeline for Review

Initial Application Review

- *HSRD: 5 - 7 days*
- *Exempt: 1 - 2 weeks*
- *Expedited: 2 - 3 weeks*

Continuing Review [Expedited]: *1 - 2 weeks. At most 30 days prior to Expiration Date*

Amendment [Expedited]: 1 – 2 *weeks depending on the type and number of changes.*

Full Board Transactions [All]: *One month – Be sure to check the submission deadlines!*

Best Practices – Advertisement/Recruitment

Answers who, what, when, where, and how

- Who – eligibility criteria
- What – description of what research is
- When – gives duration of project
- Where – logistics

Compensation

- Research Participant Support Payments
- HSWG-Admin@umd.edu for questions related to participant payments
- Type: raffle, cash, extra credit, Tango, etc.
  - Outlined clearly in Consent Form
  - Receipt template

Ad is the first step in informed consent process

- Must be reviewed and approved by IRB

Protect your data!

- Inform participants that ***suspected abuse and fraud*** will result in forfeiture of compensation and removal of data

Online study of young children's daily emotions and behaviors

Are you a parent of a child between the ages of 3 and 5 years old?

Researchers at UMD are investigating a number of phenomena related to children's emotional and behavioral development from early childhood through adulthood.

Participants will be asked to complete online surveys each evening for 14 days.

Parent must be the primary caregiver and read and speak English. Children must not have major medical or developmental disabilities. One child per family can participate.

Compensation: $50

Research possible through Federal award.

Required Training – CITI Program

- Log in through My Institution at: https://www.citiprogram.org/
- Complete one of the following:
  - Social and Behavioral Research Investigators
  - Biomedical Research Investigators
- Research Team Members
  - Anyone interacting w/human subjects and/or identifiable data from human subjects must have their training linked to the project prior to approval.
- Valid for 3 years – Refresher due.
- Provided at no cost to you.
- Good Clinical Practices: Required if you are conducting a Clinical Trial.
- Optional courses: Conflict of Interest/Export Compliance/Responsible Conduct of Research.

Contact Information & Resources

- Research Compliance Offices: research.umd.edu/compliance
- IRB: research.umd.edu/irb
- Integrated Research Resources: irroc.umd.edu/
- IRBNet: www.irbnet.org
- CITI Training: www.citiprogram.org
- IRB Contact: irb@umd.edu or 301-405-4212
- Reliance Agreements: relianceagreements@umd.edu
- Reporting Non-Compliance: adminvp.umd.edu/ethics-integrity-and-compliance-reporting

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