Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

Waiver of Consent

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Informed Consent (IC)

- One of the primary ethical requirements underpinning **human research**
- It reflects the basic principle of **respect for persons** outlined in the *Belmont Report*
- This is a process, not just a form

Core Ethical Functions

- Protecting subject's welfare
- Respecting subject's autonomy
- Providing transparency
- Fostering trust

Informed Consent Waivers

1. **Waiver of Consent Documentation** – No signature

2. **Waiver of Informed Consent**

   a) Alteration of some elements of Informed Consent – (e.g., deception – intentionally misleading subjects; incomplete disclosure – not giving subjects accurate or adequate info), OR

   b) Full Waiver – Alteration of all elements of Informed Consent (waiving the requirement to obtain informed consent)

Waiver of Consent Documentation

The IRB may approve a waiver of written documentation of informed consent if it finds and documents any of the below:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality
    - Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context
    - For FDA-regulated studies, this is the only criterion that allows for a waiver of documentation of informed consent as stated in 21 CFR 56.109(c)(1)

Waiver of Consent Documentation (cont.)

3. That the research presents no more than minimal risk, participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, and there is an appropriate alternative mechanism for documenting that informed consent was obtained

- *The PI should submit a consent script or cover letter that will be used in lieu of a signed consent*

Waiver of Informed Consent (IC)

- The IRB may approve a waiver of informed consent if it finds and documents that:
  - The research is not FDA-regulated
  - The research does not involve non-viable neonates
  - The required justifications on the next slide are met

Waiver Justifications

- The research involves no more than minimal risk to the participants
- The research could not practicably be carried out without the waiver or alteration
- The research involves using identifiable private information or identifiable biospecimens and the research could not practicably be carried out without using such information or biospecimens in an identifiable format
- The waiver or alteration will not adversely affect the rights and welfare of the participants
- Whenever appropriate, the participants will be provided with additional pertinent information after participation

Continuing Review: Memory Review

Goal: This study examines the effects of fitness and Vit. D on cardiovascular function

Target Population: 40 young, healthy adults

Time Commitment: 3 lab visits including screening (6.5 hours)

Incentive: $100 ClinCard

Procedures:

1. Screening – measure height, weight, BP, skin reflectance, blood sample
2. Blood sampling using venipuncture (Visits 2 & 3)
3. Complete exercise testing on a stationary bicycle
4. Local heating – up to 45C (113F) for about 20 mins; Laser Doppler flowmeter
5. Cold Pressor Test – immersing one hand in ice water for 3 minutes
6. Wearing of physical activity monitor for 7 days
7. Complete questionnaires on health, social, & economic status

Previous Concern: Blood flow occlusion protocol – IRB thinks that this is a common protocol from the Kinesiology Department

RNI 498 – Approval Expiration (5 days lapsed)

RNI: Memory Review

- This study was approved under Expedited categories 3, 4, 6 & 7. One of the modifications went to a full board meeting (10/20/23) due to its complexities but remained expedited
- **Goal:** Understand how families and communities promote strength and resilience
- **Funding Source:** NIH
- **Population**: Children, their parent/guardian, and their teacher
- **Time Commitment**: 6 hours across waves 1-3; teacher – 45 minutes
- **Study Procedures**:
  1. Home Visit: Body measurement – height, weight, waist size, BP; hair and saliva sample collection
  2. Games and tasks (with deception) – while wearing electrodes and eye-tracking glasses & surveys
  3. Child will wear actigraphy watches for 14 days – track sleep & complete surveys
  4. MRI scan while watching video in BIRC
- Has previous RNI submission to add re-scanning options due to blurry images (acknowledged; not non-compliance)
- Home visit by student researchers without faculty. Some issues encountered:
  1. Parent Absence during home visit (RNI 483)
  2. Unexpected health concern (current submission - RNI 478)

New Study: Memory Review

- Risks listed includes:

1. Pharmacist handing identifiable information during conversation
   - ➢ This will be stripped out during transcription

2. Participants' potential reactions to deception: Feelings of anger, being offended, feeling used

   - ➢ Participants will be fully debriefed via email once data collection and analysis are complete to clarify that the data collection process was designed to mirror routine interactions and was essential to accurately assess current practices and identifying barriers
   - ➢ Participants have the option to withdraw their data from the study if they are not satisfied with the explanation provided

Something to Ponder:

Will it make a big difference if debriefing will happen sooner?

Old Business: Memory Review

- This study was approved with modifications required to secure final approval in the March 2024 meeting
- Review of responsive materials has been assigned to the primary and secondary reviewers. However, the PI added items that not were reviewed during the IRB meeting. Hence, study came back to the meeting
- This study involves Transcranial Magnetic Stimulation (TMS)
- The Regulatory Expert was consulted about the use of the devices and confirmed that these will only be used as tools to collect data, so the IRB did not do a Significant Risk or Non-Significant Risk Device determination
- This study was determined to be **More Than Minimal Risk** (Approval Period: **1 year**)
- During the initial review, question was raised whether pregnancy testing will be required. It was explained to the board that the first TMS study that IRB 2 has approved requiring pregnancy testing was later modified and approved for it to be optional once PI provided a lot of citations and references for the IRB to consider. Hence, pregnancy testing is now optional for TMS studies

Helpful Links

- 45 CFR 46.116: General Requirements for Informed Consent
- 45 CFR 46.116(f)(3): Requirements for Waiver and Alteration
- 45 CFR 46.117: Documentation of Informed Consent
- 21 CFR 56.109 (c)(1) – IRB Review of Research
- Checklist 409 – Informed Consent Elements Checklist

Thank you!