Oak Ridge Sitewide Institutional Review Board (IRB#: IRB00000547)

March 12, 2024

Title of Study:	Message Testing for Infant Feeding Communication in a Radiation Emergency
Investigator:	Matthew Schnupp
Type of Review:	Initial Study
Exempt Category:	(2)(ii) Tests, surveys, interviews, or observation (low risk), (2)(i) Tests, surveys, interviews, or observation (non-identifiable)
Submission ID:	ORAU001127
Funding Source:	Centers for Disease Control and Prevention (CDC), Funding Source ID: CDC Contract 75D30120C09950
Documents Reviewed:	• CDC - Radiation Studies Section Contract, Category: Sponsor Attachment; • HRP 503 - Protocol - Infant Feeding Message Testing, Category: IRB Protocol; • Individual Investigator Agreement - Karen Carera, Category: Other; • Messages to be tested, Category: Other; • Non-ORAU Research Team Member List, Category: Other; • Participant Information Sheet Provided during Recruitment , Category: Consent Form; • Recruitment Grid provided to Recruiting Firm, Category: Recruitment Materials; • Screening Instrument (Verbal Consent), Category: Recruitment Materials; • Study Focus Group Moderator's Guide, Category: Other; • Study Protocol Details, Category: Other;
Action:	Approved
Approval Date:	3/7/2024
Consent Waiver:	Waiver of Documentation of Consent Process

As noted above your study has been reviewed by the Oak Ridge Sitewide Institutional Review Board (ORSIRB) and determined to be **Exempt** human subjects research. This

determination is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized, to the extent practicable. All research must be conducted in accordance with this approved submission.

Annual follow-up is required on exempt studies. Before the IRB approval anniversary date or within 30 days of study closure, whichever is earlier, you must provide an update to the IRB in IRB8, following the directions provided by the IRB.

Please note that all principal investigators must **immediately** report to the IRB:

- **Upon finding of a suspected or confirmed data breach involving PII in printed or electronic form (see DOE Order 443.1C).**
- **All unanticipated problems, adverse events, non-compliance issues, and complaints (see DOE Order 443.1C).**
- Any new information that might increase the risks or decrease the benefits to research subjects, or affect a subject's willingness to continue participation in the study.

If annual review is not received before the anniversary date of all study activity that involves human subjects must cease.

All research records must be retained for a minimum of three years after the completion of the study.

Sincerely,

Kelli Bursey, MPH, CHES
IRB Chair
ORSIRB@orau.org
513-245-1286

Attachment:
Reminder: What are my obligations as a PI after IRB approval?

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1) Do not start Human Subjects Research activities until you have the final IRB approval letter.
2) Do not start Human Subjects Research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources.
3) Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
4) Ensure that research staff are qualified (e.g., including, but not limited to, appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study. Note that all members of the research team who have access to PII or who are responsible for subject interaction or intervention must complete training on the protection of human subjects research. DOE offers this training to researchers at DOE laboratories/sites and to DOE-funded researchers from institutions outside the DOE complex.
5) Update the IRB office with any changes to the list of study personnel.
6) Personally conduct or supervise the research.
    a) Conduct the research in accordance with the relevant current protocol as approved by the IRB.
    b) When required by the IRB, ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
    c) Do not modify the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
    d) Protect the rights, safety, and welfare of subjects involved in the research.
7) Submit to the IRB:
    a) Proposed modifications.
    b) A continuing review application as requested in the approval letter.
    c) A continuing review application when the research is closed.
8) Report any of the new information items in a Reportable New Information (RNI) in the IRB Electronic System to the IRB immediately. In the case of loss of PII, for example, reporting to the IRB and other authorities is required immediately.
9) Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

10) Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees.”)
11) Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)
12) Ensure that you comply with the requirements of sponsoring organizations/agencies, which may be in addition to those that are required by the Federal Regulations and DOE. **You must comply with the more stringent requirements**. Consult with the IRB if you need clarification.