



To: Gerardo Cruz-Ortiz

From: Meghan Hammock

CC: BRANY IRB File # 22-12-791-1334
Research Coordinator)

Date: 05/11/2023

Re: Determination of EXEMPT Status for Investigator Initiated Protocol 369 /

Protocol Title: GSA Equity Study

1. **BRANY IRB Decision:** Thank you for your submission. BRANY IRB has determined your submission is **exempt from IRB review** under category(ies) # **5, 7(i), 7(ii), and 7(iii)**, as detailed in 45 CFR 46.104(d) and BRANY's Standard Operating Procedures (category excerpted below).

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a **limited IRB** review and makes the determinations required by §46.111(a)(8).

BRANY IRB conducted a limited IRB review and determined the criteria at §46.111(a)(8) are satisfied.

**This determination requires that all procedures and activities are performed in accordance with relevant state and law (including tribal law, when applicable).*



2. Items Considered by BRANY IRB for Exempt Determination:

- Investigator Initiated Protocol 369, BRANY Stamped Version 05/11/2023
- GSA Identity Proofing Equity Study Marketing, BRANY Stamped Version 05/11/2023
- GSA Identity Equity Study- Consent Forms and Attachments, BRANY Stamped Version 05/11/2023
- GSA Identity Proofing Equity Study- Landing Page Content, BRANY Stamped Version 05/11/2023
- DRAFT Equity Study Consent Language, BRANY Stamped Version 05/11/2023

3. Requirement to Obtain HIPAA Authorization: HIPAA authorization requirements do not apply because use or access to PHI is not required for this research, and the data to be collected will not include any PHI.

4. Approved Study Personnel:

- a. Gerardo Cruz-Ortiz
- b. Christina Lee
- c. Anbuchellam Vijay
- d. Courtney Farnsworth
- e. Dmitriy Zaslavskiy
- f. Peter Shumate
- g. Stephanie Schuckers
- h. Daqing Hou
- i. Michael Schuckers
- j. Kaniz Fatima
- k. Sandip Purnapatra

5. IRB Approval Period/Expiration of IRB Approval:

While research that has been determined to be exempt from IRB review is not subject to continuing review, the Principal Investigator must notify the IRB of any changes in the protocol (e.g., study design, procedures, etc.), as such changes may call for IRB review.

Your Exempt Annual Report to BRANY IRB is due on 05/09/2024. BRANY IRB requires you "check in" at least annually to ensure your study status is up to date, and your study remains in compliance. If your research is completed before then, you must submit a notification of study closure to BRANY IRB (use the xForm #04).

If you have any questions or require any additional information, please call me at 281-796-1797 or send an email to me at hammockm@thehrpconsultinggroup.com. Thank you.