MU eCompliance

IRB #2098694 MU

Project number	2098694
Principal investigator	Hsu, Albert Li-Yuan
Project title	DRIVERs: Data systems Research to Identify driVers of Ethnic & Racial Inequities in Maternal Mortality
Project status	
App. status	Acknowledged
App. approved	09/28/2023
Expiration date	

September 28, 2023

To	hsual@health.missouri.edu
Subject	IRB Determination Notice Project #2098694 Review #398856

Project #2098694
Project Title: DRIVERs: Data systems Research to Identify driVers of Ethnic & Racial Inequities in Maternal Mortality
Principal Investigator: Albert Li-Yuan Hsu
Primary Contact: Albert Li-Yuan Hsu

Dear Investigator,

The MU Institutional Review Board reviewed your application and supportive documents. It has been determined that this project does not constitute human subjects research according to the Department of Health and Human Services regulatory definitions. As such, there are no further IRB requirements.

If you have questions, please feel free to contact the MU IRB office at 573-882-3181 or email at muresearchirb@missouri.edu.

Sincerely,

MU Institutional Review Board

September 26, 2023

To	hsual@health.missouri.edu
Subject	IRB #2098694 MU - HSR Determination Form: 398856

Project Title: DRIVERs: Data systems Research to Identify driVers of Ethnic & Racial Inequities in Maternal Mortality
IRB Number: 2098694 MU

Dr. Hsu - Melissa alerted me to your conversation earlier today. I can move this HSR forward, but I need you to remove anyone from the study personnel list that is involved in the de-identification of the data. By nature "third party" needs to be somebody not listed on this form....this form is a bit different than our IRB application. It is fine Dr. Song and others are working on this data from the PCORnet standpoint....they just need to not be listed as study personnel.

Also, you will then want to choose "yes" instead of "no" for this option and it will allow you to discuss their role:

7E. Does the study involve analyzing de-identified information that will be de-identified by a third party unrelated to the research? Yes No

Thanks and if you need to discuss further, my direct line is 573-882-2460.

Lori Wilcox, EdD, MS
Director HRPP/IRB

The identity of sections and question numbers needing revision are based on the current submission. As you work through the revisions, question numbers are likely to shift because the forms in eCompliance are built with logic. If you are unsure what question needs revision, please reply to this email. Also, it is recommended to save a PDF of the current submission to help identify the questions needing revision. To obtain a PDF, go to "Open Saved IRB Project". Locate the submission from your list. Instead of clicking "continue form" on the right, click the down arrow next to "continue form" and select "print view". From that page, you can "export as PDF".

HOW TO RESUBMIT YOUR FILE

1. Login to eCompliance.
2. Under the **Submission to IRB header**, click **Open Saved IRB Project**.
3. Locate the file that has been returned, click **Continue Form**.
4. Navigate to the appropriate section(s) of the form and edit, then click save and continue.
5. Go to the **Attached Files** section to upload requested documents.
6. Go to the **Submit** section to resubmit your file.

Access consent and protocol templates: research.missouri.edu/human-subjects-research/researcher-resources
View our frequently asked questions: research.missouri.edu/human-subjects-research/frequently-asked-questions

September 26, 2023

To	hsual@health.missouri.edu
Subject	IRB Received Notice Project #2098694 Review #398856

Project #2098694
Review #398856
Project Title:
Principal Investigator: Albert Li-Yuan Hsu
Primary Contact: Albert Li-Yuan Hsu

The IRB is in receipt of the Human Subjects Research Determination Form (Including QI Projects) submitted by Hsu, Albert Li-Yuan. The IRB office will be working directly with the submitter to ensure a complete submission for IRB review. The PI (if not the submitter) will also be copied if they requested to be copied on all IRB communications.

Thank you,
MU Institutional Review Board
Office: 573-882-3181
Fax: 573-884-4401
Email: muresearchirb@missouri.edu

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IRB #2098694 MU

Human Subjects Research Determination Form (Including QI Projects) #398856

Submission date: **09/26/2023**
Submitted by: **Hsu, Albert Li-Yuan**

1. Human Subjects Research Determination

1. Project Investigators

Role	Investigator	Department	Consent personnel role	Primary contact	Truman VA Hospital personnel
Principal Investigator	Hsu, Albert Li-Yuan	Ob, Gyn & Women's Health		☑	☐
Co-Investigator	Ernst, Rebecka Marie	Dean - Medical Education		☐	☐
Co-Investigator	Florio, Karen Lynn	Ob, Gyn & Women's Health		☐	☐
Co-Investigator	Niu, Xiaofan	Biomed Informatics Biostat EPI		☐	☐
Co-Investigator	Song, Xing	Biomed Informatics Biostat EPI		☐	☐
Co-Investigator	Spinka, Christine Marie	Biomed Informatics Biostat EPI		☐	☐
Research Staff	Jones, Anna Christena	Ob, Gyn & Women's Health		☐	☐

2. Contact Information

Principal investigator

Hsu, Albert Li-Yuan

Job title	ASSISTANT PROFESSOR OF CLINICAL OBSTETRICS & GYNECOLOGY
Department	Ob, Gyn & Women's Health
Division	Medicine
Business unit	University of MO-Columbia

Primary contact

Hsu, Albert Li-Yuan	
Job title	ASSISTANT PROFESSOR OF CLINICAL OBSTETRICS & GYNECOLOGY
Department	Ob, Gyn & Women's Health
Division	Medicine
Business unit	University of MO-Columbia

3. Project Title:

DRIVERs: Data systems Research to Identify driVers of Ethnic & Racial Inequities in Maternal Mortality

4. Describe the purpose of your project.

Note: If you are using an investigational invitro diagnostic device on biospecimens, you must complete the IRB application, even if the biospecimens are unidentified.

Our overall objective is to better-understand hospital- and structural-level factors associated with maternal mortality and severe maternal mortality (SMM) in the US. Our central hypothesis is that social determinants of health and hospital factors significantly impact maternal and pregnancy outcomes, and are more prognostic for BIPOC (Black, Indigenous, People of Color) populations. We will test this hypothesis with this aim:

- Aim: to elucidate the impact of structural and social determinants of health, on rates of maternal mortality and SMM, and to assess the extent to which these factors explain or predict inequity in these outcomes among Black birthing people. We hypothesize that components of structural racism such as racial residential segregation, and downstream consequences of structural racism such as neighborhood walkability, greenspace access, employment, insurance status, and allostatic load, will have a significant association with mortality and SMM, and will help explain inequity in mortality and SMM rates between Black and White birthing people. We will utilize the Greater Plains CollaborativeTM (PCORnet) data system to link clinical and demographic data with social security death files, obituary files, and geocoded residence data. Geocoding allows us to link structural measures via the Census and American Community Survey. We will leverage a generalized linear mixed model (GLMM) to estimate the smoothed relative risks (RRs) of mortality and SMM.

THERE WILL BE NO INVOLVEMENT OF HUMAN SUBJECTS IN THIS RETROSPECTIVE STUDY.

5. What do you intend to do with the data collected?

Using the PCORnet data system, our collaborators (Drs. Song and Niu) will link PCORnet clinical and demographic data with social security death files, obituary files, and geocoded residence data at MU. This dataset will be deidentified, and then used to determine predictors of maternal morbidity and mortality in Missouri.

Similarly, our collaborator Dr. Michelle Debbink will perform a similar linkage of PCORnet clinical and demographic data with social security death files, obituary files, and geocoded residence data at the University of utah. This dataset will be deidentified, and then used to determine predictors of maternal morbidity and mortality in Utah.

6. Quality Improvement Activities VS Human Subject Research Determination

A. Do you consider the activities you will perform to be Quality Improvement instead of human subject research?

If yes, you will be prompted with additional questions.

○ Yes ● No

7. De-Identified Biospecimens and/or Information

A. Does this project involve analyzing de-identified, secondary information?

● Yes ○ No

B. Is this a dataset requiring a contract or other data use agreement to be in place (and potentially an IRB approval)?

Typically datasets requiring a contract or other data use agreement have the potential for identification making the dataset not truly "de-identified".

If yes to this question, you can stop here and not submit this form. You will need to submit, at minimum, the IRB application for an exemption under category 4 if it applies. However, if it's part of a federally funded, multi-site expedited or full board study, and we are not the IRB of Record, you should contact our office to discuss a reliance agreement and not continue this form.

○ Yes ● No

C. Does the project involve analyzing de-identified biospecimens (and possibly corresponding de-identified health information) obtained through pathology, an MU associated repository, or another source?

○ Yes ● No

D. Identifiers

Select all potential identifiers that may be accessed and/or included in the research records for the study.

- ☐ Names
- ☐ Dates
- ☐ Postal Addresses
- ☐ Phone Numbers
- ☐ Fax Numbers
- ☐ Email Addresses
- ☐ Social Security Numbers
- ☐ Medical Record Numbers
- ☐ Health Plan Numbers
- ☐ Account Numbers
- ☐ License or Certificate Numbers
- ☐ Vehicle ID Numbers
- ☐ Web URLs
- ☐ IP Addresses
- ☐ Biometric Identifiers
- ☐ Facial Photos or Images
- ☐ Any other unique identifier
- ☐ No identifiers (none of the above apply)

E. Does the study involve analyzing de-identified information that will be de-identified by a third party unrelated to the research?

● Yes ○ No

F. Describe the de-identification process including (a) information about how these data or biospecimens are already publicly or commercially available in de-identified form, OR (b) what process a third-party has available to provide the information or biospecimens in a de-identified form.

The BMI data engineering team will perform all data linkage and de-identification, and our investigators will only be involved with analysis of the de-identified data.

This dataset will be used to determine predictors of maternal morbidity and mortality in Missouri.

G. Identify the third party or parties providing oversight to ensure appropriate de-identification processes are in place and that no attempt to re-identify subject or their identifiers will occur.

NextGen BMI (Bioinformatics) service center, https://nextgenbmi.umsystem.edu/

8. DHHS Human Subject Research

A project falls under DHHS regulations if it is research and involves human subjects. The questions below will assist in making this determination.

A. Is the project a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge?

This is the DHHS definition of research. MU defines a “systematic investigation” as an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question. MU defines “generalizable knowledge” as those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program.

● Yes ○ No

B. Human Subject

The following questions break down this definition to assist in making this determination.

i. Will investigators conduct research about living individuals?

“About” means the information and/or biospecimens collected must be about the living individuals. It may not necessary to obtain IRB approval if the study is about a particular policy, agency, program, technology, technique, or best practice. If information collected is not about the human subject themselves, but rather about an external topic, then it doesn’t meet the definition of human subject including “…about whom..”.

● Yes ○ No

ii. Will you obtain information or biospecimens through intervention or interaction with the individual, and use, study, or analyze the information or biospecimens?

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject.

○ Yes ● No

iii. Will you obtain identifiable private information or biospecimens?

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). **Identifiable private information or biospecimens** is when the identity of the subject is or may be readily ascertained by the investigator or associated with the information or biospecimen.

○ Yes ● No

Note: If you marked yes to (A) research and yes to (i) living human subjects and yes to (ii) and/or (iii), the activity is human subjects research requiring an IRB application. Please exit this form and complete the IRB Application under IRB Forms.

C. The following activities have been deemed NOT human subject research. Please select from any of the following if it applies to the proposed activities:

☐ **Publicly or commercially available information/data** with no restrictions on the use of the information.

☐ **Publicly or commercially available biospecimens** with no restrictions on the use of biospecimens.

☐ **Public health surveillance activities,** including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

☐ Collection and analysis of information, biospecimens, or records by or for **criminal justice agency** for activities authorized by law or court solely for criminal justice or criminal investigative purposes.

☐ Authorized operational activities (as determined by each federal agency) in support of **intelligence, homeland security, defense, or other national security missions**.

☐ **Scholarly and journalistic activities focused on a person/family/group** (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

9. FDA Human Subject Research - Clinical Investigations

A project falls under FDA regulations if it is research and involves human subjects. The questions below will assist in making this determination.

A. Does the project involve a test article regulated by the FDA?

A test article is any product that is regulated by the FDA, including: food, dietary supplements, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, or certain electronic products used for human health care.

○ Yes ● No

NOTE: Registered Nurses as PI or Co-I : If you are a Registered Nurse and Employee of MU Health Care, please contact Renae McIntosh, Coordinator of EBP and Nursing, for additional information regarding MU Health Care project tracking at mcintoshr@health.missouri.edu.

Generated at: **09/28/2023 03:33 PM**