PROTOCOLS

#809331 - ENACT Hub Enclaves for De-identified data

Protocol Information

Review Type	Status	Approval Date	Continuing Review Date
Expedited	**Approved**	**Jan 05, 2024**	**Jan 05, 2024**

Expiration Date	Initial Approval Date	Initial Review Type
--	**Jan 05, 2024**	**Expedited**

Feedback

Approval Comment

The above-referenced project was reviewed and approved through the expedited IRB review process in accordance with the requirements of the Code of Federal Regulations on the Protection of Human Subjects (45 CFR 46) including its relevant Subpart, for federally funded/ support research studies.

This study was reviewed through the expedited review procedure as authorized by 45 CFR 46.110 and falls under the following research categories;
(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes, such as medical treatment or diagnosis.

It was determined that waiver of informed consent may be granted for this project as it meets the requirements outlined in 45 CFR 46.116(f); the research is minimal risk; the waiver or alteration will not adversely affect the rights; welfare of the subjects; the research could not practicably carried out without the waiver or alteration.

In addition, a waiver of individual authorization for the use of Protected Health Information (PHI) was granted as stipulated by the HIPAA Privacy Rule,
45 CFR 164 section 512(I) and that the proposed research satisfies following criteria:
1. The use or disclosure of PHI involves no more than minimal risk.

2. Granting of waiver will not adversely affect privacy rights and welfare of the individuals whose records will be used.
3. The project could not practicably be conducted without a waiver.
4. The project could not practicably be conducted without use of PHI.
5. The privacy risks are reasonable relative to the anticipated benefits of research.
6. An adequate plan to protect identifiers from improper use and disclosure is included in the research proposal.
7. An adequate plan to destroy the identifiers at the earliest opportunity, or justification for retaining identifiers, is included in the research proposal.
8. The project plan includes written assurances that PHI will not be re-used or disclosed for other purposes.

The PHI for which use has been determined to be necessary includes the following:
1. Medical records of patients with at least two recorded medical encounters since 01 JAN 2000 - Prospective until end of study.
2. Data variables collected will include; patient demographics, medical diagnosis, interventions, procedures, related clinical encounters, clinical measurements (clinical labs, vital signs), associated conditions, pharmacological treatments.
3. Inclusion criteria: patient records with a longitudinal phenotype defined as having at least two encounters in EMR, over any two year period and having at least one measurement (clinical lab or vital sign).
4. Exclusion criteria: patient records in which conditions, medications, procedures or measurements appear in less than 10 individual encounters.

This waiver was granted using expedited review procedures.

It was determined that this project presents no more than minimal risk to human subjects in that 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.

The protocol listed the following funding (or potential funding) information:
Federal / NIH National Center for Advancing Translational Sciences
University of Pittsburgh
Award #311038-00001: ENACT (Evolve to Next-Gen ACT)

Please note the PI and study team are also required to maintain their responsibilities under UC San Diego PPM 100-5 (Responsibilities section, item d) as well as other approvals or permissions required by applicable laws or university policies.

This approval, based on the degree of risk, does not expire unless otherwise stated in this letter.

You may contact our office at 858-246-HRPP (858-246-4777) or at irb@health.ucsd.edu. Your call or email will automatically generate a support ticket for the Office of IRB Administration to track and respond to your request.

Best wishes for the successful conduct of the protocol.

Project Basics

STUDY TITLE

ENACT Hub Enclaves for De-identified data

PRINCIPAL INVESTIGATOR

HOGARTH, MICHAEL

Lead Department:

Medicine

Facesheet Inclusion

General Information

SUBMISSION TYPE

IRB Review

Submission for IRB Review.

Human Subjects Research – Expedited/Full Board

PI is a PI-eligible UCSD employee

Yes

LOCATION WHERE ACTIVITY(IES) WILL BE PERFORMED

UCSD Facilities or Sites (e.g., school, hospital or clinics, etc.)

LAY LANGUAGE SYNOPSIS OF THE PROPOSED ACTIVITY

ENACT is a CTSA-funded national federated electronic health record (EHR) network for translational research. This project involves making EHR data de-identified to HIPAA LDS available to institutional investigators within the ENACT data enclave, an “air-gapped” HIPAA compliant private cloud

managed by UC San Diego. Users access the de-identified EHR data through a virtual research desktop and are blocked from connecting to resources outside of its internal private network boundary. ENACT users must be from participating sites and must sign a data use agreement (DUA) prior to accessing the data in the enclave.

Will UCSD serve as the IRB of Record for other institutions/organizations?

Yes, UCSD IRB will be IRB of record for other sites. (Please complete the Participating Site Section.)

Study Personnel

List the names of all UCSD/RCHSD employees conducting the research or acting as a point of contact on the study.

Instructions to add or update person.

- **Click "+ Add Line" to insert additional person.**
- **Select the Edit Pencil next to a person to edit or update. Be sure to choose Permission as Full Permissions or Read Only for each person.**

Person

HOGARTH, MICHAEL

Home Unit

Medicine

Institutional Title

Professor

Researcher Role

Principal Investigator

Permissions

Please choose ONLY ONE option from the below.

Full Access

Person

Westermann, Amy

Home Unit

VC-HEALTH SCIENCES

Institutional Title

Project and Grant Manager

Researcher Role

Key Person

Permissions

Please choose ONLY ONE option from the below.

Full Access

Will any of the personnel listed above NOT be involved in the consent process?

Not Applicable - No direct contact with research participants

Do any of the personnel listed above have any potential conflict of interest related to the research?

No

Unnamed personnel will help conduct the research at or under the direction of UCSD/RCHSD, such as:

- **Residents or students who rotate through for short periods**
- **Volunteers**
- **Outside Contractors (e.g., survey firm)**