IRB APPROVAL OF APPLICATION

December 20, 2022

Dear Aaron Lee:

On 12/16/2022, University of Washington IRB Committee D reviewed the following application:

Type of Review:	Initial Study
Title of Study:	AI Ready and Equitable Atlas for Diabetes Insights (AI-READI)
Investigator:	Aaron Lee
IRB ID:	STUDY00016228
Funding:	Name: National Institutes of Health (NIH), Grant Office ID: A171325, Funding Source ID: OT2OD032644
IND, IDE, or HDE:	None

The modifications required to secure approval were reviewed and the application fully approved on 12/20/2022.

IRB Approval

Under FWA #00006878, the IRB approved your activity from 12/16/2022 to 12/15/2023.

- **Depending on the nature of your study, you may need to obtain other approvals or permissions to conduct your research. For example, you might need to apply for access to data or specimens (e.g., to obtain UW student data). Or, you might need to obtain permission from facilities managers to approach possible subjects or conduct research procedures in the facilities (e.g., Seattle School District; the Harborview Emergency Department).**
- You are required to **(1)** obtain IRB approval before making any changes (modifications) to your research, and **(2)** provide the IRB with any Reportable New Information such as breaches of confidentiality or unanticipated problems.
- COVID NOTE: See the HSD website for the latest COVID guidelines for conducting human subjects research.
- Tracking IRB approval periods and preventing a lapse is ultimately the researcher's responsibility. However, the Zipline system sends courtesy reminders prior to expiration of approval. If a renewal application or study closure is not received within 90 days of expiration, HSD may administratively close the study. In some circumstances, HSD may refuse to review additional submissions from the researcher until a status report is received, the lapse may be considered continuing non-compliance, and the study may be "terminated" by the IRB.
- This approval applies only to the activities described in your application (including any references to specific grant sections). It does not include other activities that may be described in your grant or contract.

- This approval applies only to the generic protocol and the UW site. You will receive a separate approval notice for each additional participating site.
- This approval is for the number of subjects described in your application (in total and for each group). Submit a Modification to request an increase in the number of approved subjects, if necessary. Exceeding the IRB-approved number (**over-enrollment**) will be considered non-compliance.
- Your study has a Certificate of Confidentiality (CoC) because you have federal funding or because you have applied for and received one from a federal agency. See this INFORMATION SHEET for a description of the CoC protections and responsibilities.
- If you plan to continue data collection past the expiration of the CoC, contact the Human Subjects Division prior to expiration. We will help you determine whether you need to apply for a CoC extension.
- Before enrolling non-English speaking subjects, the IRB must receive all translated consent materials that will be provided to subjects in written or electronic form.

Determinations, waivers, and regulations

The IRB made the determinations and waivers listed in the table below. Note that any granted waivers of consent or parent permission do not override a subject's refusal to provide broad consent.

Requirement	Determination or Waiver
Consent	Waiver of consent for pre-screening subjects to determine eligibility, waiver of consent to ask subjects to fast for the blood draw
HIPAA Authorization	Waived for prescreening to determine eligibility

Location of documents

Use the consent forms that were approved and stamped by the IRB. They can be downloaded from the Final column under the **Documents tab** in Zipline.

In addition, HSD has uploaded the following documents to the **Documents tab** in Zipline:

- Unsigned Genomic Data Sharing Certification letter

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,

Rachel Thomas, CIP
Pronouns: she/her/hers
Senior Review Administrator, Committee D
Human Subjects Division
University of Washington
206-685-9379
Rthomas2@uw.edu