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**IRB:** [IRB 00190712](#)

**Responsible Investigator:** Mark Yandell

**Title:** Personalized Risk Stratification in Atrial Fibrillation using Portable, Explainable Artificial Intelligence

**Date:** 5/16/2025

The above-referenced protocol has received an IRB exemption determination and may begin the research procedures outlined in the University of Utah IRB application and supporting documents.

#### EXEMPTION DOCUMENTATION

**Review Type:** Exemption Review

**Exemption Category(ies):** Category 4

**Exemption Date:** 5/16/2025

**FWA Designation:** Federal Oversight

Note the following delineation of categories:

- Categories 1-8: Federal Exemption Categories defined in 45 CFR 46.101(b)
- Categories A-E: Non-Federal Exemption Categories defined in University of Utah IRB policy in [Investigator Guidance Series, Exempt Research](#)

#### DETERMINATIONS

- **Waiver/Alteration Determination:** The IRB has determined that the request for the **waiver of authorization** as described in this application is approved for this research under 45 CFR 164.512(i).

You must adhere to all requirements for exemption described in University of Utah IRB policy in ([Investigator Guidance Series, Exempt Research](#)). This includes:

- All research involving human subjects must be approved or determined exempt by the IRB before the research is conducted.
- All research activities must be conducted in accordance with the Belmont Report and must adhere to principles of sound research design and ethics.
- Orderly accounting and monitoring of research activities must occur.

#### Ongoing Submissions for Exempt Projects

- **Continuing Review:** Since this determination is not an approval, the study does not expire or need continuing review. This determination of exemption from continuing IRB review only applies to the research study as submitted to the IRB. You must follow the protocol as proposed in this application.
- **Annual HRPP Progress Updates:** For studies that do not receive formal continuing review, an Annual HRPP Progress Update must be submitted in order to keep the study open and active with the University of Utah IRB and HRPP: <https://irb.utah.edu/submit-application/progress-updates.php>
- **Amendment Applications:** Substantive changes to this project require an amendment application to the IRB to secure either approval or a determination of exemption. **Investigators should contact the IRB Office if there are questions about whether an amendment consists of substantive changes.** Substantive changes include, but are not limited to

- Changes to study personnel (to secure Conflict of Interest review for all personnel on the study)
- Changes that increase the risk to participants or change the risk:benefit ratio of the study
- Changes that affect a participant's willingness to participate in the study
- Changes to study procedures or study components that are not covered by the Exemption Category determined for this study (listed above)
- Changes to the study sponsor
- Changes to the targeted participant population
- Changes to the stamped consent document(s)
- **Report Forms:** Exempt studies must adhere to the University of Utah IRB reporting requirements for unanticipated problems and deviations: <http://irb.utah.edu/submit-application/forms/index.php>
- **Final Project Reports for Study Closure:** Exempt studies must be closed with the IRB once the research activities are complete: <http://irb.utah.edu/submit-application/final-project-reports.php>

## SUPPORTING DOCUMENTS

### Grant Application

R01 AF PBC SAs Research de novo BAS 05

Click [IRB 00190712](#) to view the application.

Please take a moment to complete our [customer service survey](#). We appreciate your opinions and feedback.