UCSRS ATLAS Trial — Study Protocol

ATLAS — Assessment of Transnational Performance of Universal Cardiac Surgical Risk Score Across International Sites

Principal Investigator: Atiq Rehman, MD · atiqmd@aol.com **Reference:** J Cardiothorac Surg 2026 (DOI 10.1186/s13019-026-04433-x) · Calculator: ucsrs-calculator.netlify.app **Protocol version 4.3 · 24 October 2026** — current version *This version reflects the UCSRS v3.2 engine, including the v3.0 architecture change: Layer 1 is now a single log-odds baseline (the STS/EuroSCORE-inspired blend is retired); EuroSCORE II is not computed by the engine; each site calculates it independently and it is recorded only as a comparator. See "What changed in v4.0" below.*

What changed in v4.0

The trial documents are updated to match the UCSRS v3.2 engine (SPEC_VERSION 3.2.0). The v3.0 release changed Layer 1's architecture after the v2.1 protocol was written, as follows (the v3.1 and v3.2 calibration and weight changes are described under "Version locking" below):

1. **No blend. Layer 1 was a 50/50 blend of a physiology-derived baseline and an internally-computed EuroSCORE II. It is now a single log-odds baseline. EuroSCORE II is not computed by the engine at all; each site submits its own independently-run EuroSCORE II value, used centrally as the external comparator, and it never enters the UCSRS score.**

2. **Renal term. The Layer 1 renal term now reads serum creatinine directly.Dialysis patients are scored, in both Layer 1 and the MELD calculation, as if creatinine = 4.0 mg/dL — a fixed substitution, not a separate flat weight. Sites still submit the patient's actual measured creatinine.**

3. **Age term.** Age is now **banded**, each band set to EuroSCORE II's own log-odds delta at the band midpoint, with an accelerated step above age 80. Because the bands are fitted to EuroSCORE II's own curve, UCSRS's added value no longer rests on any claim that Layer 1 is independent of EuroSCORE II — see point 5.

4. **Frailty instrument.** The Frailty Test **(FT, 0–6)**: (chair-rise, cognition assessment, hemoglobin, albumin) plus a second hemoglobin point scored when hemoglobin is below 8.0 g/dL and a second albumin point scored when albumin is below 3.0 g/dL (the total is capped at 6).

5. **MELD correction.** The MELD log-odds slope is now two-segment (replacing the earlier single-segment slope). As issued at v3.0 it was 0.18 per point from MELD 9–20 and 0.08 per point above MELD 20; at v3.2 these were lowered to 0.086 per point from MELD 9–20 and 0.038 per point above MELD 20.

6. **Procedure increments** were re-anchored to EuroSCORE II's own published intervention-class baselines plus a UCSRS-specific adjustment, rather than scaled from the earlier blend.

No data collection field, outcome definition, consent model, or ethics/regulatory position changes as a result of this update — see the companion v4.3 Data Dictionary and Ethics/Consent/Data Protection Statement for field-level and consent-level detail.

Background

UCSRS is a physiology-informed risk model. Its first layer is a **single log-odds baseline**, computed from the patient's own clinical variables — age (banded, fitted to EuroSCORE II's own log-odds delta at each band midpoint, with an accelerated step above age 80), renal function (serum creatinine directly; dialysis substituted at creatinine 4.0), and other established risk factors. To the baseline UCSRS adds one mandatory input — frailty, assessed by Frailty Test (FT, 0–6: chair-rise time, cognition assessment, hemoglobin [with a second point below 8.0 g/dL], albumin) — and further optional physiologic domains (MELD/Layer 2a, LV geometry and SYNTAX/Layer 2c, right-heart catheterization/Layer 3) applied as additive and multiplicative corrections.

This study validates UCSRS v3.2, whose specification was settled, dated and archived before first enrollment. It departs from the published v1.0 in several documented respects, each recorded in a dated Specification of Record rather than absorbed silently:

1. **Frailty instrument** — the Layer 2b instrument is Frailty Test (FT, 0–6) in place of the Clinical Frailty Scale, adopted at the request of participating sites for objectivity and inter-rater reliability.

2. **Layer 1 architecture** — Layer 1 no longer uses STS-PROM as an input and, since v3.0, is no longer blended with EuroSCORE II. It's a single log-odds baseline built from the patient's own clinical variables; EuroSCORE II and STS-PROM are reported only as comparators, calculated independently by the site. Requiring STS-PROM would mean three scores per patient, and a score built from or blended with a comparator can't be fairly validated against it. UCSRS's value comes from Layers 2a–3 (MELD, frailty, LV/SYNTAX, right-heart), not from Layer 1 being independent of EuroSCORE II — the age bands are deliberately fitted to EuroSCORE II's own curve.

3. **Weight reduction** — the frailty ladder and the MELD slopes were each reduced from the originally published values, and the baseline floor lowered, before being re-derived (v3.0, and again at v3.2) against calibration targets (median observed/expected = 1.00 across thirteen anchorable registries) rather than against EuroSCORE II.

4. **Baseline form** — the Layer 1 baseline is derived in log-odds rather than percentage points.

STS-PROM and EuroSCORE II remain required in the dataset as comparators. They are what UCSRS is tested against, not what it is built from, and keeping them is what makes the three-way head-to-head comparison possible. The STS coefficients are not public, so the coordinating center cannot recompute STS-PROM centrally from raw variables; the site's own value is the only source.

No performance claim accompanies the current specification. The model constants were set against published registry mortality using synthetic cohorts in which no simulated patient has an outcome. Established scores are frequently miscalibrated outside their derivation populations; whether UCSRS improves prediction of early post-operative outcomes is what this study exists to determine, prospectively and across diverse international centers.

Objective

To prospectively compare the discrimination and calibration of UCSRS, STS-PROM, and EuroSCORE II for 30-day outcomes after adult cardiac surgery.

Design

Prospective, observational, multicenter cohort. All three risk scores are recorded for each patient; no score influences clinical management. The same protocol is applied at every participating site. More than one site may participate per country to increase that country's total patient numbers.

Population & Enrollment

Consecutive adult patients (≥18 years) undergoing cardiac surgery at each site, enrolled over a 12-month period (one full year of consecutive cases per center).

Primary Endpoint

30-day MACCE — a composite (as defined for this study) of:

- All-cause mortality
- Permanent stroke
- Renal failure (per the current STS Adult Cardiac Surgery Database definition)

- Prolonged ventilation (>24 hours)

STS standard definitions are applied uniformly at all sites.

Data Collection

1. Per patient: the clinical variables from which the scores are computed, the two comparator score values, and the four outcome components (30-day MACCE).

2. **Required inputs** are the demographic, procedural and comorbidity variables the site already enters into the STS-PROM and EuroSCORE II calculators, together with ejection fraction and creatinine; the site's own **STS-PROM and EuroSCORE II values, recorded as comparators**; and the Frailty Test (FT) components — pre-operative hemoglobin and albumin (routine labs, required for every patient, with a second hemoglobin point below 8.0 g/dL), and the five-repetition chair-rise time and a cognition assessment (eyeball evaluation of normal or impaired cognition), which may be deferred where the patient's condition does not allow them (urgent/emergency). The score is then computed from the available components as a partial FT, with the missing components recorded.

3. Where an optional UCSRS domain is unavailable or not used — MELD, LV dimensions (LVEDD/LVESVI), SYNTAX, or RHC — the site records that the domain was missing and, briefly, why if possible. There is no minimum set and none is expected; missingness must be uniform across the cohort rather than patient-selected.

4. **Sites compute nothing derived.** No MELD, no creatinine clearance, no body surface area, no volume index, no frailty total. Raw measurements are submitted and every derived quantity is computed by the same code for every site, which is what makes the comparison between sites meaningful. Sites always submit the patient's actual measured creatinine, even for dialysis patients — the substitution used internally (creatinine treated as 4.0 for dialysis patients, in both Layer 1 and MELD) is applied centrally, not by the site.

5. Most fields already exist in routine surgical databases.

6. Each site contributes one year of consecutive cases; pooled target ≈ 5,000 patients (≥150 events at an expected 3% mortality) or more across all sites.

7. Center demographics and case-mix (age, sex, BMI/BSA, comorbidities, LVEF, procedure type, urgency) are derived automatically from the score inputs — no separate demographic collection is needed.

8. Region is the primary population descriptor; self-identified ethnicity is an optional field, recorded only where locally permitted and specifically ethics-approved (chiefly relevant in multi-ethnic countries).

Data Handling & Analysis

All data are de-identified at the site before any sharing — no patient identifiers leave your institution. De-identified datasets are analyzed centrally using standard, validated statistical and machine-learning packages (Python: pandas, scikit-learn, XGBoost), with the analysis pipeline orchestrated using LLM-based tooling; all statistical computations are performed by these validated packages. Where national rules restrict export of patient-level data, or where a site simply prefers it, the site instead runs the identical standardized analysis locally and shares only summary results (c-statistic, observed/expected ratio, calibration slope and intercept), which are combined by summary-level meta-analysis. Comparison is head-to-head: discrimination (c-statistic, DeLong test) and calibration (calibration plots, observed/expected ratio, calibration slope and intercept) for each score.

Secure transmission. Where a site transmits anything to the coordinating center — a summary result or a de-identified patient-level file — it uses either its own institutional secure file-transfer service, or a password-protected 7-Zip (.7z) archive using AES-256 encryption, with the archive emailed and the password sent separately by telephone or a different email, never in the same message as the file. 7-Zip is a free download from 7-zip.org.

Version locking. The model constants live in a single reference implementation whose SPEC_VERSION (currently 3.2.0) is written into every site's output, so each site's result records which specification produced it. A parity test confirms that the analysis engine and the published browser calculator agree to within 0.005 percentage points across 4,000 random patients, so the number a site computes and the number the published calculator shows at the bedside are the same number. Addendum, 24 October 2026: v3.2 changed four scoring elements and added one operation — aortic disease is counted once, the MELD slopes were lowered, the frailty ladder is applied to the odds rather than to the log-odds contribution, and the calibration constant was re-solved against thirteen published surgical registries — and added CABG + AVR + MVR as an operation. No data collection field, outcome definition, consent model or ethics position changes. The v3.2 constants were set by the investigator before first enrollment, as a documented exception to the earlier commitment not to move coefficients before 5,000 patients are enrolled; thereafter they are not moved before that point. See UCSRS_ATLAS_Model_Change_Statement_v3.2.docx for the release in full.

Trial Registration

ATLAS is not yet registered on ClinicalTrials.gov. Registration requires an IRB of record; WCG IRB approved the study for the coordinating investigator (Union Hospital) on 14 October 2026 (IRB tracking number 20263741). Registration is pending and will be updated once the study is registered; it will be registered as an observational cohort study. The NCT number will be circulated to all participating sites when issued, and no patient will be enrolled at any site before then.

Ethics & Regulatory

There is no central or sponsor ethics approval for ATLAS that covers participating sites, and none is issued to them. This is a design choice, not an omission: the study has no commercial sponsor and no central enrolling institution, so no body could hold an approval on a site's behalf. Ethical oversight is **local by design** — each participating center obtains approval from its own ethics committee, under its own national law, **before enrolling any patient**. Sites should plan their local approval process into the enrollment schedule; in some jurisdictions it runs to three or four months. WCG IRB (IRB tracking number 20263741; study number 1417588) reviewed ATLAS for the coordinating investigator, Atiq Rehman, MD, at Union Hospital, Terre Haute, Indiana. On 14 October 2026 it determined the research exempt under 45 CFR 46.104(d)(4), with no continuing review required, and approved a waiver of HIPAA authorization (letter of 15 October 2026). That determination covers the coordinating investigator's own activity under US regulations only. It is not an approval for any other site, and each participating center still obtains approval from its own ethics committee under its own national law before enrolling any patient. The WCG IRB certificates of action and waiver letter are included in the IRB submission folder and may be forwarded with a site's application.

No regulatory authorization is engaged in any jurisdiction. ATLAS deploys no investigational medicinal product, no device, no implant, and no biological sample collection. The scores are computed but are **never returned to the treating team** and appear nowhere in the patient record, so UCSRS is not deployed as clinical decision-support and no medicines-or-devices pathway (SAHPRA, MHRA, EMA, FDA, or equivalent) is triggered. ATLAS is **not a clinical trial** under ICH-GCP or ICMJE definitions, since there is no prospective assignment to an intervention.

Risk category. The study is of no more than minimal risk: no intervention, no additional imaging or invasive test, and no change to clinical management. The only study-specific bedside items are the two Frailty Test (FT) performance components — a five-repetition chair-rise and a brief cognition assessment — which are non-invasive, take minutes, and are already part of routine pre-operative assessment in many programs; where they are not routine, they constitute a minimal-risk patient interaction (see the Ethics Statement, §5). The residual risk is informational, addressed by de-identification at source. Sites should ordinarily submit under their committee's **minimal-risk or expedited** category.

Consent. The consortium does not prescribe a consent model — the local committee decides. A **waiver of individual informed consent** is ordinarily appropriate (minimal risk; no adverse effect on rights or welfare; no individually actionable finding generated; impracticable to obtain, since valid calibration assessment requires *consecutive, unselected* cases). Sites may instead rely on general institutional consent to use of clinical information, or obtain individual written consent, without affecting eligibility to participate. Some jurisdictions do not provide an express waiver pathway; sites should establish their local position before drafting.

Coordinating-center status. The coordinating center has no contact with patients, obtains no identifiable private information, holds no code key, and cannot re-identify any record. Its activity is therefore secondary analysis of de-identified data. WCG IRB determined it exempt under 45 CFR 46.104(d)(4) on 14 October 2026 (IRB tracking number 20263741, study number 1417588) and approved a waiver of HIPAA authorization; the certificates of action are included in the IRB submission folder. No site may rely on, or cite, that determination as its own approval.

Competing interest, declared: the coordinating investigator is the developer of UCSRS. This is declared in all study documentation and in every publication. Negative results will be published.

*Full detail is set out in the **UCSRS ATLAS Ethics, Consent & Data Protection Statement (v4.3)**, which is written to be attached directly to a site's own ethics-committee application, together with country-specific annexes where issued.*

Site Leadership & Authorship

Each participating center designates a local Site Principal Investigator (PI), who secures local ethics approval and oversees local data collection.

- **Single-site / institutional papers.** The Site PI is **first author and corresponding author**, and selects the paper's co-authors. Atiq Rehman, MD (Consortium Coordinator) is senior (last) author.
- **Countrywide and regional papers.** Where a country or region runs more than one site, a **Country Lead or Regional Lead** is designated to coordinate that country's sites and is first author on that country's pooled paper. Atiq Rehman, MD remains senior (last) and corresponding author, with that country's site PIs as co-authors and secondary authors accordingly.
- **Pooled multinational paper.** The single combined cross-country analysis is led and first-authored by Atiq Rehman, MD, who is also corresponding author. Site and Country PIs are co-authors, ordered by each site's or country's enrollment volume, with their own secondary authors following in turn; the UCSRS ATLAS Consortium is credited as a collaborative group.

- **Group authorship.** Contributors not meeting individual byline criteria are acknowledged as PubMed-indexed Consortium collaborators.

Terms are set out in the one-page Authorship & Publication Agreement, provided on affirmation of interest.

To participate, or to request the full data dictionary, the Ethics & Data Protection Statement, or a country annex, reply to atiqmd@aol.com.