BIO-001 Psychophysiology Protocol

Matched-community HRV and salivary-cortisol study framework
Working Draft 0.1 / July 28, 2026

NOT IRB APPROVED. No recruitment, consent, data collection, or public claims may begin until a qualified Institutional Review Board has approved the final protocol and consent materials.

1. RESEARCH QUESTION

In an adult volunteer sample, does participation in the Old Glory Peak field-station program correspond with longitudinal changes in resting heart-rate variability and diurnal salivary cortisol compared with a matched control community?

2. DESIGN

- Prospective, quasi-experimental, repeated-measures comparison of an Alpha Node and matched Control Node.
- Pre-registration on OSF before recruitment or analysis.
- Measurement schedule: 5-minute resting RMSSD recordings three times weekly; paired morning and evening saliva samples monthly.
- Observation window, sample size, matching variables, and six supplementary outcomes must be fixed in the IRB submission and pre-registration.

3. PARTICIPANTS

Proposed participants are adults age 18 or older who can understand the consent form and safely complete the procedures. Final inclusion, exclusion, pregnancy, medication, cardiovascular, endocrine, and acute-illness criteria require clinical and IRB review before use.

4. PROCEDURES

Procedure	Schedule	Standardized conditions
Resting HRV	Three times weekly	Polar H10 chest strap; seated or supine; 5-minute RMSSD segment after a defined stabilization period; same time window when practical.
Salivary cortisol	Morning and evening, monthly	Salivette collection; exact clock time recorded; food, caffeine, exercise, nicotine, sleep, medication, and acute illness documented.
Context survey	At each session or scheduled interval	Minimal covariates needed for interpretation; avoid collecting unnecessary sensitive information.
Field-program exposure	Ongoing	Attendance, task type, duration, and environmental conditions recorded without evaluating individual performance.

5. HRV ACQUISITION

- Use the same sensor model and firmware where possible; record device identifier and firmware version.
- Document posture, time of day, recent exertion, caffeine, nicotine, alcohol, sleep, illness, and medications relevant to interpretation.
- Inspect beat-to-beat data for signal loss and artifacts using a pre-registered algorithm and threshold.
- Retain raw RR-interval files. Derive RMSSD in a versioned analysis pipeline without overwriting source data.

6. CORTISOL ACQUISITION

- Use one validated Salivette collection procedure and laboratory assay across all time points.
- Record wake time and actual collection time. Define the morning and evening windows before recruitment.
- Specify storage temperature, maximum pre-freeze interval, chain of custody, shipment, assay batch, and duplicate policy with the selected laboratory.
- Do not collect or ship specimens until biospecimen handling, exposure control, and disposal procedures are approved.

7. OUTCOMES AND ANALYSIS

- Primary physiological outcomes: resting RMSSD and pre-specified salivary-cortisol measure.
- Analysis: repeated-measures model or ANOVA appropriate to the final design, with assumptions and missing-data strategy pre-specified.
- Apply Bonferroni correction to the six supplementary outcomes described in the final pre-registration.
- Report effect sizes, uncertainty intervals, protocol deviations, exclusions, missingness, and negative results.
- Do not interpret association as causation in a non-randomized design.

8. RISKS AND SAFEGUARDS

- Foreseeable risks include temporary chest-strap discomfort or skin irritation, saliva-collection discomfort, fatigue, embarrassment, and privacy loss.
- Participants may pause or stop any procedure without penalty. Establish referral and adverse-event procedures before recruitment.
- Separate contact information from research records. Use coded study IDs and the minimum data necessary.
- Store identifiable linkage files offline with access limited to approved study personnel. Publish only de-identified or aggregated data.

9. GOVERNANCE AND OPEN SCIENCE

The final IRB determination, consent form, protocol, and statistical analysis plan control the study. Pre-registration must precede collection. Public releases must follow the consent scope, privacy review, biospecimen policy, and any restrictions required by the IRB.

10. REQUIRED BEFORE ACTIVATION

- Named qualified principal investigator and scientific or clinical advisor.
- IRB-reviewed protocol, consent form, recruitment language, and data-security plan.
- Final sample size, matching rules, primary and supplementary outcomes, stopping rules, and compensation.
- Laboratory agreement, biospecimen SOP, adverse-event plan, and participant contact procedures.