Standard Operating Procedure (SOP)

Project’s title: Immediate Effects of Therapeutic Group Drumming on Affective States and Stress Biomarkers in College Students

# 1 Purpose

To describe the standardized procedures for administering the therapeutic group drumming intervention and for collecting all pre‑ and post‑session blood pressure, heart rate, self‑report survey, and saliva biomarker data in a safe, consistent, and IRB‑compliant manner.

# 2 Scope

This SOP applies to all principal investigators, co‑investigators, research assistants, and volunteers involved in data collection during scheduled drumming sessions with Lynn University students aged 18 years or older.

# 3 Definitions & Abbreviations

* BP – Blood pressure (systolic/diastolic, mmHg)
* HR – Heart rate (beats min⁻¹)
* QMS – Quick Mood Scale
* SII – Social Interest Index
* ID Token – Numeric code linking all participant data
* PASCO cuff – PASCO Bluetooth blood‑pressure cuff with AirLink transmitter
* Saliva kit – Self‑collection kit with preservative reservoir, funnel, and green screw‑cap

# 4 Responsibilities

* Session Lead (PI or designee): Oversees the entire session and ensures protocol fidelity.
* Data‑Collection Lead: Trains assistants, monitors timing, and verifies data accuracy.
* Research Assistants (RAs): Obtain consent, assign ID tokens, administer surveys, collect saliva, BP, HR, and manage sample chain‑of‑custody.

# 5 Required Materials & Equipment

* Tablet or laptop with Qualtrics survey links and secure Wi‑Fi connection
* ID tokens (laminated cards with unique numbers)
* PASCO BP cuff, AirLink transmitter, and iPad with PASCO Capstone app
* Saliva Self‑Collection Kit (2 mL tube pre‑filled with preservative, detachable funnel, green screw‑cap)
* Nitrile gloves, 70 % ethanol wipes, and disinfectant wipes for drums and BP cuff
* Ice rack or cooled bio‑transport container for saliva tubes
* Access to −80 °C freezer for long‑term sample storage
* Identical hand drums—one per participant—arranged in a circle
* Paper data‑entry backup sheets
* Incident log and adverse‑event report forms

# 6 Participant Flow & Timing Overview

* Check‑in – Consent & ID token assignment (≈ 5 min)
* Pre‑test Surveys (Demographic & Health, QMS, SII) – 10 min
* Pre‑test Saliva, BP & HR – 10 min
* Therapeutic Group Drumming Intervention – 45 min
* Post‑test Surveys (QMS, SII) – 5 min
* Post‑test Saliva, BP & HR – 10 min
* Debrief & Dismissal – 5 min

# 7 Detailed Procedures

## 7.1 Set‑Up (30 min prior)

1. Disinfect drums, BP cuff, table surfaces, and any reusable equipment.
2. Pair PASCO cuff with iPad and verify calibration (0 ± 2 mmHg baseline).
3. Prepare ice rack for saliva tubes.
4. Launch Qualtrics survey links or display QR codes at the Survey Station.
5. Post signage reminding participants of inclusion/exclusion criteria and 30‑min fasting requirement.

## 7.2 Participant Arrival & Consent

1. Greet participant and verify eligibility (≥ 18 yr and enrolled student).
2. Present electronic informed‑consent form; answer questions and obtain agreement.
3. Issue ID token; record link between token and e‑consent (PI‑only file).
4. Direct participant to the Survey Station.

## 7.3 Pre‑Test Surveys

1. Participant completes Demographic & Health Questionnaire, QMS, and SII on Qualtrics.
2. If exclusion criteria are triggered (e.g., pacemaker), mark “Survey‑only” and skip BP/HR collection.

## 7.4 Pre‑Test Saliva Collection — Funnel Kit Method

1. Confirm 30‑min fast except water; allow water rinse if needed and wait 1 min.
2. Provide sealed saliva kit; instruct participant to keep the tube upright.
3. Participant spits through funnel until liquid (not bubbles) reaches the 2 mL fill line.
4. While the tube remains upright, RA unscrews the pink cap and pours the entire preservative liquid into the funnel; wait until volume reaches ~4 mL.
5. Unscrew and discard funnel into biohazard waste.
6. Seal tube with green screw‑cap and invert five (5) times to mix.
7. Label tube with participant ID token and “Pre”; wipe exterior, place upright in ice rack, and log collection time.

## 7.5 Pre‑Test Blood Pressure & Heart Rate

1. Read standardized script to participant.
2. Place PASCO cuff on right upper arm (bare skin).
3. Start measurement; allow automatic inflation (max 200 mmHg).
4. Record systolic, diastolic, and HR in electronic spreadsheet and paper backup.

## 7.6 Group Drumming Intervention (45 min)

1. 5 min warm‑up: basic hand technique and call‑and‑response patterns.
2. 30 min guided rhythmic patterns with progressive complexity and focus on synchrony.
3. 10 min cool‑down: slower tempo, soft dynamics, and silent reflection.
4. Monitor for participant distress; pause or stop if adverse event occurs.

## 7.7 Post‑Test Surveys

1. Participant completes second QMS and SII on Qualtrics.
2. Flag completion in master list.

## 7.8 Post‑Test Saliva Collection — Funnel Kit Method

1. Ensure at least 20 min have elapsed since pre‑collection.
2. Repeat steps 1‑7 of Section 7.4 using a new saliva kit labeled with the same ID token and “Post”.

## 7.9 Debrief & Dismissal

1. Offer participant their BP/HR values upon request.
2. Provide brief explanation of study purpose and contact information for results summary.
3. Remind participant that credit or compensation is given regardless of results; thank them for participation.

# 8 Quality Control & Safety

* Equipment: Verify PASCO cuff calibration at the start of each session.
* Data Entry: Cross‑check electronic and paper BP/HR values at end of session.
* Sample Integrity: Keep saliva tubes on ice and transfer to −80 °C within 30 min.
* Participant Safety: Observe for dizziness, hyperventilation, or anxiety; stop drumming if needed.
* Incident Logging: Record adverse events within 2 h and notify PI/IRB.

# 9 Sample Handling & Storage

* Transport mixed saliva samples on ice to the designated lab (Assaf 104).
* Log receipt in the sample inventory sheet (record ~4 mL volume).
* Store tubes at −80 °C in locked freezer (rack labeled “Drumming Study”).
* Retain samples for planned ELISAs; discard after analyses per biosafety rules.

# 10 Data Management

* Qualtrics exports saved to encrypted university drive.
* Saliva, BP, and HR values merged by ID token; master key stored securely by PI.
* Data retained for at least 3 years post‑study in accordance with IRB policy.

# 11 Decontamination & Session Close‑Out

* Wipe drums, BP cuff, and surfaces with 70 % ethanol.
* Dispose of used funnels, gloves, and wipes in biohazard waste.
* Power down equipment and secure digital and physical records.

# 12 References

Full protocol document and appendices (version 05232025).