DATA MONITORING COMMITTEE (DMC) CHARTER

1. Study Title

Effectiveness of Inspiratory–Expiratory (I:E) Ratio in Pursed-Lip Breathing on Respiratory Outcomes in Patients with Chronic Obstructive Pulmonary Disease (COPD)

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2. Purpose of the DMC

The Data Monitoring Committee (DMC) is established to provide independent oversight of participant safety, data integrity, and study conduct.

The DMC will:

- Monitor participant safety and well-being
- Review study progress and protocol adherence
- Evaluate data quality and completeness
- Provide recommendations on study continuation, modification, or termination

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3. Scope of Responsibilities

3.1 Safety Monitoring

- Review any adverse events (e.g., dizziness, fatigue during PLB)
- Ensure risks remain minimal and acceptable
- Recommend actions if safety concerns arise

3.2 Data Monitoring

- Assess completeness and accuracy of collected data
- Review consistency of outcome measurements (RR, SpO_2, dyspnea)
- Ensure adherence to data collection procedures

3.3 Study Conduct

- Monitor recruitment progress
- Review protocol compliance
- Identify any deviations or operational issues

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4. DMC Composition

The DMC will consist of independent members with no direct involvement in the study:

- **Chairperson:** Clinician with expertise in respiratory care
- **Statistician:** Experienced in clinical trial analysis
- **Clinical Expert:** Pulmonology or nursing specialist

(Optional: Ethics expert if required by committee)

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5. Independence and Conflict of Interest

All DMC members must:

- Be independent from the research team
- Declare any potential conflicts of interest
- Maintain objectivity in all assessments

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6. Meetings

6.1 Frequency

- At least **one formal review meeting** during the study
- Additional meetings if safety concerns arise

6.2 Format

- Meetings may be conducted in person or virtually

6.3 Documentation

- Minutes will be recorded for each meeting
- Recommendations will be documented and communicated to the principal investigator

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7. Data Review Plan

The DMC will review:

- Recruitment and dropout rates
- Baseline characteristics
- Outcome trends (RR, SpO_2, dyspnea)
- Adverse events (if any)

Given the short intervention duration, **no formal interim efficacy analysis is planned**.

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8. Stopping Rules

The DMC may recommend pausing or terminating the study if:

- Unexpected safety concerns arise
- Protocol violations significantly affect validity
- Ethical concerns are identified

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9. Communication

- The DMC will provide written recommendations to the Principal Investigator (PI)
- The PI is responsible for implementing actions and informing the ethics committee if required

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10. Confidentiality

- All data reviewed by the DMC will remain confidential
- No unauthorized disclosure is permitted

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11. Amendments to the Charter

Any changes to this charter must be:

- Agreed upon by DMC members
- Documented and approved before implementation