Kemenkes
Poltekkes Palangka Raya

CLINICAL STUDY PROTOCOL

The Effect of Pregnancy Exercise on Sleep Quality in Third Trimester Pregnant Women in Palangka Raya City, Central Kalimantan

Erina Eka Hatini | Vissia Didin Ardiyani | Addina Yusti Islamadina
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Protocol ID: 121/II/KE.PE/2024

1. GENERAL INFORMATION

- **Principal Investigator:** Erina Eka Hatini
- **Affiliation:** Midwifery Department, Health Polytechnic of Palangka Raya – Indonesia Ministry of Health
- **Co-Investigators:** * Addina Yusti Islamadina (Midwifery Dept, Polkesraya)
  - Vissia Didin Ardiyani (Nursing Dept, Polkesraya)
- **Study Site:** [Insert specific clinic/hospital names or "Community Health Centers in Palangka Raya"]
- **Sponsor/Funder:** [Insert Funder if applicable, e.g., Self-funded or Ministry of Health]

2. BACKGROUND AND RATIONALE

2.1 Problem Statement

Sleep disturbances are highly prevalent among pregnant women, particularly in the third trimester. Poor sleep quality can lead to adverse maternal and fetal outcomes, including increased risk of preeclampsia, prolonged labor, and depressive symptoms. While pharmacological interventions are often avoided during pregnancy due to safety concerns, non-pharmacological interventions such as physical activity are recommended.

2.2 Rationale

Physical activity is known to improve sleep quality in the general population. However, comparative data regarding specific types of exercise—specifically Traditional Pregnancy Exercise (Senam Hamil) versus Stretching Exercises—is limited. Understanding which modality is more effective for improving sleep quality (assessed via PSQI) will help healthcare providers prescribe the most appropriate activity for third-trimester mothers.

2.3 Research Hypothesis

1. There is a significant difference in sleep quality scores between pregnant women performing traditional pregnancy exercises and those performing stretching exercises.
2. Both exercise modalities will result in improved sleep quality scores compared to baseline.

3. STUDY OBJECTIVES

3.1 Primary Objective

To compare the effectiveness of Traditional Pregnancy Exercise versus Stretching Exercise on sleep quality scores in third-trimester pregnant women.

3.2 Secondary Objectives

- To assess the change in anxiety levels (HARS scores) associated with both exercise interventions.
- To evaluate physiological responses (blood pressure/diastolic measures) pre- and post-intervention.

4. STUDY DESIGN

4.1 Study Type

- **Type:** Interventional (Clinical Trial)
- **Design:** Quasi-Experimental (Non-randomized trial)
- **Allocation:** Non-randomized Parallel Assignment (Two Arms)
- **Masking:** Open Label (Participants and instructors know the intervention; Outcome assessors should ideally be blinded if possible).

4.2 Study Timeline

- **Estimated Start Date:** 4th August 2025
- **Estimated Completion Date:** 4th October 2025
- **Intervention Duration:** 3 weeks per participant, 45-60 minutes per session.

5. STUDY POPULATION

5.1 Sample Size

Total sample size: N = 60

- Intervention Group: n = 30
- Control (Comparator) Group: n = 30

$$n = 2\left[\frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)S}{X_1 - X_2}\right]^2$$

$$n = 2\left[\frac{(1{,}96 + 0{,}84)2{,}9910925540121}{6{,}84 - 10{,}10}\right]^2$$

$$n = 2\left[\frac{(2{,}8)2{,}9910925540121}{-3{,}26}\right]^2$$

$$n = 2\left[\frac{8{,}3750591512338}{-3{,}26}\right]^2$$

$$n = 2[-2{,}569036549458]^2$$

$$n = [-5{,}138073098916]^2$$

$$n = [26{,}399795169806]$$

n= 26,399795169806 adding 10%.

Therefore, a minimum of 30 respondents per group is required

S value is calculated in the following:

$$S = \sqrt{\frac{S_1^2(n_1 - 1) + S_2^2(n_2 - 1)}{n_1 + n_2 - 2}}$$

$$S = \sqrt{\frac{2{,}86^2\ (39 - 1) + 3{,}12^2\ (38 - 1)}{39 + 38 - 2}}$$

$$S = \sqrt{\frac{2{,}86^2\ (39 - 1) + 3{,}12^2\ (38 - 1)}{39 + 38 - 2}}$$

$$S = \sqrt{\frac{8{,}1796(38) + 9{,}7344(37)}{75}}$$

$$S = \sqrt{\frac{310{,}8248 + 360{,}1728}{75}}$$

$$S = \sqrt{\frac{670{,}9976}{75}}$$

$$S = \sqrt{\frac{670{,}9976}{75}}$$

$$S = \sqrt{8{,}9466346666}$$

$$S = 2{,}9910925540121$$

Notes :

n	: Sample size
Z	: Z-score
$Z_{1-\alpha/2}$	: 1.96 at the 95% confidence interval
$Z_{1-\beta}$	: Statistical power at 0.84
S	: Standar deviasi gabungan
$X_1 - X_2$	: The minimum significant mean difference observed in prior research (6,84) (6,84 – 10,10 = -3,26) (Blanquea,dkk. 2018)
S	: Weighted average of standard deviations from two groups (2,99)
S_1	: Standard deviation in group 1 (2,86) (Blanquea,dkk. 2018)
n_1	: Sampel size in group 1 (39)
S_2	: Standard deviation in group 2 (3,12) (Blanquea,dkk. 2018)
n_2	: Sampel size in group 2 (38)

5.2 Inclusion Criteria

1. Pregnant women in the third trimester (Gestational age 28–40 weeks).
2. Singleton pregnancy.
3. Willing to participate and sign informed consent.
4. Able to perform moderate physical activity.
5. Based in the study catchment area (Palangka Raya).

5.3 Exclusion Criteria

1. History of high-risk pregnancy (e.g., placenta previa, history of preterm labor, preeclampsia).
2. Contraindications to exercise as defined by ACOG guidelines (e.g., ruptured membranes, incompetent cervix).
3. Taking sleep medication.
4. Severe musculoskeletal disorders preventing exercise.

6. INTERVENTIONS

6.1 Group A: Traditional Pregnancy Exercise (Intervention Group)

- **Description:** A structured exercise program specifically designed for pregnant women ("Senam Hamil").
- **Components:** Includes breathing exercises, muscle strengthening (pelvic floor,

abdominal), and relaxation techniques specifically standardized for pregnancy preparation.
- **Frequency:** [Insert Frequency, e.g., 1 session per week supervised + home practice].
- **Duration:** [Insert Time, e.g., 45 minutes per session].

6.2 Group B: Stretching Exercise (Active Control Group)

- **Description:** A regimen focusing on static stretching and flexibility.
- **Components:** Gentle stretching of major muscle groups (calves, hamstrings, lower back, neck) to relieve tension and improve circulation without the aerobic or intensive strengthening components of the traditional class.
- **Frequency:** Matched to Group A.
- **Duration:** Matched to Group A.

6.3 Adherence Monitoring
Participants will utilize a logbook to record exercise sessions. Attendance at supervised sessions will be recorded by the instructor.

7. OUTCOME MEASURES

7.1 Primary Outcome

- **Measure:** Sleep Quality.
- **Instrument:** Pittsburgh Sleep Quality Index (PSQI) - Indonesian validated version.
- **Time Frame:** Baseline (Pre-test) and Post-intervention (Post-test, after [X] weeks).
- **Metric:** Total PSQI score (Range 0-21; lower scores indicate better sleep quality).

7.2 Secondary Outcomes

- **Anxiety Levels:** Measured using the Hamilton Anxiety Rating Scale (HARS).
- **Hemodynamics:** Systolic and Diastolic Blood Pressure.

7.3 Confounding Variables

- Age, Parity, BMI, Gestational Age.

8. STATISTICAL ANALYSIS PLAN

8.1 Data Management
Data is collected via paper questionnaires and entered into a digital database (SPSS). Data cleaning is performed to check for outliers and missing values.

8.2 Statistical Methods

- **Descriptive Statistics:** Means/Standard Deviations for continuous variables; Frequencies/Percentages for categorical variables.
- **Baseline Comparability:** Independent t-tests or Chi-square tests to ensure groups are balanced at baseline (specifically checking HARS and Diastolic BP as noted in preliminary analysis).
- **Outcome Analysis:** A **Linear Mixed Model** is used to analyze the difference between groups while adjusting for baseline scores and confounding variables (e.g., Age, Parity).
- **Significance Level:** p-value < 0.05.

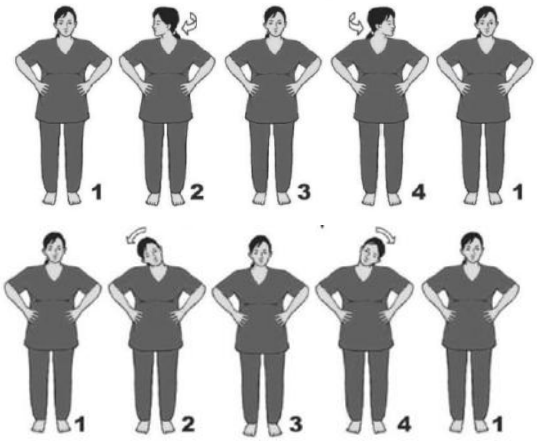
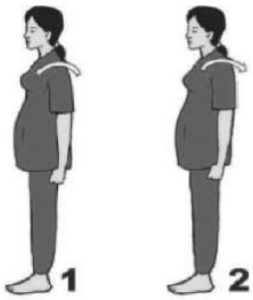
9. ETHICS AND SAFETY

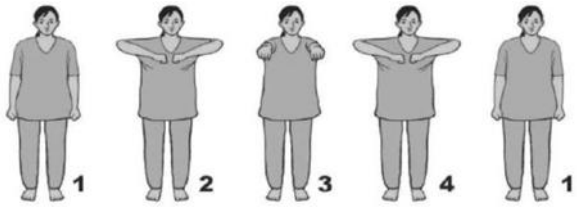
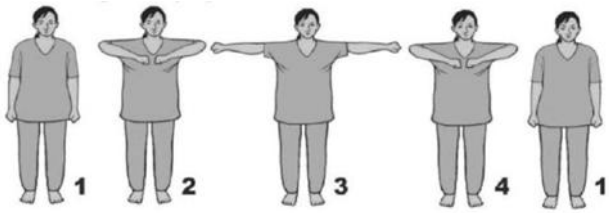
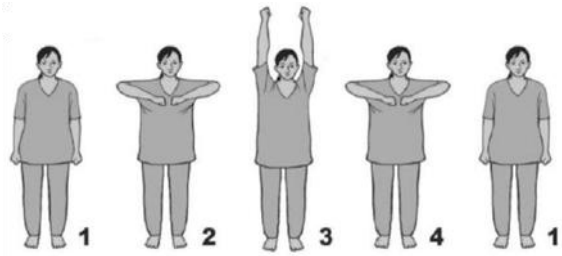
9.1 Ethical Approval
This protocol will be submitted to the Ethical Review Board of [Insert Name, e.g., Health Polytechnic of Palangka Raya].

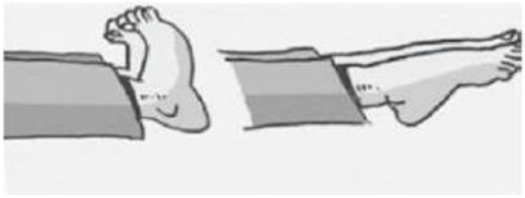
9.2 Informed Consent
Written informed consent will be obtained from all participants prior to enrollment. Participants will be informed of the benefits and potential risks of physical activity during pregnancy.

9.3 Safety Monitoring
Participants will be monitored for any adverse events (dizziness, contractions, pain). The intervention will be stopped immediately if any warning signs of pregnancy complications occur.

Figure S1. Traditional Pregnancy Exercise

No	Movement	Position	
1	Warm-up		**Position:** Standing, feet shoulder-width apart. **Instructions:** • Begin with slow breathing: inhale through the nose, exhale through the mouth. • Gently roll shoulders forward and backward 5–10 times. • Rotate the neck slowly in both directions. • March lightly in place for 1–2 minutes to warm the muscles. **Purpose:** Prepare the body, increase circulation, and reduce injury risk.
2	Deep Breathing and Chest Opening		**Position:** Standing or sitting upright **Instructions:** • Place both hands on the sides of the ribcage. • Inhale deeply, expanding the chest and ribs outward. • Exhale slowly while relaxing the shoulders. • Repeat 8–10 times. **Purpose:** Improve oxygenation, reduce tension, and promote relaxation.

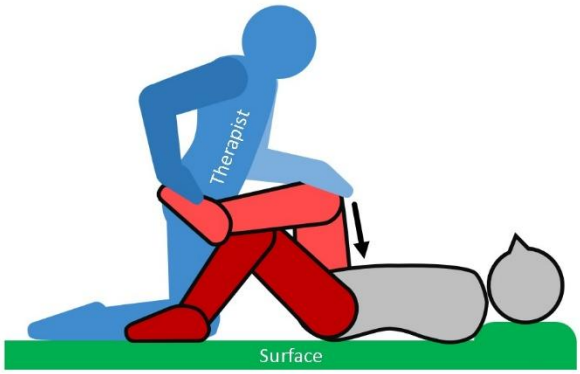
3	Pelvic Tilts		**Position:** Standing with back against a wall or on hands and knees **Instructions:** • Gently tilt the pelvis forward and backward, tightening the abdominal muscles. • Avoid arching the lower back excessively. • Perform 10–12 repetitions. **Purpose:** Reduce lower-back discomfort and strengthen core stability.
4	Cat–Cow Stretch		**Position:** Hands and knees ("tabletop" position) **Instructions:** • Inhale while dropping the belly and lifting the head (cow). • Exhale while rounding the back and tucking the chin (cat). • Move slowly with the breath for 10 cycles. **Purpose:** Relieve back tension and improve spinal flexibility.
5	Hip Circles		**Position:** Standing, hands on hips **Instructions:** • Gently rotate the hips in a circular motion clockwise for 10 repetitions. • Repeat counterclockwise for another 10 repetitions.

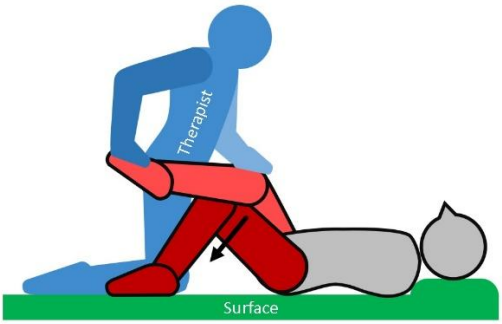
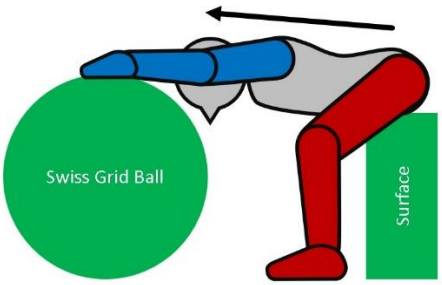
			Purpose: Loosen pelvic muscles and prepare for childbirth.
6	Side Stretch		**Position:** Standing or sitting **Instructions:** • Raise the right arm overhead and gently bend to the left. • Hold for 10–15 seconds while breathing normally. • Switch sides and repeat. **Purpose:** Stretch the torso, reduce ribcage tightness, and improve breathing comfort.
7	Squat with Support		**Position:** Standing, holding a chair or wall for balance **Instructions:** • Slowly lower into a comfortable squat, keeping feet wide and knees aligned. • Hold for 5–10 seconds, then rise slowly. • Repeat 8–10 times. **Purpose:** Strengthen legs and pelvic floor, improve hip flexibility.
8	Butterfly Stretch		**Position:** Sitting on the floor **Instructions:** • Bring the soles of the feet together and let the knees fall outward. • Hold the ankles and gently press

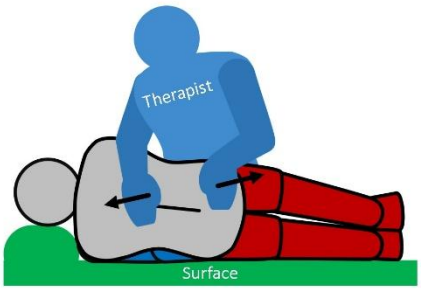
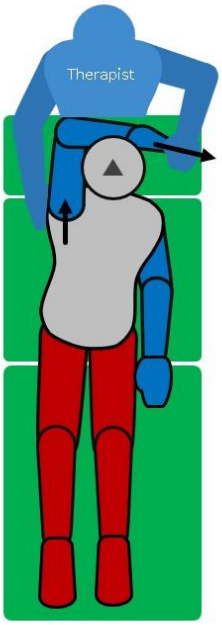
			the knees toward the floor. • Maintain the stretch for 20–30 seconds. **Purpose:** Open the hips and improve pelvic flexibility.
9	Pelvic Floor (Kegel) Exercise		**Position:** Sitting or lying down **Instructions:** • Contract the pelvic floor muscles as if stopping urine flow. • Hold for 5 seconds, then relax for 5 seconds. • Repeat 10–15 times. **Purpose:** Strengthen pelvic muscles to support pregnancy and childbirth.
10	Ankle and Leg Stretch		**Position:** Sitting with legs extended **Instructions:** • Point and flex the feet 10 times. • Rotate ankles clockwise and counterclockwise 10 times each. • Gently stretch the calves by pulling toes toward the body. **Purpose:** Improve circulation and reduce leg cramps or swelling.
11	Cool-Down and Relaxation		**Position:** Sitting or lying on the left side **Instructions:** • Take slow, deep breaths for 1–2 minutes.

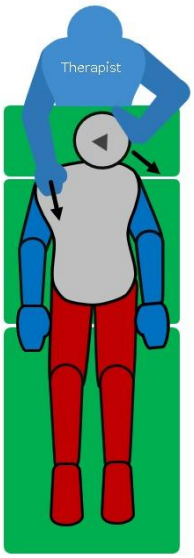
			• Relax the shoulders, jaw, and hands. • Visualize calmness and release tension throughout the body. **Purpose:** Lower heart rate, promote relaxation, and complete the session safely.

Figure S2. Stretching Exercise

No	Movement	Position	
1	Iskium Tibialis		Lying on the surface, the therapist elevates the lower limb in extension and ankle dorsiflexion (3 x 20 sec repeats, bilaterally and alternately).
2	Gluteus Maksimal		Lying on the surface, with one lower limb in flexion and external rotation of the hip and knee, and the ankle resting on the contralateral thigh, the therapist manually increases hip flexion towards the opposite shoulder (3 x 20-second repetitions, bilateral and alternating).

3	Piriformis		Lying on the surface with one lower limb in flexion and external rotation of the hip and knee, and the ankle resting on the contralateral thigh, the therapist manually conducts hip adduction towards the opposite lower limb (3 x 20-second repetitions, bilaterally and alternating).
4	Paravertebral		Sitting on the edge of a surface with abducted lower limbs and feet resting on the floor. Perform trunk flexion for freight and sideways while supported up on a Swiss grid ball (3 x 15 sec reps, bilaterally and alternating).

5	Kuadratus Lumborum		The therapist manually stretches the lumbar square in lateral decubitus, performing two 20-second repetitions on each side.
6	Latissimus Dorsi		In a supine position with the upper extremities in 180º flexion, the therapist manually lateralises the pregnant woman's upper trunk to contralateral elongation (2 x 20 second repetitions, bilaterally).

7	Skalane		The therapist conducts cervical rotation and flexion in a supine position to lengthen the contralateral scalene (2 x 20 second repetitions, bilaterally).
8	Trapesium		The therapist conducts lateral tilt and cervical flexion to the contralateral trapezius in a supine position, with two 20-second repetitions performed bilaterally.

Source: (Fontana Carvalho et al., 2020)

Fontana Carvalho, A. P., Dufresne, S. S., Rogerio de Oliveira, M., Couto Furlanetto, K., Dubois, M., Dallaire, M., Ngomo, S., & da Silva, R. A. (2020). Effects of lumbar stabilization and muscular stretching on pain, disabilities, postural control and muscle activation in pregnant woman with low back pain. *Eur J Phys Rehabil Med*, *56*(3), 297-306. https://doi.org/https://doi.org/10.23736/S1973-9087.20.06086-4

Informed Consent Form for Participation in a Research Study

Study Title: *Effects of Traditional Pregnancy Exercise on Sleep Quality Among Third-Trimester Pregnant Women*

Version Date: July 12, 2025

Introduction and Purpose of the Study

You are being invited to take part in a research study that aims to understand how different types of exercise may affect sleep quality during the third trimester of pregnancy. Many pregnant women experience difficulty sleeping due to physical discomfort, hormonal changes, and increased anxiety as they approach childbirth. Poor sleep can affect daily functioning, emotional well-being, and overall pregnancy health. Although exercise is often recommended to support comfort and relaxation during pregnancy, there is limited research comparing specific types of exercise programs and how they influence sleep..

Your participation is entirely voluntary. Before you decide, please read this form carefully. It explains why we are doing this study, what will happen if you take part, what the possible benefits and risks are, and your rights as a participant. Please ask the study team any questions you have.

Why you are chosen

You are being invited because you are:

- A pregnant woman in your third trimester
- Receiving antenatal care at this clinic
- Able to participate in light to moderate exercise

What will happen if I participate?

If you agree to participate, you will be part of a study involving 60 pregnant women.

You will then be assigned to one of two study groups

1. **Group 1: Traditional Pregnancy Exercise**
    - Attend two supervised exercise sessions per week for three weeks
    - Each session lasts 45–60 minutes
    - Complete questionnaires on sleep quality and anxiety before and after the program
    - You may also receive printed or video materials for home practice

2. **Group 2: Stretching Exercise (Control Group)**
    - Attend two supervised exercise sessions per week for three weeks
    - Each session lasts 45–60 minutes
    - Complete questionnaires on sleep quality and anxiety before and after the program
    - You may also receive printed or video materials for home practice

How long will I be in the study?

Your total participation in this study will last about three weeks. During this time, you will attend supervised exercise sessions twice a week and complete questionnaires at the beginning and end of the program.

Risks and Discomforts

The exercises are low-to-moderate intensity and generally safe for pregnant women. However, you may experience:

- Mild muscle soreness
- Temporary fatigue
- Discomfort during certain movements

If you feel pain, dizziness, shortness of breath, or any unusual symptoms, you should stop immediately and inform the instructor or midwife.

There are **no known serious risks** associated with these exercise programs when performed correctly.

Benefits of Participation

Participating in this study may offer several personal benefits. The exercise sessions are designed specifically for women in their third trimester and may help you feel more comfortable as your pregnancy progresses. Many women find that gentle movement, stretching, and breathing exercises can reduce muscle tension, improve posture, and promote relaxation. These effects may help you feel more at ease during daily activities and may support better physical comfort overall.

Another possible benefit is improved sleep. Many pregnant women experience difficulty sleeping due to discomfort, anxiety, or changes in their body. The exercise programs used in this study are intended to support better sleep quality by helping your body relax and by reducing some of the physical discomforts that can interfere with rest. While we cannot guarantee that your sleep will improve, the activities included in the program have been shown to be safe and may help you feel more rested.

In addition to any personal benefits, your participation will contribute to a better understanding of how different types of exercise affect sleep during late pregnancy. The information gathered from this study may help improve antenatal care programs and support other pregnant women in the future.

Confidentiality

Your privacy and the confidentiality of your data will be strictly protected.

- All information collected during this study will be kept confidential and will be identified only by a unique study code, not by your name.
- Any personal identifying information will be removed from your data as soon as possible.
- Study data will be stored securely on password-protected computers and in locked cabinets.
- The anonymized individual participant data (IPD) from this study may be shared with other qualified researchers in the future to further scientific discovery. This sharing will occur after the study's main results are published, and only under strict data use agreements that ensure

your privacy is protected through de-identification and anonymization methods, as outlined in our study's data sharing plan. No information that could identify you will ever be shared.

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Voluntary Participation and Right to Withdraw

Your decision to participate in this study is entirely voluntary. You are free to refuse to participate or to withdraw your consent and discontinue participation at any time, for any reason, without penalty or loss of benefits to which you are otherwise entitled. If you choose to withdraw, your decision will not affect your standard antenatal care.

Costs

There are no costs to you for participating in this study.

Who to Contact for Questions or Problems

If you have any questions about this research study, please feel free to contact the lead researcher:

Erina Eka Hatini
Midwifery Department, Health Polytechnic of Palangkaraya
Phone: +62812-5456-4640

If you have any questions about your rights as a research participant, or if you have concerns or complaints about the study, you may contact:

Research Committee of the Health Polytechnic of Palangka Raya (Polkesraya)
Yeni Lucin (Ethics Committee Coordinator)
+62 812-5087-359; Email: lucinyeni@polkesraya.ac.id
as per approval number 470/II/KE.PE/2025

Statement of Consent

I have read and understood the information provided in this consent form. I have had the opportunity to ask questions, and my questions have been answered to my satisfaction. I understand that my participation is voluntary and that I may withdraw at any time without penalty.

By signing below, I freely and voluntarily agree to participate in this research study.

Participant's Name: _____

Participant's Signature: _____

Date: _____

Person Obtaining Consent Name: _____

Person Obtaining Consent Signature: _____

Date: _____