APPENDIX A: INFORMED CONSENT FORM

Protocol Title: Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Trial to Evaluate the Efficacy and Safety of Nimsai Herbal Capsules in Participants with Grade 2-3 Internal Hemorrhoids

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1. INTRODUCTION

You are invited to participate in a research study evaluating a new herbal treatment for hemorrhoids called Nimsai Herbal. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Please ask the study doctor or study staff if anything is unclear or if you would like more information.

2. WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine if Nimsai Herbal is effective and safe in treating Grade 2-3 hemorrhoids compared to a placebo (an inactive substance that looks like the study drug). This study will help us understand more about hemorrhoid treatment based on a new scientific model.

3. HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 300 participants aged 18 to 70 years with Grade 2 or 3 hemorrhoids will participate in this study at Nimsai Academia.

4. WHAT WILL I BE ASKED TO DO?

If you agree to participate, you will first undergo a screening visit to confirm you meet the study criteria. If eligible, you will be randomly assigned (like flipping a coin) to receive either Nimsai Herbal or a placebo. You will not know which treatment you receive, and neither will the study doctor or staff. Your participation will involve:

- Screening Visit (Day -7 to Day 0): You will undergo a detailed medical history, physical examination, and anoscopic examination to confirm hemorrhoid grade.
- Intervention Period (Day 1 to Day 10): You will take one capsule of either Nimsai Herbal or placebo by mouth once daily for 10 days. You will be asked to maintain daily symptom logs (recording pain, bleeding, itching).
- Follow-up Visit (Day 10): You will return to the clinic for a final anoscopic examination and clinical evaluation to assess hemorrhoid regression and symptom resolution. You will also return any unused medication.
- Safety Monitoring: Throughout the 10-day period, you will be asked about any adverse events or discomfort you experience.

5. WHAT ARE THE RISKS OF PARTICIPATING?

We do not anticipate any serious risks from participating in this study. Based on previous research, Nimsai Herbal is generally well-tolerated. Potential mild side effects may include gastrointestinal discomfort (e.g., mild stomach upset), similar to what might be experienced with the placebo. If you experience any severe or unexpected symptoms, you should immediately contact the study staff.

6. WHAT ARE THE BENEFITS OF PARTICIPATING?

You may or may not directly benefit from participating in this study. If you receive Nimsai Herbal, your hemorrhoid symptoms may improve. If you receive the placebo, your symptoms may or may not improve. Your participation will contribute to scientific knowledge about hemorrhoid treatment, which may benefit future patients.

7. WHAT ARE THE ALTERNATIVES TO PARTICIPATING?

You may choose not to participate in this study. If you choose not to participate, your standard medical care will not be affected. You can discuss other available treatments for hemorrhoids with your doctor.

8. CONFIDENTIALITY

All information collected during this study will be kept strictly confidential. Your name will not be linked to any study data or publications. Data will be stored securely on password-protected computers, accessible only to authorized study personnel.

9. VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your decision to participate in this study is completely voluntary. You are free to refuse to participate or to withdraw at any time, for any reason, without any penalty or loss of benefits to which you are otherwise entitled. If you withdraw, your medical care will not be affected.

10. CONTACT INFORMATION

If you have any questions about the study, your rights as a research participant, or if you experience a research-related injury, please contact:

- Study Principal Investigator: Cem Atabiner at cem.atabiner@kecioutdoor.com.tr
- Ethics Committee: Nimsai Academia Ethics Committee at info@kecioutdoor.com.tr

11. STATEMENT OF CONSENT

I have read this Informed Consent Form. I have had the opportunity to ask questions and have received answers to my satisfaction. I understand that my participation is voluntary and that I may withdraw at any time. I hereby consent to participate in this research study.

Participant's Name (Print): _____

Participant's Signature: _____

Date: _____

Witness's Name (Print): _____

Witness's Signature: _____

Date: _____

Investigator/Person Obtaining Consent Name (Print): _____

Investigator/Person Obtaining Consent Signature: _____

Date: _____