APPENDIX B: CASE REPORT FORMS (CRFs) TEMPLATE

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

NCT Number: NCT07034820

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Submission Format: PDF/A

Study Protocol Number: NA-2024-01 Participant ID: _____ Site ID:_____

CRF Section 1: Screening & Baseline Demographics (Day 0)

Participant ID: _____

Date of Birth: //____ (DD/MM/YYYY)

Age (Years): ____

Gender: [ ] Male [ ] Female

Ethnicity: [ ] Caucasian [ ] Asian [ ] African [ ] Other:_____

Medical History (Relevant):

- IBD: [ ] Yes [ ] No
- Diabetes: [ ] Yes [ ] No
- Obesity (BMI): [ ] Yes [ ] No (BMI: ____ kg/m^2)
- Pregnancy/Lactation: [ ] Yes [ ] No
- Other Relevant Conditions: _____

Hemorrhoid Symptom Duration: ____ weeks / months / years

Anoscopic Examination (Investigator Assessment):

- Hemorrhoid Grade (Goligher): [ ] Grade 1 [ ] Grade 2 [ ] Grade 3 [ ] Grade 4
- Presence of other anorectal conditions (Abscess, Warts, Furuncles, Fissure, etc.):
  - [ ] None
  - [ ] Abscess
  - [ ] Warts
  - [ ] Furuncles
  - [ ] Anal Fissure
  - [ ] Other: _____

Inclusion/Exclusion Met? [ ] Yes [ ] No

Informed Consent Obtained? [ ] Yes [ ] No

Date of Randomization: //____ (DD/MM/YYYY)

Allocated Group: [ ] Nimsai Herbal [ ] Placebo (Investigator blinded)

CRF Section 2: Daily Symptom Log (Participant Reported - Day 1 to Day 10)

Participant ID: _____ Study Day:___

Symptom	VAS Score (0-10) - 0=None, 10=Worst imaginable
Pain	___
Bleeding	___
Itching	___

Medication Adherence: (Number of capsules taken today) ___

Any New/Worsening Symptoms or Adverse Events? (Describe briefly)
_____

(This section would be repeated for each day of the 10-day intervention period.)

CRF Section 3: Final Assessment & Adverse Events (Day 10)

Participant ID: _____ Study Day: 10 Date of Final Assessment: //___ (DD/MM/YYYY)

Anoscopic Examination (Investigator Assessment):

- Hemorrhoid Grade (Goligher) at Day 10: [ ] Grade 1 [ ] Grade 2 [ ] Grade 3 [ ] Grade 4
- Hemorrhoid Regression (Reduction of ≥1 Goligher Grade): [ ] Yes [ ] No

Symptom Resolution (Investigator Assessment based on Participant Logs):

- Complete Symptom Resolution (VAS=0 for Pain, Bleeding, Itching): [ ] Yes [ ] No

VAS Scores (Investigator Verified):

- Pain (Day 10): ___
- Bleeding (Day 10): ___
- Itching (Day 10): ___

Adherence Assessment (Capsule Count):

- Number of capsules prescribed: ___
- Number of capsules returned: ___
- Calculated Adherence (%): ___%

Adverse Events (AEs) Overview (Throughout 10-day period):

- Total Number of AEs reported: ___
- Serious AEs (SAEs): [ ] Yes [ ] No (If Yes, attach SAE form)
- Most Frequent AEs (e.g., mild GI discomfort):
    - GI discomfort: [ ] Yes [ ] No (Severity: [ ] Mild [ ] Moderate [ ] Severe)
    - Other AE 1: _____ (Severity: [ ] Mild [ ] Moderate [ ] Severe)
    - Other AE 2: _____ (Severity: [ ] Mild [ ] Moderate [ ] Severe)
- Relationship to Study Drug: [ ] Related [ ] Unrelated [ ] Unlikely