INFORMED CONSENT FORM

CLINICAL TRIAL HUMAN DOSE ESCALATION

Phase 1 Clinical Trial to Determine the Maximum Tolerable Intake of African Bitter Root Food Supplement (ABRS)

Trial Acronym: ABRS-P1-DOSE | Version A1 15th May 2026 | ISRCTN No. ISRCTN51184184

Please read this form carefully alongside the Participant Information Leaflet. Initial each box below only if you agree with the statement. Sign and date at the end.

Section A — Understanding

☐	I have read and understood the Participant Information Leaflet for this trial (Version A1, 15th May 2026). Contact details for the Principal Investigator are in your copy of the Participant Information Leaflet.
☐	I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.
☐	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my care being affected. I understand that if I withdraw, I will be asked whether I wish any data already collected to be withdrawn also, and that I may choose either option.

Section B — The trial

☐	I understand that I will receive two tubs of capsules (A and B), one containing ABRS and one containing a placebo, and that I will not know which is which during the trial. I need to take the dose in front of an investigator, or with the investigator on a video call with me.
☐	I understand that I will take the dose on an empty stomach, at least one hour before a meal, from Tub A first, then Tub B after a 7-day washout period.
☐	I understand that a doctor will perform one physical examination before I take any capsules, and one physical examination after completing both tubs. The physical exam will include blood tests and ECG. I understand that if I am of childbearing potential, a pregnancy test will be included.
☐	I understand that an investigator will contact me before dosing, 30 minutes after, 1 hour after, 1 day after, and 1 week after dosing to ask about how I feel.
☐	I agree to inform the investigator immediately of any side effect or adverse event, however minor it seems.

Section C — Contraception and pregnancy (if female of childbearing potential)

☐	I confirm that I am not pregnant and I am using a reliable form of contraception, including a long-acting reversible contraceptive (LARC) or equivalent.

☐	I understand that ABRS must not be taken in pregnancy, and that if I become pregnant during the trial I will stop immediately and inform the Principal Investigator.

Section D — Data

☐	I understand that my personal data will be held securely and separately from trial data, identified only by a reference number. I give my explicit consent to that data being used for the purposes of this trial and into research into ABRS subject to measures being taken to maintain my personal confidentiality.
☐	I consent to my anonymised data being used in publications and presentations arising from this trial.
☐	I understand that my data will be retained for 15 years in accordance with the sponsor's quality management system.

Section E — Consent

☐	I agree to take part in this trial.

Participant details

Full name (print):	
Contact Number:	
Address:	

Participant signature		**Date**
Signature		DD / MM / YYYY

I confirm that I have explained the nature and purpose of this trial to the participant and answered their questions.

Investigator / person taking consent		**Date**
Signature		DD / MM / YYYY

Investigator to complete:

Participant Number: _____

Dose stage assigned: Stage _____

Dose Serial Numbers: _____ A

_____ B

One copy for participant — one copy for the trial file — original to the Principal Investigator