

INFORMED CONSENT FORM**CLINICAL TRIAL HUMAN DOSE ESCALATION***Phase 1 Clinical Trial to Determine the Maximum Tolerable Dose of African Bitter Root Food Supplement (ABRS)*Trial Acronym: ABRS-P1-DOSE | Version A0 9th May 2026 | ISRCTN (ADD NUMBER ONCE ASSIGNED)

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

<input type="checkbox"/>	I have read and understood the Participant Information Leaflet for this trial (Version A0, 9 May 2026). Contact details for the Principal Investigator are in your copy of the Participant Information Leaflet.
<input type="checkbox"/>	I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.
<input type="checkbox"/>	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 I understand that if I withdraw, I will be asked whether I wish any data already collected to be withdrawn also, and that I may choose either option.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

<input type="checkbox"/>	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.
<input type="checkbox"/>	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.
<input type="checkbox"/>	I understand that a doctor will perform one physical examination before I take any capsules, and one physical examination after completing both tubs. I understand that if I am of childbearing potential, a pregnancy test will be included in my physical examination.
<input type="checkbox"/>	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.
<input type="checkbox"/>	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)

<input type="checkbox"/>	I confirm that I am not pregnant and (if of childbearing potential) I am using a reliable form of contraception, including a long-acting reversible contraceptive (LARC) or equivalent.
<input type="checkbox"/>	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

<input type="checkbox"/>	I understand that my personal data will be held securely and separately from trial data, identified only by a reference number, and accessible only to the Principal Investigator and the sponsor's IT Manager.
<input type="checkbox"/>	I consent to my anonymised data being used in publications and presentations arising from this trial.
<input type="checkbox"/>	I understand that my data will be retained for 15 years in accordance with the sponsor's quality management system.

Section E — Consent

<input type="checkbox"/>	I agree to take part in this trial.
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Participant details

Full name (print):	
Contact Number:	
Address:	

Participant signature		Date
Signature		DD / MM / YYYY

Person obtaining consent (name and role)		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