Study brief for ingredient research

Reputable Health | Editable worksheet | Version 1.0 | November 18 2026

Use pages 1 and 2 to prepare a first conversation with a research partner. Pages 3 and 4 show a hypothetical sleep-ingredient example. Replace the bracketed fields and expand the space as needed.

This brief starts the discussion. The research team must develop and approve the protocol, analysis plan and participant protections before a study begins.

Project and decision

Project details Sponsor, contact, version, date and intended markets.

[Complete here]

Decision to inform What do you need to learn? How will the findings be used? Identify any proposed claim as unapproved wording for review.

[Complete here]

Study material and existing evidence

Material to test Exact ingredient, specifications, formulation, proposed dose, batch documentation and conditions of use. Mark unknowns.

[Complete here]

Evidence to assess List relevant research, including null or unfavorable findings, and explain differences from your material or intended users. [1]

[Complete here]

People and research question

Intended participants Describe the intended users, eligibility questions, relevant exclusions and recruitment setting for clinical review.

[Complete here]

Main question State the population, intervention, comparison if applicable, outcome and assessment period. Leave unresolved choices explicit.

[Complete here]

Design and measurements to discuss

Study objective Feasibility, exploratory or confirmatory? Ask the team to justify the design, comparator, randomization and blinding where appropriate. [2]

[Complete here]

Outcomes Name the proposed primary outcome and supporting measurements. Ask how each instrument fits the question, population and assessment window. [3]

[Complete here]

Study brief continued

Complete with the research team before agreeing to a proposal

Schedule and analysis

Collection schedule Separate baseline, intervention, follow-up and questionnaire recall periods. Specify device and software versions, quality checks and usable-recording rules where relevant.

[Complete here]

Sample size and analysis Ask for a justified recruitment and analysis target, the underlying assumptions, and prespecified methods. Define missing-data rules, discontinuation versus withdrawal, and sensitivity analyses where appropriate. [2, 4]

[Complete here]

Participant protection and data use

Ethics and safety Who determines review and consent requirements? Who handles adverse events, participant concerns and escalation? Record decisions and owners.

[Complete here]

Data permissions Agree access, security, retention, consent limits, de-identification, permitted reuse and ownership. Do not assume participant-level data can be shared.

[Complete here]

Responsibilities and deliverables

Responsibilities and milestones Assign protocol, recruitment, product supply, participant support, measurement, analysis and reporting owners. Request separate setup, recruitment, follow-up and reporting milestones.

[Complete here]

Agreed outputs Specify protocol, analysis plan, participant flow, planned results, missing data, deviations, safety reporting and limitations. Confirm any dataset access. For Reputable pilot studies, manuscript and journal-submission support are separately scoped add-ons.

[Complete here]

Interpretation and open decisions

Limits and approvals What could this design support? What would remain unanswered? Who approves the protocol and any customer-facing use of results?

[Complete here]

Unresolved decisions and owner: _____

Planning resources

Ingredient manufacturers buyer's guide | Research methodology

Numbered methodological references appear on page 4. This worksheet is educational and does not establish claim substantiation or regulatory approval.

Hypothetical sleep ingredient brief

Completed example | Fictional sponsor inputs | Not a recommended protocol

This example shows how a sponsor can complete a brief without making unsupported design choices. Ingredient X is fictional. No study has been conducted and no results, product benefits or client information are reported.

Project and decision

Sponsor: A fictional ingredient manufacturer considering a sleep application.

Decision: Determine whether a future controlled study of perceived sleep quality is justified and workable. The immediate proposal request is for feasibility planning, not a claim of efficacy.

Intended use: Internal study planning. Any later customer-facing claim requires a separate review of the evidence and proposed wording. [1]

Material and participants

Study material: Ingredient X in a capsule formulation. The sponsor must supply identity, specifications, batch testing, stability information and existing evidence. Dose and conditions of use remain open for clinical and safety review.

Intended participants: Adults reporting occasional poor sleep. The clinical team must define eligibility, screening and relevant exclusions. This brief does not propose studying or treating insomnia.

Research question and design

Feasibility question: Can eligible participants complete the proposed questionnaires and wearable recordings, and can the team obtain data of adequate quality for the planned assessments?

Design to discuss: A feasibility pilot of remote procedures. A comparator, randomization or blinding decision requires the clinical team's rationale. Do not use a single-group before-and-after pilot to claim that Ingredient X caused a sleep benefit. [2]

Proposed measurements for review

Primary feasibility measure: Completion of scheduled questionnaire assessments. Prespecify the denominator, assessment windows and progression criteria before enrollment.

Supporting feasibility measure: Availability of usable wearable recordings. The clinical team must define the device, quality criteria and what counts as a usable night. [3]

Exploratory sleep assessment: A questionnaire suitable for perceived sleep quality and the intended population. Any device-derived sleep measure is a separate assessment. Do not combine questionnaire and device results into an unvalidated overall score.

Hypothetical example continued

Decisions to resolve before the proposal becomes a protocol

Schedule and missing data

The team must choose baseline and follow-up periods, questionnaire timing and device collection windows. Match the instrument's recall period to the assessment plan. Duration and sample size remain undetermined; the team must justify them against the feasibility objectives. [2]

Record missing assessments and reasons where known. Do not turn missing nights into zeros. Prespecify the handling of incomplete recordings, questionnaires, discontinuation and withdrawal. A later efficacy trial needs a separate analysis and sample-size rationale. [4]

Protection and responsibilities

Assign clinical, consent, ethics-review, safety and escalation responsibilities before recruitment. Agree which data the sponsor can access, how results will be reported and what consent permits. Do not assume that study participation authorizes marketing use of participant data.

Outputs and interpretation

Request a feasibility report covering recruitment, questionnaire completion, usable recordings, missingness, protocol deviations and participant burden. Describe exploratory findings with their uncertainty and limitations. A small pilot cannot establish efficacy or reliably characterize rare harms. [2]

Any feasibility percentage must identify its numerator, denominator, assessment period and study population. If manuscript preparation or journal-submission support is requested for a Reputable pilot, scope it separately. Journal acceptance cannot be promised.

References and planning links

References checked November 18 2026. These sources inform the planning questions; they do not validate Ingredient X or a specific Reputable protocol.

[1] FDA dietary supplement claim substantiation guidance

[2] NCCIH pilot study uses and misuses

[3] FDA remote digital measurement guidance

[4] ICH E9 R1 estimands and sensitivity analysis

FDA digital measurement and ICH E9 R1 guidance concern medical-product investigations and drug development, respectively. They are methodological references here, not blanket legal requirements for supplement studies.

Sleep research partner checklist | Claims and evidence guide

Published open-label sleep pilot | PubMed record

The published pilot is a separate real study with its own limitations. Its findings are not evidence for the fictional ingredient in this example.