Required Study Documents

Guidance for Study Staff

Ian Hambleton, Selvi Jeyaseelan

13 Jan 2026

Table of contents

Legend

Priority

- = Must-have (MH)
- = Nice-to-have (NH)

Category

- = Data-related
- = Management / operations
- = Participant-facing
- = Staff-facing delivery
- = Research / evaluation / implementation science
- = Governance / ethics / information governance
- = Research-evidence

Phases / timepoints

- P0 = Pre-screening / set-up (before screening starts)
- P1 = Screening period
- P2 = Baseline start
- P3 = Total Meal Replacement (TMR) phase (weeks 0–12)
- P4 = Food reintroduction (weeks 12–18)
- P5 = Weight maintenance / follow-up (weeks 19+)
- P6 = Close-out / reporting

Required documents by timepoint

P0 — Pre-screening / set-up (early Jan → before screening starts 26/01/26)

- ☒ Study protocol (P0)
- ☒ Service evaluation justification document (P0)
- ☐ Ethics / REGG submission pack + local ethics pack (P0)
- ☒ Data Protection Impact Assessment (DPIA) (P0)
- ☒ Data sharing agreement / outline (single combined document) (P0)
- ☒ Caldicott Guardian sign-off record (P0)
- ☒ Data Monitoring Group Terms of Reference (P0)
- ☒ Data flow diagram (participant → clinic → registry → analysis) (P0)
- ☒ Data dictionary (final, aligned to SAP) (P0)
- ☒ Statistical Analysis Plan (final, aligned to DD) (P0)
- ☒ Derived variables specification (added to DD appendix) (P0)
- ☒ Anonymisation & small-numbers suppression rules (P0)
- ☒ Programme delivery timeline (operational) (P0)
- ☐ Risk register + issues/deviations log (single combined log) (P0)
- ☒ Evidence brief (GRADE-based or structured evidence narrative) (P0)
- ☐ Data linkage protocol (registry screening main DB) (P0)

P1 — Screening (from 26/01/26)

- ☒ Telephone screening script (P1)
- ☒ Screening visit information sheet (P1)
- ☒ Participant information sheet (P1–P2)
- ☒ Consent form (P2)
- ☐ Participant privacy notice (*NOTE include in information sheet*) (P1)
- ☒ Screening visit SOP and checklist (P1)
- ☐ Eligibility confirmation & escalation guide (brief SOP section) (P1–P2)
- ☐ Screening export process / eligibility report spec (P1)
- ☐ Recruitment tracking + appointment scheduling log (**...in REDCap?**) (P1–P5)

Gate — Ethics approval / waiver required before baseline proceeds (09/02/26)

- ☐ Ethics approval / waiver record filed in repository (Gate)
- ☐ Protocol amendment log (simple running log) (P1–P6)

P2 — Baseline start (from 09/02/26)

- ☒ Baseline visit "What to expect" handout (P2)
- ☒ Participant commitment summary (P2–P5)
- ☒ Baseline visit SOP and checklist (P2)
- ☒ Missed appointment / disengagement protocol (short SOP) (P2–P5)
- ☐ Data quality checks + validation rules (single living document) (P2–P6)

P3 — Total Meal Replacement phase (weeks 0–12)

- ☐ Total Meal Replacement phase overview (participant-friendly) (P3)
- ☐ What to do if you feel unwell (participant safety leaflet) (P3)
- ☐ Medication changes explained (plain language) (P2–P3)
- ☐ Withdrawal / stopping the programme information (P3–P5)
- ☐ Medication adjustment + safety escalation protocol (single combined SOP) (P3)
- ☐ Adverse event identification, reporting & governance pathway (single document) (P3–P5)

P4 — Food reintroduction (weeks 12–18)

- ☐ Food reintroduction phase overview (P4)
- ☐ Product supply & stock management notes (brief SOP or appendix) (P4)

P5 — Weight maintenance / follow-up (weeks 19+)

- ☐ Weight maintenance phase overview (P5)
- ☐ Data retention & archiving plan (draft during follow-up, final at close-out) (P5–P6)
- ☐ Participant feedback survey + intro text (optional) (P5–P6)
- ☐ Staff reflections / notes template (very lightweight) (P5–P6)

P6 — Close-out / reporting

- ☐ Final evaluation report template (P6)
- ☐ Final archiving pack (dataset, codebook, suppression rules) (P6)
- ☐ End-of-pilot close-out note (short narrative) (P6)
- ☐ End-of-programme summary for participants (P6)
- ☐ Dissemination plan (outline only) (P6)