RESEARCH PROJECT LIFECYCLE

Light-Touch Trial Protocol

Stage: Gate 2 (eligibility confirmed) → Gate 3 · Previous template: Feasibility and Business Capability Assessment · Next template: Delivery Tracking and Regular Review

How to use this form

The Light-Touch Trial Protocol is for **simple, low-risk trials**. It replaces the Full Research Plan, the Experimental Planning Document, the Ethical Oversight Review and the Gate 3 Readiness checklist with **one document of two to three pages**. It doubles as your **pre-registration**.

- **Good examples:** testing the wording of a letter or message, changing the order of a routine process, or randomly allocating an existing service that has more demand than it can meet.
- **Who completes it:** the Research Lead and the Project Lead together.
- **Who checks it:** the ethics screening in section F is completed by an Ethics Reviewer. The Gate 3 decision in section H is made by the Gate 3 Reviewer, then signed off by the Sponsor.
- **Check eligibility first.** Section B confirms the trial is suitable for the light-touch route. If any answer is No, use the full route instead.
- **Light touch does not mean less care.** Small trials still need a fair comparison, delivery tracked in every group, and the plan written down before the trial starts.
- **Changes are allowed, but must be visible.** After sign-off, record every change as a dated amendment with the reason.

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A. The project

Most of this section carries forward from earlier templates.

Field	Your answer
A1. Project title *(essential)* As on the Feasibility and Business Capability Assessment.	
A2. Project reference From the Research Portfolio Register.	
A3. Research Lead and Project Lead *(essential)* Names and roles.	

Field	Your answer
A4. Gate 2 decision date *(essential)* The date the project was judged "This research project is feasible".	Date: _____ / _____ / _____
A5. Protocol version *(essential)* For example, version 1.0. Every amendment after sign-off gets a new version number.	

B. Light-touch eligibility

Every answer must be Yes to use this route. If any answer is No, use the full route.

Field	Your answer
B1. Low risk of harm *(essential)* The trial is very unlikely to cause emotional, physical, privacy or fairness harm.	☐ Yes ☐ No **Notes:**
B2. No change to entitlements *(essential)* No one receives less than they are entitled to. Any change to the service is trivial, such as wording or timing.	☐ Yes ☐ No **Notes:**
B3. Outcomes from routine data *(essential)* The outcome is already recorded as part of normal business.	☐ Yes ☐ No **Notes:**
B4. No new data collection from participants *(essential)* No questionnaires, interviews or extra contact are needed for the research.	☐ Yes ☐ No **Notes:**
B5. Within existing resources *(essential)* The trial can be delivered with the staff and budget already in place.	☐ Yes ☐ No **Notes:**

Field	Your answer
B6. Within the organisation's control *(essential)* The organisation can deliver the treatment and allocate cases without needing new partners.	☐ Yes ☐ No **Notes:**

C. The trial

Field	Your answer
C1. Research question *(essential)* The question the trial will answer. For example: "Does a shorter reminder letter increase the number of people who attend?"	
C2. Hypothesis *(essential)* What you expect to find, written so the result could prove it wrong.	
C3. What each group receives *(essential)* What the treatment group receives, and what the control group receives. The control group usually receives business as usual.	
C4. Eligibility criteria *(essential)* Which cases are included and excluded, written so someone else could apply them.	
C5. How cases are identified, and how many *(essential)* How eligible cases are found, and the number expected each month. Efficient identification increases power, so the trial finishes sooner and the findings can be used sooner.	
C6. Unit of allocation *(essential)* Pick one.	☐ Individual people ☐ Places ☐ Groups or teams ☐ Time periods

Field	Your answer
C7. How cases are allocated and protected *(essential)* The randomisation method, who carries it out, and how the allocation is logged so it cannot be changed or re-run. The person allocating should not deliver the treatment or choose which cases are referred.	
C8. Sample size and smallest detectable change *(essential)* The number of cases needed, the smallest change the trial could reliably detect, and how this was worked out.	
C9. Primary outcome *(essential)* One main outcome: exactly how it is measured, where the data comes from, and when.	
C10. Who knows about the trial, and who does not? *(essential)* Who will know there is a trial, and who will know which group a case is in. For example: participants, delivery staff, and the person analysing the data. Where people do know, say how you will stop that changing what they do.	
C11. Are control sites or groups told about the trial? *(essential)* Pick one, then explain. Control sites that know may copy the treatment, try harder, or lose motivation.	☐ Yes, told fully ☐ Told a study is running, not the details ☐ Not told until the study ends ☐ Not applicable: no control sites or groups **Notes:**

D. Delivery and tracking

Field	Your answer
D1. How will you track delivery in all groups? *(essential)* Who was offered the treatment, who received it, and how much, in every group. Track the control group too, so you know whether anyone received the treatment by mistake. Say the level of delivery you will treat as acceptable.	
D2. How will you make sure the treatment is delivered well? *(essential)* For example: a short briefing for staff, a named delivery lead, and a regular check. Say what you will do if delivery falls short.	
D3. Staff briefing *(essential)* Who will be briefed, and by when. Explain why the trial matters and why a control group is needed.	
D4. Review frequency *(essential)* How often delivery will be checked, using the Delivery Tracking and Regular Review form.	☐ Weekly ☐ Fortnightly ☐ Monthly ☐ Other
D5. Trial starts *(essential)*	Date: ____ / ____ / _____
D6. Recruitment ends *(essential)*	Date: ____ / ____ / _____
D7. Final outcome data available *(essential)*	Date: ____ / ____ / _____

E. Analysis

Write this before the trial starts. It is the core of the pre-registration.

Field	Your answer
E1. Main analysis *(essential)* The test or model for the primary outcome. Analyse every case in the group it was allocated to.	
E2. Missing data *(essential)* How missing outcome data will be handled.	
E3. What a null result would mean *(essential)* If you find no difference, what would that tell you, and what would you do next?	
E4. Known limitations *(essential)* The main weaknesses of the trial, and how far the findings could be generalised.	

F. Ethics screening

Completed by an Ethics Reviewer. If any answer is No or Unsure, the trial needs a full Ethical Oversight Review.

Field	Your answer
F1. Is there genuine uncertainty about which option is better? *(essential)*	☐ Yes ☐ No ☐ Unsure **Notes:**
F2. Does the control group receive at least business as usual? *(essential)*	☐ Yes ☐ No ☐ Unsure **Notes:**

Field	Your answer
F3. Are the risks of harm minimal? *(essential)* Consider emotional, physical, privacy and fairness harms.	☐ Yes ☐ No ☐ Unsure **Notes:**
F4. Is the information given to people appropriate? *(essential)* Including whether consent is needed, and the reason if it is not.	☐ Yes ☐ No ☐ Unsure **Notes:**
F5. Is the data handled lawfully and securely? *(essential)*	☐ Yes ☐ No ☐ Unsure **Notes:**
F6. Are safeguarding arrangements unaffected? *(essential)*	☐ Yes ☐ No ☐ Unsure **Notes:**
F7. Will the results be published whatever they show? *(essential)*	☐ Yes ☐ No ☐ Unsure **Notes:**
F8. Screening result *(essential)* Pick one.	☐ Light-touch route confirmed ☐ Full Ethical Oversight Review needed
F9. Screened by *(essential)* Ethics Reviewer name and role, and whether internal or external.	
F10. Screening date *(essential)*	Date: ____ / ____ / _____

G. Pre-registration

Register this protocol before the first case is allocated. See the ResearchCore guide "Where to Pre-register" for options in different fields, including internal registration and your own website.

Field	Your answer
G1. Where it is registered *(essential)* Pick one.	☐ External registry ☐ Registered Report ☐ Internal pre-registration ☐ Our own website
G2. Registry name and reference The registry, the ID or link, or the internal document reference.	
G3. Date registered *(essential)*	Date: ____ / ____ / _____
G4. Embargo until If the details are hidden until a later date.	Date: ____ / ____ / _____

H. Gate 3 and sign-off

The statement that must be true to pass Gate 3: "Research is ready to conduct". Pick an answer for each readiness check, then add the evidence.

Field	Your answer
H1. Staff briefed *(essential)* Briefing complete, or booked before the trial starts.	☐ Ready ☐ Not ready **Notes:**
H2. Tracking ready *(essential)* The tracking tool is set up, and the people recording data know what to do.	☐ Ready ☐ Not ready **Notes:**
H3. Data access in place *(essential)* The outcome data can be obtained for every group.	☐ Ready ☐ Not ready **Notes:**

Field	Your answer
H4. No overlap with other studies *(essential)* The Research Portfolio Register has been checked for other studies with the same people, places or outcomes.	☐ Ready ☐ Not ready **Notes:**
H5. Gate 3 decision *(essential)* Pick one.	☐ Proceed ☐ Not ready ☐ Return to Gate 2 ☐ Stop
H6. Reasons and any conditions *(essential)* A short explanation of the decision, and any actions with an owner and a date.	
H7. Gate 3 Reviewer *(essential)* Name and role.	
H8. Decision date *(essential)*	Date: ____ / ____ / _____
H9. Signed off by the Sponsor *(essential)* Name and role.	
H10. Sign-off date *(essential)*	Date: ____ / ____ / _____
H11. Amendments after sign-off List each change: the date, the version number, what changed and why.	

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