RESEARCH PROJECT LIFECYCLE

Full Research Plan: Trials and Quasi-Experiments

Stage: Research Development → Gate 3 · Previous template: Feasibility and Business Capability Assessment (Gate 2) · Next templates: Experimental Planning Document and Ethical Oversight Review

How to use this form

Use this form to set out exactly what will be tested, how, and how it will be analysed, **before anything starts**. It doubles as your **pre-registration**: once signed off, it is the record you point back to when you report the results. It takes **four to six pages**.

- **Who completes it:** the Research Lead.
- **Who checks it:** the Ethics Reviewer, then the Gate 3 Reviewer, as part of the Gate 3 Readiness and Project Sign-Off.
- **Write the analysis now.** If you haven't planned the analysis before the trial starts, no amount of statistics afterwards will fix it.
- **Pick the design first.** Section C has notes for randomised controlled trials, quasi-experimental designs and qualitative studies. Answer the parts that apply to your design.
- **Be specific enough to be held to it.** Someone else should be able to read this plan and know exactly what you will do and measure.
- **Changes are allowed, but must be visible.** After sign-off, record every change as a dated amendment with the reason. Never overwrite the signed-off version.

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A. The project

Most of this section carries forward from earlier templates. Check it is still right.

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 *(essential)* Name and role.	

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

B. Question and hypotheses

Field	Your answer
B1. Research question *(essential)* The single main question this study will answer. For example: "Do plain-English reminder letters increase the share of bills paid on time?"	
B2. Hypotheses *(essential)* What you expect to happen, written so the results could prove it wrong. Include the direction of the change. For example: "On-time payments will be higher in the treatment group than in the control group."	
B3. Why this matters *(essential)* A short summary of the evidence and the gap this study fills. Carry this forward from the Evidence Scoping Summary and update it.	

C. Design

Field	Your answer
C1. Study design *(essential)* Pick one. **Randomised controlled trial:** people, places or time periods are allocated to groups at random. **Quasi-experimental:** a comparison group is built from data, for example by matching. **Qualitative:** interviews, focus groups or observation, to understand how and why. **Mixed methods:** a trial or comparison, together with qualitative work.	☐ Randomised controlled trial ☐ Quasi-experimental ☐ Qualitative ☐ Mixed methods
C2. Unit of allocation *(essential)* Pick one. What is allocated to each group: individual people, places, groups such as schools or teams, or time periods.	☐ Individual people ☐ Places ☐ Groups or clusters ☐ Time periods ☐ Not applicable
C3. Groups and what each receives *(essential)* Describe every treatment group and any control group. Say exactly what each group receives. A control group often receives "business as usual": describe what that is.	
C4. How the groups are formed *(essential)* For a randomised controlled trial: the randomisation method, the ratio between groups, and any stratification. For a quasi-experimental design: how the comparison group is built, and the checks that the groups are alike at the start. For a qualitative study: who is sampled, and how.	

Field	Your answer
C5. Protecting the allocation How you will stop anyone predicting or changing which group someone goes into. For example: a secure randomiser that records every allocation, with no option to re-run it.	

D. Participants

Field	Your answer
D1. Eligibility criteria *(essential)* Who is included and excluded, carried forward from the Feasibility and Business Capability Assessment.	
D2. Sample size and power *(essential)* The number needed in each group, the smallest change worth detecting, the significance level and the power. Attach the calculation.	
D3. Recruitment start date *(essential)*	Date: ____ / ____ / _____
D4. Recruitment end date *(essential)* Or the date by which the sample size will be reached.	Date: ____ / ____ / _____
D5. Information and consent *(essential)* How participants are told about the study, and whether consent is needed. Agree this with the Ethics Reviewer.	

E. Outcomes and data

Field	Your answer
E1. Primary outcome *(essential)* The one main outcome the study is designed to detect. Define exactly how it is measured, and when.	
E2. Secondary outcomes A short list of other outcomes, each defined in the same way. Keep this list short.	
E3. Data sources *(essential)* Where each outcome comes from, who holds it, and any agreements needed. You must be able to get the outcome data for any control group, as well as for treatment groups.	
E4. Follow-up period *(essential)* How long after taking part each outcome is measured.	
E5. Delivery data *(essential)* What will be recorded to show the intervention was delivered as planned, to the right people. This feeds the tracking design in the Experimental Planning Document.	
E6. How will you track delivery in all groups? *(essential)* How you will measure the rate of delivery in each group: who was offered the treatment, who received it, and how much they received. Track any control group too, so you know what they received and whether anyone received the treatment by mistake. Say who records it, how often it is checked, and the level of delivery you will treat as acceptable.	

Field	Your answer
E7. How will you make sure the treatment is delivered well? *(essential)* Your strategies for making sure the treatment is delivered as intended, and that delivery capability is as strong as it can be. For example: training and guidance for staff, a named delivery lead, enough capacity for the expected numbers, regular check-ins, and a plan for staff changes. Say what you will do if tracking shows delivery falling short, in the treatment group or the control group.	
E8. How will you maximise response rate? *(essential)* Complete this if any outcome is measured by questionnaire or survey. Otherwise write "Not applicable". A low response rate can stop the study answering its question, and the people who reply may differ from those who do not. Aim for similar response rates in every group. If one group responds less, the comparison is no longer fair. List the steps you will take. For example: a short questionnaire, a trusted sender, advance notice, reminders, a format that works on a phone, or a thank-you for taking part. Say how you will monitor responses as they arrive, and what you will do if the rate falls below your target.	

F. Analysis plan

Write this before any outcome data is seen. It is the core of the pre-registration.

Field	Your answer
F1. Main analysis *(essential)* The test or model you will use for the primary outcome, and the result that would count as a difference. For a randomised controlled trial, analyse people in the group they were allocated to, whether or not they received the intervention.	
F2. Missing data and dropout *(essential)* How you will handle people who leave, cannot be followed up, or have missing outcome data.	
F3. Secondary and subgroup analyses Only the analyses you plan now. Anything added later must be labelled as exploratory.	
F4. Interim analyses When you will look at the data during the study, what you will look at, and any rules for stopping early.	
F5. Qualitative analysis For qualitative or mixed-method studies: how the data will be coded and analysed.	
F6. Costs and benefits What you will measure so that a Benefits Assessment can be done at the end. For example: delivery costs, staff time, and changes in use of other services.	

G. Limitations

Field	Your answer
G1. Known limitations *(essential)* The weaknesses of this design, and what you will do about them.	
G2. What a null result would mean *(essential)* If no difference is found, what would that tell us, and what would it not tell us? A small study may not be able to show that something does not work.	

H. Pre-registration

Register this plan before any allocation or delivery starts. See the ResearchCore guide "Where to Pre-register" for options in different fields, including internal registration and your own website.

Field	Your answer
H1. Where it is registered *(essential)* Pick one.	☐ External registry ☐ Registered Report ☐ Internal pre-registration ☐ Our own website
H2. Registry name and reference The registry, the ID or link, or the internal document reference.	
H3. Date registered *(essential)*	Date: ____ / ____ / _____
H4. Embargo until If the details are hidden until a later date.	Date: ____ / ____ / _____

I. Plan status and sign-off

Field	Your answer
I1. Plan status *(essential)* Pick one.	☐ Draft ☐ Ready for Ethical Oversight ☐ Signed off ☐ Amended after sign-off
I2. Signed off by *(essential)* Research Lead name and role.	
I3. Sign-off date *(essential)*	Date: ____ / ____ / _____
I4. Amendments after sign-off List each change: the date, the version number, what changed and why.	

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