RESEARCH PROJECT LIFECYCLE

Experimental Planning Document

Stage: Research Development (draft) → Project Sign Off (final) · Previous template: Full Research Plan · Next templates: Ethical Oversight Review, Gate 3 Readiness and Project Sign-Off

How to use this form

The Experimental Planning Document turns the Full Research Plan into **day-to-day delivery**. It says who does what, how cases move through the study, how delivery is tracked, and how the pilot will run. It takes **three to four pages**.

- **Who completes it:** the Project Lead and the Delivery Lead, with the Research Lead.
- **When:** draft it during Research Development, alongside the Full Research Plan. **Finalise it after Project Sign Off**, before the pilot starts, and update it if the pilot shows something needs to change.
- **Who checks it:** the Gate 3 Reviewer, as part of the Gate 3 Readiness and Project Sign-Off.
- **Design out the problems now.** Most trials that fail do so in delivery, not analysis. Low referrals, people receiving the wrong treatment, and missing data are far cheaper to prevent than to fix.
- **Bring forward, do not repeat.** Groups, outcomes, delivery tracking and response rate plans are already in the Full Research Plan. Refer to them here and add the practical detail.
- **Not running a trial?** For questionnaires, interviews or secondary data, complete sections A, B, E, F, H, I and J. In section C, describe how people or records are selected and approached, instead of allocated.

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A. The project

Most of this section carries forward from the Full Research Plan.

Field	Your answer
A1. Project title *(essential)* As on the Full Research Plan.	
A2. Project reference From the Research Portfolio Register.	
A3. Full Research Plan version *(essential)* The version this document is based on. If the plan is amended, check this document still matches it.	

Field	Your answer
A4. Study design *(essential)* Pick one.	☐ Randomised controlled trial (RCT) ☐ Cluster RCT ☐ Quasi-experimental ☐ Questionnaire or survey ☐ Interviews or focus groups ☐ Secondary data analysis ☐ Mixed methods

B. Roles

Name the person in each role. One person can hold more than one role, except where the help text says otherwise.

Field	Your answer
B1. Sponsor *(essential)* Signs off the project and funding, and makes the decision on continuing afterwards.	
B2. Project Lead *(essential)* Owns the project day to day.	
B3. Research Lead *(essential)* Responsible for the design, data and analysis.	
B4. Delivery Lead *(essential)* Runs delivery and tracking, and is the first contact for delivery staff.	
B5. Allocation owner *(essential)* The person who carries out randomisation or allocation. This should not be someone who delivers the treatment or chooses which cases are referred, but it can also be the person who designed the randomiser, if software oversees the allocation in practice.	

Field	Your answer
B6. Data lead Responsible for data extracts, data sharing and data quality.	
B7. Partners and their roles Other teams or organisations involved, and what each one does.	

C. Case flow and allocation

Field	Your answer
C1. How cases are found and referred *(essential)* Step by step, from the moment a case becomes eligible to the moment it is referred into the study. Attach a flow diagram if it helps.	
C2. Eligibility check *(essential)* Who checks each case against the eligibility criteria, and when. The check must happen before allocation.	
C3. Expected cases per month *(essential)* The number of eligible cases you expect each month, and where this figure comes from. Carry this forward from the Feasibility and Business Capability Assessment.	
C4. Allocation procedure *(essential)* Step by step, how an eligible case is allocated to a group, and how the result is passed on. For example: the referrer enters the case, the app allocates it, and the Delivery Lead is notified.	

Field	Your answer
C5. Protecting the allocation *(essential)* How the allocation is kept secure: who can see the sequence, how each allocation is logged, and how you stop it being re-run or changed. Allocation should happen after eligibility is confirmed and consent is taken, if consent is needed.	
C6. What happens next for each group *(essential)* What each group is told, what it receives, and who delivers it.	
C7. Who knows about the study, and who does not? *(essential)* Blinding means keeping some people unaware of the study, or of which group a case is in, so that knowing cannot change what they do or how they record outcomes. For each group of people, say what they will know: participants, referrers, delivery staff, staff at control sites, the people recording outcomes, and the analyst. Where people do know, say how you will stop that knowledge changing what they do or how outcomes are recorded.	
C8. Are control sites or groups told about the trial? *(essential)* Pick one, then explain. Knowing that other sites are getting a new treatment can change what control sites do. They may copy it, try harder, or lose motivation. Any of these can bias the comparison. If control sites are told, say what they are told and when, and how you will check whether their practice changes. This must fit the consent and information arrangements agreed in the Ethical Oversight Review.	☐ 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. Keeping people in the study

Field	Your answer
D1. Designing out dropout *(essential)* How you will keep people in the study and keep their outcome data. For example: allocating only after consent, keeping the burden low, or using routine data for outcomes so no one needs to be contacted again.	
D2. Crossover *(essential)* What counts as crossover: someone receiving the treatment meant for another group. How you will prevent it, and how you will record it if it happens.	
D3. People who leave the service How you will still collect outcome data for people who stop taking part. They stay in the analysis in the group they were allocated to.	

E. Staff briefing and buy-in

Field	Your answer
E1. Who needs briefing *(essential)* Every team that refers, allocates, delivers or records data.	
E2. Briefing plan *(essential)* How and when each team will be briefed, and the materials they will receive. Explain why the study matters and why a control group is needed. Staff who understand the reason are far more likely to follow the allocation.	
E3. Briefing complete by *(essential)*	Date: ____ / ____ / _____

Field	Your answer
E4. Raising concerns *(essential)* How staff can raise concerns or report problems during delivery, and who responds.	
E5. Keeping staff engaged For example: regular updates on numbers, thanking teams, or sharing early lessons from the pilot.	

F. Tracking plan

This is the tracking solution for the study. It puts the delivery tracking and response rate plans from the Full Research Plan into practice.

Field	Your answer
F1. What is recorded for each case *(essential)* For every group: eligibility, allocation, what was received and how much, crossover, dropout, and outcome data. Use the delivery tracking answer in the Full Research Plan as the starting point.	
F2. Tracking tool *(essential)* Pick one.	☐ ResearchCore app ☐ Case management system ☐ Spreadsheet ☐ Other
F3. Who records it, and how often *(essential)* Who enters each item, and how soon after it happens.	
F4. Review meetings *(essential)* How often delivery is reviewed, and who attends. Each review uses the Delivery Tracking and Regular Review form.	☐ Weekly ☐ Fortnightly ☐ Monthly ☐ Other

Field	Your answer
F5. Triggers for action *(essential)* The levels that will prompt action, and the action each one prompts. For example: delivery below the acceptable level, crossover above an agreed limit, referrals below target, or the response rate below target.	
F6. Response rate tracking If any data is collected by questionnaire: how responses will be counted as they arrive, in each group. Write "Not applicable" if no questionnaire is used.	

G. Pilot plan

The pilot tests the delivery, not the outcome. It checks that the study can run as planned before the main delivery starts.

Field	Your answer
G1. Pilot scope *(essential)* How many cases, in which areas or teams, and for how long.	
G2. Pilot start *(essential)*	Date: ____ / ____ / _____
G3. Pilot end *(essential)*	Date: ____ / ____ / _____
G4. What the pilot will test *(essential)* For example: referrals arrive as expected, allocation works, each group receives what it should, tracking is complete, and outcome data can be obtained.	
G5. Go, adjust or stop criteria *(essential)* What result would let you go ahead, what would need changes first, and what would stop the study.	

Field	Your answer
G6. Pilot cases in the main analysis *(essential)* Pick one. Decide this before the pilot starts, and record it in the pre-registration.	☐ Included in the main analysis ☐ Excluded from the main analysis ☐ Included only if nothing changes after the pilot

H. Timeline

Field	Your answer
H1. Main delivery starts *(essential)*	Date: ____ / ____ / _____
H2. Recruitment ends *(essential)*	Date: ____ / ____ / _____
H3. Final outcome data available *(essential)* The date the last follow-up period ends and the data can be extracted.	Date: ____ / ____ / _____
H4. Interim analysis dates As set in the Full Research Plan, with the stopping rule for each.	
H5. Research Outcomes Report due *(essential)*	Date: ____ / ____ / _____
H6. Other milestones For example: funding decisions, data sharing renewals, or partner board meetings.	

I. Risks to delivery

Field	Your answer
I1. Main risks and how they will be reduced *(essential)* For example: staff changes, fewer referrals than expected, delays in data access, or a policy change that affects the service.	

Field	Your answer
I2. If referrals fall short *(essential)* What you will do if cases arrive more slowly than expected. For example: adding areas, extending recruitment, or accepting a larger smallest detectable change.	
I3. Anything that would end the study early Events outside the stopping rules that would mean the study could not continue, and who would decide.	

J. Status and sign-off

Field	Your answer
J1. Document status *(essential)* Pick one.	☐ Draft ☐ Final, after Project Sign Off ☐ Updated after the pilot ☐ Updated during delivery
J2. Signed off by *(essential)* Project Lead name and role.	
J3. Sign-off date *(essential)*	Date: ____ / ____ / _____
J4. Agreed by the Delivery Lead *(essential)* Name and date.	
J5. Changes after the pilot or during delivery List each change: the date, what changed and why. Check whether the Full Research Plan also needs an amendment.	

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