RESEARCH PROJECT LIFECYCLE

Gate 4 Review and Root Cause Analysis

Stage: Gate 4 · Previous templates: Research Outcomes Report, Benefits Assessment · Next template: Publication, Implementation and Next Iteration Record

How to use this form

This is the check at **Gate 4: "Research was conducted as intended"**. It compares what happened with what was planned, element by element. Where there were major differences, a **root cause analysis** finds out why, so the next study goes better. It takes **one page**, plus a root cause analysis if needed.

- **Who completes it:** the Gate 4 Reviewer, with the Project Lead and Research Lead. The reviewer should not be someone who delivered the study.
- **What it uses:** the Full Research Plan or protocol, the Experimental Planning Document, the Delivery Tracking and Regular Review record, and the Research Outcomes Report.
- **This is about learning, not blame.** Studies rarely go exactly to plan. The aim is to understand what the differences mean for the findings, and what to change next time.
- **Passing Gate 4 does not depend on the result.** A null result from a well-delivered study passes. A positive result from a poorly delivered study may not.

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A. The review

Field	Your answer
A1. Project title *(essential)* As on the Full Research Plan or protocol.	
A2. Project reference From the Research Portfolio Register.	
A3. Gate 4 Reviewers *(essential)* Name, role, and whether internal or external, for each reviewer.	
A4. Documents reviewed *(essential)* The versions of the plan, the Experimental Planning Document, the delivery record and the Research Outcomes Report.	

Field	Your answer
A5. Date submitted for Gate 4 *(essential)*	Date: _____ / _____ / _____

B. Check against the plan

For each element, pick an answer and add a short note. Every "Major differences" answer needs a root cause analysis in section C.

Field	Your answer
B1. Cohort *(essential)* Were the right cases identified and included, using the eligibility criteria?	☐ As planned ☐ Minor differences ☐ Major differences ☐ Not applicable **Notes:**
B2. Recruitment and sample size *(essential)* Was the target sample reached, in the planned time?	☐ As planned ☐ Minor differences ☐ Major differences ☐ Not applicable **Notes:**
B3. Allocation *(essential)* Was allocation carried out as planned, and kept protected?	☐ As planned ☐ Minor differences ☐ Major differences ☐ Not applicable **Notes:**
B4. Delivery in every group *(essential)* Did each group receive what was intended, at or above the acceptable level? Was crossover kept low?	☐ As planned ☐ Minor differences ☐ Major differences ☐ Not applicable **Notes:**

Field	Your answer
B5. Blinding and control sites *(essential)* Did people who should not know stay unaware? Did practice at control sites stay the same?	☐ As planned ☐ Minor differences ☐ Major differences ☐ Not applicable **Notes:**
B6. Outcome data *(essential)* Was outcome data collected for every group, with dropout and response rates as expected?	☐ As planned ☐ Minor differences ☐ Major differences ☐ Not applicable **Notes:**
B7. Analysis *(essential)* Was the analysis carried out as pre-registered?	☐ As planned ☐ Minor differences ☐ Major differences ☐ Not applicable **Notes:**
B8. Reporting *(essential)* Were all pre-registered outcomes reported, and was exploratory analysis clearly labelled?	☐ As planned ☐ Minor differences ☐ Major differences ☐ Not applicable **Notes:**
B9. Ethics *(essential)* Were all ethics conditions met throughout the study?	☐ As planned ☐ Minor differences ☐ Major differences ☐ Not applicable **Notes:**
B10. Timeline and budget Was the study delivered on time and within budget?	☐ As planned ☐ Minor differences ☐ Major differences ☐ Not applicable **Notes:**

C. Root cause analysis

Complete this for each major difference. Copy the table if there is more than one.

Field	Your answer
C1. The difference *(essential)* What was planned, and what actually happened.	
C2. Five whys *(essential)* Ask "why?" until you reach the cause that, if fixed, would stop it happening again. Five times is a guide, not a rule.	**Why 1:** **Why 2:** **Why 3:** **Why 4:** **Why 5:**
C3. Root cause *(essential)* The underlying cause, in one or two sentences.	
C4. Effect on the findings *(essential)* Pick one, then explain.	☐ None ☐ Some: findings less certain ☐ Serious: findings unreliable **Notes:**
C5. Action for next time *(essential)* What will change to prevent this, who will do it, and by when.	

D. Lessons learned

Field	Your answer
D1. What worked well *(essential)* Things to keep doing in future studies.	
D2. What we would do differently *(essential)* Things to change in future studies.	

Field	Your answer
D3. Changes to our process or templates Suggested changes to how the organisation runs research, including these templates.	

E. Gate 4 decision

The statement that must be true to pass: "Research was conducted as intended".

Field	Your answer
E1. Decision *(essential)* Pick one.	☐ Conducted as intended ☐ Conducted as intended, with differences noted ☐ Not conducted as intended: treat findings with caution
E2. Reasons *(essential)* A short explanation, including how any differences affect the confidence in the findings.	
E3. Gate 4 Reviewer *(essential)* Lead reviewer name and role.	
E4. Decision date *(essential)*	Date: _____ / _____ / _____

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