RESEARCH PROJECT LIFECYCLE

Ethical Oversight Review

Stage: Research Development → Gate 3 · Previous template: Full Research Plan · Next template: Gate 3 Readiness and Project Sign-Off

How to use this form

The Ethical Oversight Review checks that the study is **the most ethical way to answer the question**, and that risks to participants, staff and the organisation have been reduced. It is a checklist of **one to two pages**.

- **Who completes it:** the Ethics Reviewer. This can be an internal panel, an external committee, or an independent person with the right experience. Each organisation decides who.
- **When:** once the Full Research Plan is marked "Ready for Ethical Oversight", and before Gate 3. If the plan changes in a way that affects risk, review it again.
- **What it reviews:** the Full Research Plan and the draft Experimental Planning Document. The Research Lead should be available to answer questions.
- **How to answer:** for each check, pick an answer and add a short note. Anything marked "No" or "Partly" needs a condition or a change in section C.
- **External approval:** if a university, health or other formal ethics committee must approve the study, record its reference in A6. This review does not replace it.
- **Light-touch trials** use the shorter ethics screening in the Light-Touch Trial Protocol. That screening can send a project back to this full review.

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A. The review

Field	Your answer
A1. Project title *(essential)* As on the Full Research Plan.	
A2. Project reference From the Research Portfolio Register.	
A3. Research Lead *(essential)* Name and role.	

Field	Your answer
A4. Ethics Reviewers *(essential)* List everyone who reviews the study: their name, their role, and whether they are internal or external to the organisation. If a panel or committee reviews it, name the panel and its chair, then list the members who took part. Add more lines if there are more than three reviewers.	**Panel or committee name, if relevant:** **Panel chair:** **Reviewer 1 name and role:** Internal or external: ☐ Internal ☐ External **Reviewer 2 name and role:** Internal or external: ☐ Internal ☐ External **Reviewer 3 name and role:** Internal or external: ☐ Internal ☐ External
A5. Documents reviewed *(essential)* The Full Research Plan version and the Experimental Planning Document version.	
A6. Other ethics approvals Any formal committee approval needed, with its reference and status.	
A7. Date of review *(essential)*	Date: ____ / ____ / _____

B. The checks

Pick an answer for each check, then add a short note explaining it.

Field	Your answer
B1. Is this the most ethical way to answer the question? *(essential)* Could the question be answered with less risk or burden, for example with existing data or a smaller study? Is there genuine uncertainty about whether the treatment works?	☐ Yes ☐ Partly ☐ No ☐ Not applicable **Notes:**
B2. Is the control group justified? *(essential)* Does any control group receive at least what it would normally receive, sometimes called business as usual? Good reasons include genuine uncertainty, or a service that cannot reach everyone yet.	☐ Yes ☐ Partly ☐ No ☐ Not applicable **Notes:**
B3. Have harms been identified and reduced? *(essential)* Consider emotional, physical, privacy and fairness harms, for participants, staff and others affected. Could the treatment backfire? How would you know?	☐ Yes ☐ Partly ☐ No ☐ Not applicable **Notes:**
B4. Is consent or information appropriate? *(essential)* Will people be told about the study and asked to agree, where that is needed? If consent is not sought, is the reason sound and recorded?	☐ Yes ☐ Partly ☐ No ☐ Not applicable **Notes:**
B5. Is data handled lawfully and securely? *(essential)* The legal basis, collecting only what is needed, secure storage, who can access it, and how long it is kept. Is a data protection impact assessment needed?	☐ Yes ☐ Partly ☐ No ☐ Not applicable **Notes:**

Field	Your answer
B6. Are safeguarding arrangements in place? *(essential)* What happens if staff learn that someone is at risk, and who the named safeguarding lead is.	☐ Yes ☐ Partly ☐ No ☐ Not applicable **Notes:**
B7. Is the study fair to everyone it affects? *(essential)* Who is excluded and why, and whether any group is affected more than others.	☐ Yes ☐ Partly ☐ No ☐ Not applicable **Notes:**
B8. Is the burden on participants reasonable? *(essential)* The time and effort asked of people, and whether any thank-you or incentive is appropriate.	☐ Yes ☐ Partly ☐ No ☐ Not applicable **Notes:**
B9. Are there clear stopping rules? *(essential)* When the study would stop early, for example because of harm or a clear benefit, and who decides.	☐ Yes ☐ Partly ☐ No ☐ Not applicable **Notes:**
B10. Are method-specific risks covered? *(essential)* For example: allocation being changed or crossover in a trial, distress or interviewer influence in interviews, survey fatigue in questionnaires, or small numbers that could identify people in secondary data.	☐ Yes ☐ Partly ☐ No ☐ Not applicable **Notes:**
B11. Will results be shared openly? *(essential)* Is the study pre-registered, and will the results be published whatever they show?	☐ Yes ☐ Partly ☐ No ☐ Not applicable **Notes:**

Field	Your answer
B12. Will the cohort identification find the right cases efficiently? *(essential)* Is the way cases are identified and referred expected to find the eligible cases reliably, without missing many or including the wrong ones? Efficient identification increases the power of the study, so it can finish sooner. That means the findings can be used sooner, and fewer people are asked to take part in a study that cannot answer its question. Check the identification and referral process and the expected cases per month in the Experimental Planning Document.	☐ Yes ☐ Partly ☐ No ☐ Not applicable **Notes:**

C. Verdict

Field	Your answer
C1. Verdict *(essential)* Pick one. **Approve:** the study can go ahead as planned. **Approve with conditions:** the study can go ahead once the conditions in C2 are met. **Revise and resubmit:** changes are needed, then a further review. **Reject:** the study should not go ahead in this form.	☐ Approve ☐ Approve with conditions ☐ Revise and resubmit ☐ Reject
C2. Conditions *(essential)* Each condition, who must meet it, and by when. Write "None" if there are no conditions.	
C3. Changes required to the plan Any changes to the Full Research Plan or the Experimental Planning Document. Each change is recorded as an amendment.	

Field	Your answer
C4. Review again If the study needs a further review, for example after the pilot. Leave blank if not needed.	Date: ____ / ____ / _____
C5. Reviewed by *(essential)* The lead Ethics Reviewer or panel chair, with their role.	
C6. Verdict date *(essential)*	Date: ____ / ____ / _____
C7. Conditions met Confirmed by the Ethics Reviewer, with the date. Gate 3 cannot be passed until every condition is met.	Date: ____ / ____ / _____

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