Research Ethics and Governance

Standard Operating Procedures (SOPs)

ORYX UNIVERSITY

In Partnership with Liverpool John Moores University

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Version History

Version	Author	Description of Changes	Date
Version 1.1	Dr. Maher Salem	Update v1.0 with clarity and More details in sections 2 and 3	2 March 2026

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1. Introduction

1.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to establish a consistent, rigorous, transparent, and operationally clear process for the ethical review and governance of research conducted at Oryx University.

This SOP serves as a practical "how-to" guide for researchers and staff, outlining step-by-step procedures for:

- Submitting research ethics applications
- Determining review pathways
- Managing research data
- Reporting and closing projects
- Seeking approval for conferences and external initiatives

This SOP ensures compliance with applicable local laws, regulations, and institutional frameworks.

1.2 Scope

This SOP applies to:

- All research conducted under the auspices of Oryx University involving human participants or their data (including staff, students, and affiliates).
- All personal data related to research, regardless of format (electronic, paper, audio, video).
- All external representation and research-related activities requiring institutional approval.

No research involving human participants or identifiable personal data may begin without written ethics approval (unless formally registered as Exempt).

1.3 Relationship to Other Policies

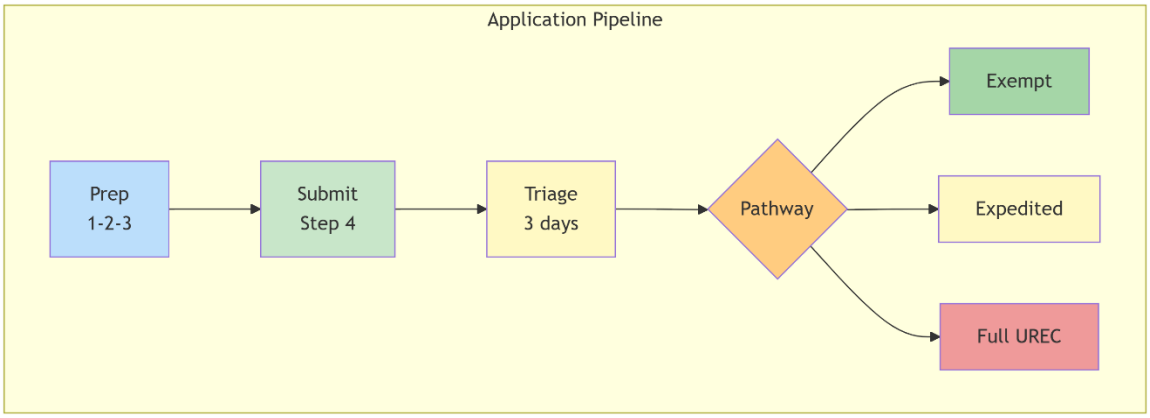
This SOP should be read in conjunction with:

- Research Ethics Policy (**`RKEO-POL-Research Ethics Policy`**)
- Research Integrity Policy (**`RKEO-POL-Research Integrity Policy`**)
- Data Protection Policy (**`RKEO-POL-Data Protection Research`**)
- UREC Terms of Reference (**`RKEO-TOR-UREC-V1.0`**)

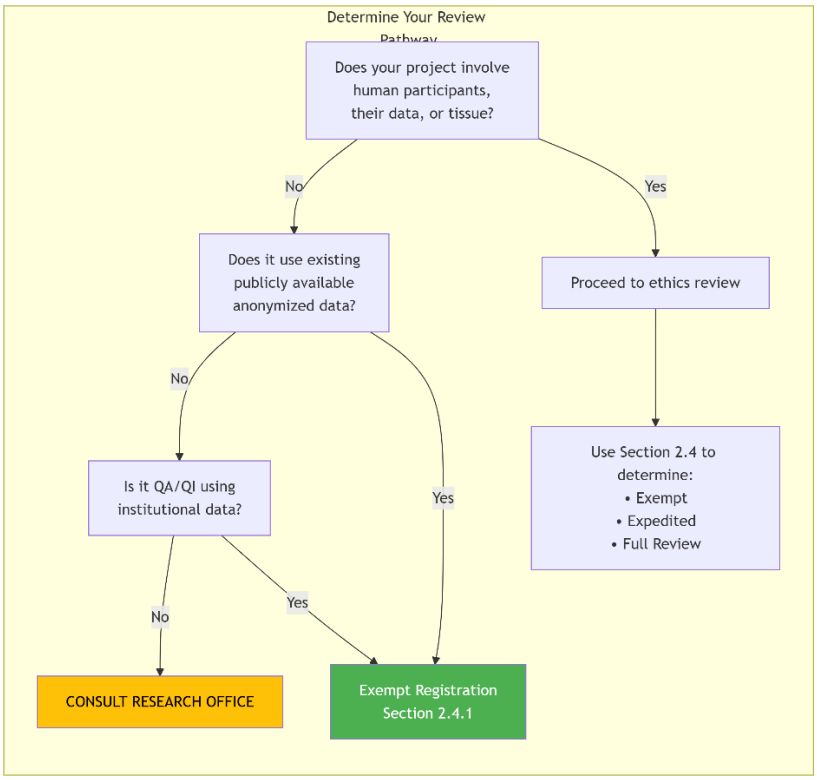
2. Application Process

2.1 Submission Requirements

Before submitting an ethics application, the Principal Investigator (PI) must complete the following steps. The Entire Process at a Glance:



Step 1 — Confirm Ethics Is Required



Action: Use Section 2.4 (Review Pathways) to determine whether your project requires:

- **Exempt Registration** – Low-risk, must still register
- **Fast-Track Review** – Minimal risk, faster process
- **Full UREC Review** – Higher risk, committee review

If unsure: Contact the Research Office before submission.

Step 2 — Complete Mandatory Training (*under processing*)
All research team members must complete required ethics training prior to submission.

Who	Requirement	Evidence Needed
Principal Investigator	Must complete ethics training	Training certificate (valid 3 years)
All research team members	Must complete ethics training	Training certificates
External collaborators	Check if training requirements apply	Email confirmation from Research Office

Training Options:

- Online ethics module (LJMU-provided)
- Recognized external ethics training
- Equivalent previous certification (must be verified)

Step 3 — Prepare Complete Application Package
All required documents must be prepared using official templates (see Appendix list).

Document Type	Status	Template Required
Ethics Application Form (RKEO-FRM-Ethics Application Form)	**REQUIRED**	Yes
Participant Information Sheet (PIS)	**REQUIRED**	Yes
Consent Forms	**REQUIRED**	Yes
Detailed Methodology	Optional	No
Data Management Plan (DMP)	Optional	Yes (if used)
Research Instruments (questionnaires, interview guides, scripts)	Optional	No
Risk Assessment	If applicable	Yes
DPIA (if personal/sensitive data involved)	If applicable	Yes
Conflict of Interest Declaration	If applicable	Yes
External approvals (from other institutions)	If applicable	As required

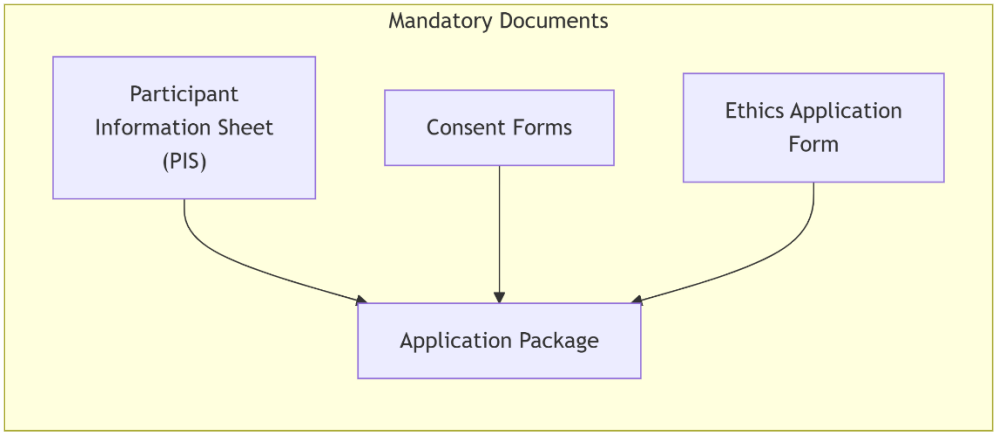
Step 4 — Submit Application
Submit the complete application package as a single PDF file via the Research Office's official submission platform or specified email address.

IMPORTANT: Incomplete submissions will be returned and will **not** enter the review process until all required documents are provided.

2.2 Submission Steps

The PI must complete the following steps in order:

1. Complete the Ethics Application Form (**`RKEO-FRM-Ethics Application Form`**).
2. Mandatory documents:



Optional Documents (Include if Applicable):

Document	When to Include
Detailed Methodology	Complex or novel research methods
Data Management Plan (DMP)	Any data collection/storage
Research Instruments	Questionnaires, interview guides, scripts
Risk Assessment	Physical/psychological risk identified
DPIA	Personal or sensitive data involved
Conflict of Interest Declaration	Any potential conflict
External approvals	Research involving other institutions

3. Compile all documents into a single, clearly labelled PDF with version numbers and dates.
4. Submit to the Research Office and You will receive an automated acknowledgment within 24 hours.

Late or improperly formatted submissions may be deferred to the next review cycle.

2.3 Completeness Check (Triage Step 1)

Upon submission, the Research Office (RO) will conduct a mandatory completeness check to ensure all required documents are included.

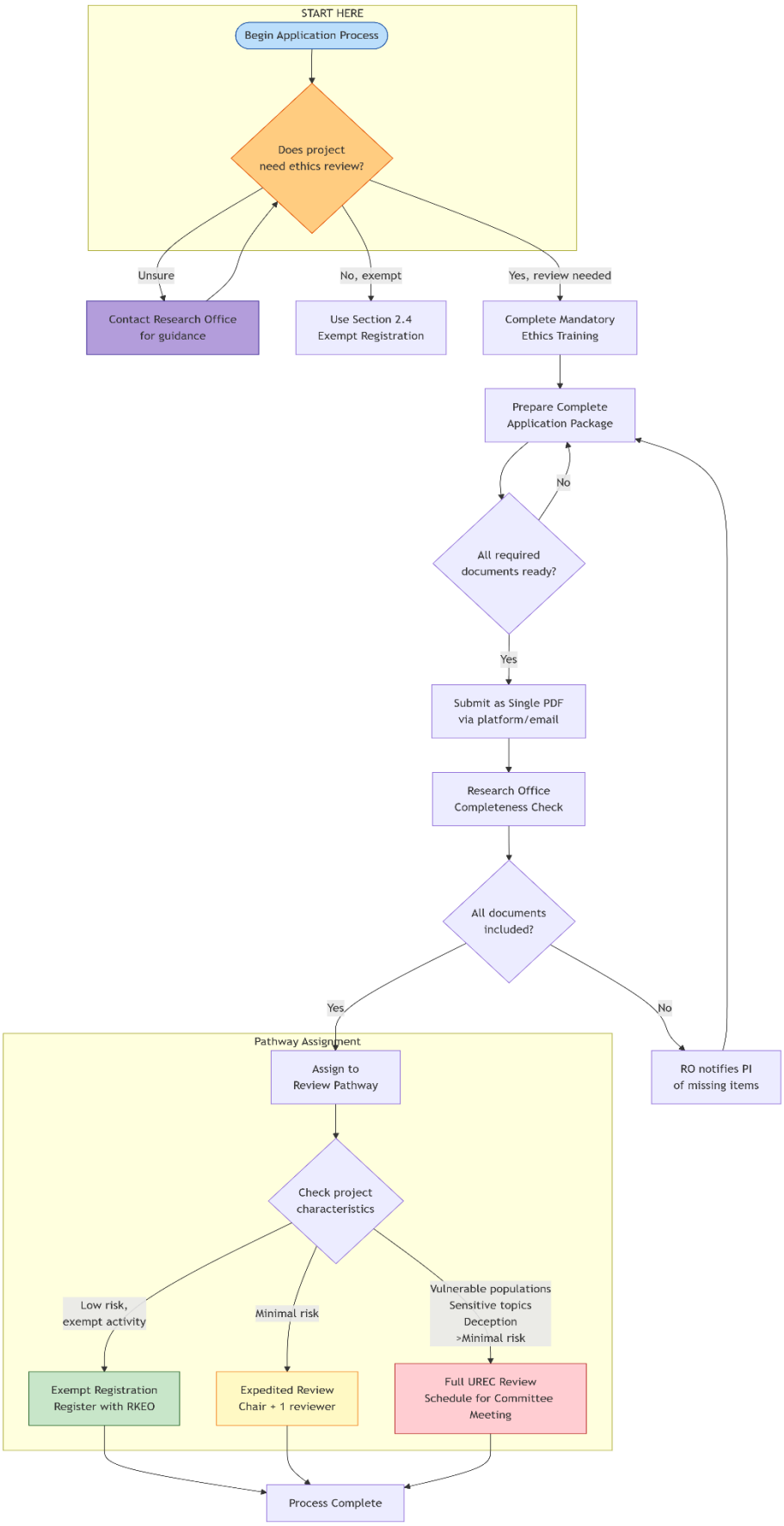
Completeness Check Decision Table

Status	Definition	Next Step	Timeline
✅ **COMPLETE**	All required documents present and correctly formatted	Proceed to Pathway Assignment (Section 2.4)	Within 3 working days
⚠️ **INCOMPLETE**	Missing documents or formatting errors	RO notifies PI with list of required corrections	Application paused until resubmission
❌ **REJECTED**	Major issues (wrong form, no signatures)	Full resubmission required	Return to start of process

Key Rule: The review period **does not commence** until all required documents are successfully resubmitted.

2.4 Review Pathways (Triage Step 2)

The full application review process can be summarised in the following diagram:


START HERE
Begin Application Process
Does project need ethics review?
Unsure
No, exempt
Yes, review needed
Contact Research Office for guidance
Use Section 2.4 Exempt Registration
Complete Mandatory Ethics Training
Prepare Complete Application Package
No
All required documents ready?
Yes
Submit as Single PDF via platform/email
Research Office Completeness Check
All documents included?
Yes
No
RO notifies PI of missing items
Pathway Assignment
Assign to Review Pathway
Check project characteristics
Low risk, exempt activity
Minimal risk
Vulnerable populations
Sensitive topics
Deception
>Minimal risk
Exempt Registration Register with RKEO
Expedited Review Chair + 1 reviewer
Full UREC Review Schedule for Committee Meeting
Process Complete

2.4.1 Exempt Activities (Registration Required)

Certain low-risk activities are deemed **Exempt** from full or Fast-Track review, but **MUST still be registered** with the RKEO for audit purposes.

Exempt Activity Criteria Table

Category	Examples	Registration Required?
Educational Practice	Standard curriculum development, teaching evaluation NOT intended for publication	✔ YES
Quality Assurance/Improvement	QA/QI studies using existing, anonymized institutional data	✔ YES
Public Data Sets	Publicly available data sets/archives with anonymized data	✔ YES

Important Notes for Exempt Activities:

◉ **Must register** – Even exempt activities require registration
◉ **Audit trail** – RKEO maintains records for compliance
◉ **No further review** – Once registered, no additional steps
❌ **Cannot involve** – Vulnerable populations, sensitive topics, or identifiable data

If unsure: Contact Research Office to confirm exempt status.

2.4.2 Fast-Track Review

Applications that meet specific criteria for **minimal risk** are approved through the Chair/Deputy Chair and one specialized reviewer.

Fast-Track Review Criteria

Criteria	Description
Risk Level	Minimal risk (see Section 3.2 for definition)
Participants	Non-vulnerable adult populations
Methods	Standard, non-intrusive methods (surveys, interviews)
Data	Anonymized or pseudonymized data
Topics	Non-sensitive subjects

Outcome: Approval typically granted within 2-3 weeks.

2.4.3 Full UREC Review

Applications that involve vulnerable populations, sensitive topics, deception, greater than minimal risk, or complex methodologies must be scheduled for the next Full UREC Meeting.

When Full Review is Required

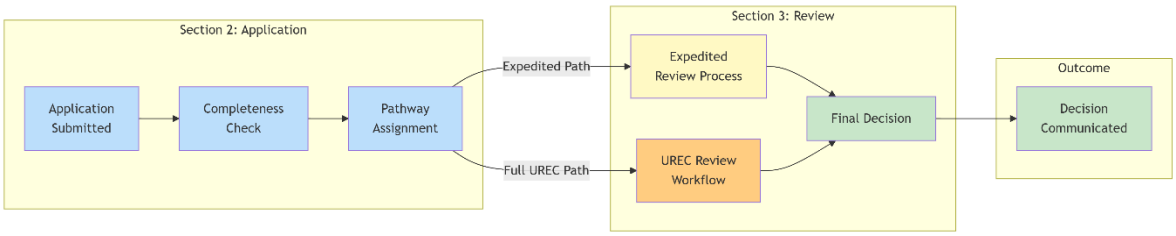
Risk Factor	Examples
Vulnerable Populations	Children, prisoners, adults with incapacity, patients
Sensitive Topics	Trauma, abuse, illegal activities, political extremism
Deception	Any deception of participants
Greater than Minimal Risk	Physical intervention, psychological stress
Complex Methodologies	Clinical trials, invasive procedures

Key Dates:

- **Submission deadline:** 2 weeks before scheduled meeting
- **Meeting frequency:** Monthly (check Research Office calendar)
- **Outcome notification:** Within 5 working days of meeting

3. Review Procedures

3.1 Overview: From Submission to Decision



Key Point: Section 2 determines *which* review path you take. Section 3 explains *what happens* in each path.

The Two Review Pathways (Recap):

pathway	When It Applies	Who Reviews	Timeline
Fast-Track Review	Minimal risk, standard methods, adults with capacity	Chair/Deputy + 1 member	10 working days
Full UREC Review	Vulnerable groups, sensitive topics, deception, >minimal risk	Full committee meeting	Next scheduled meeting

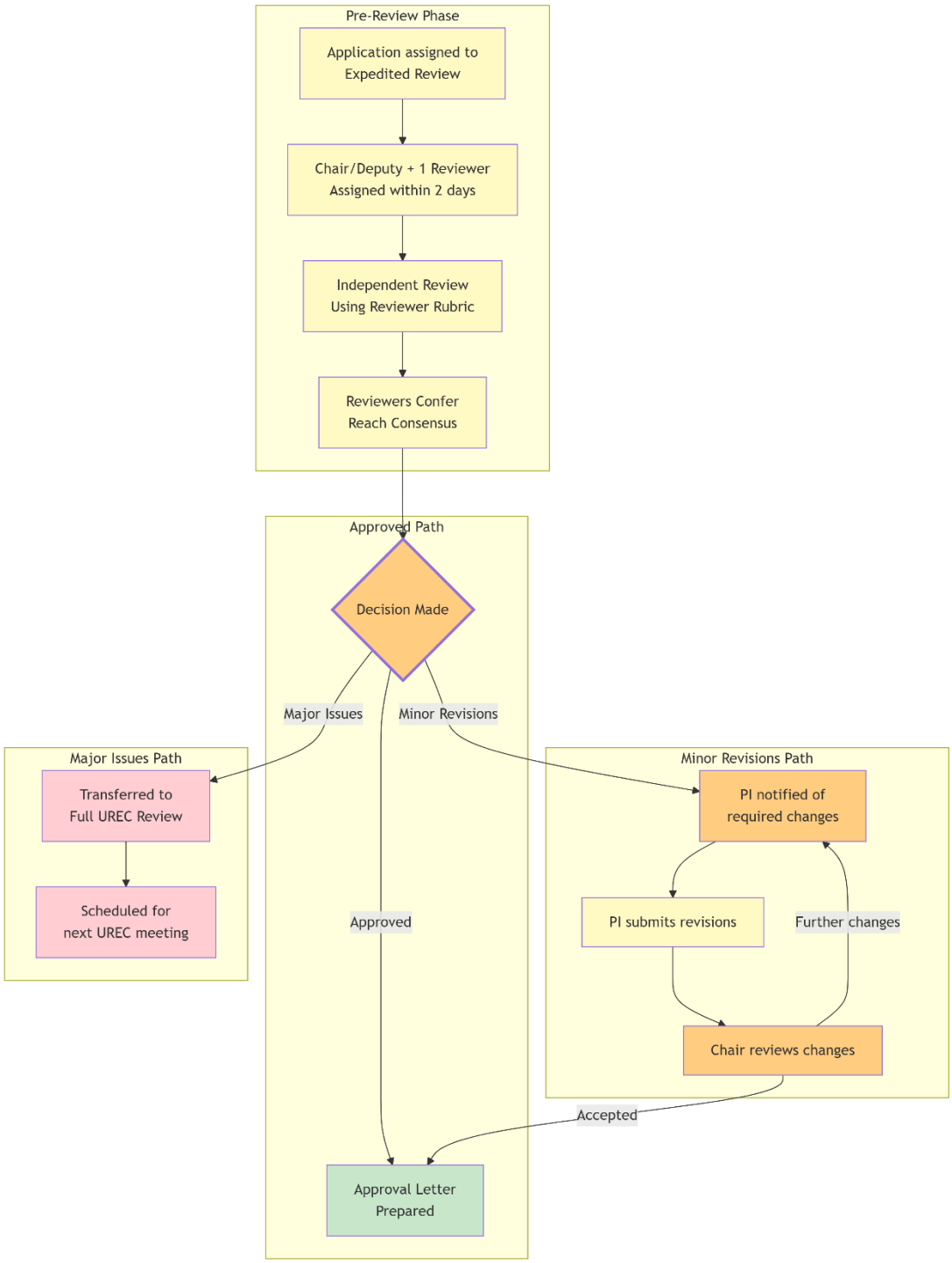
⚠️ **Note:** If you're unsure which pathway applies to your project, refer back to **Section 2.4** or contact the Research Office.

3.2 Fast-Track vs. Full UREC Review Process

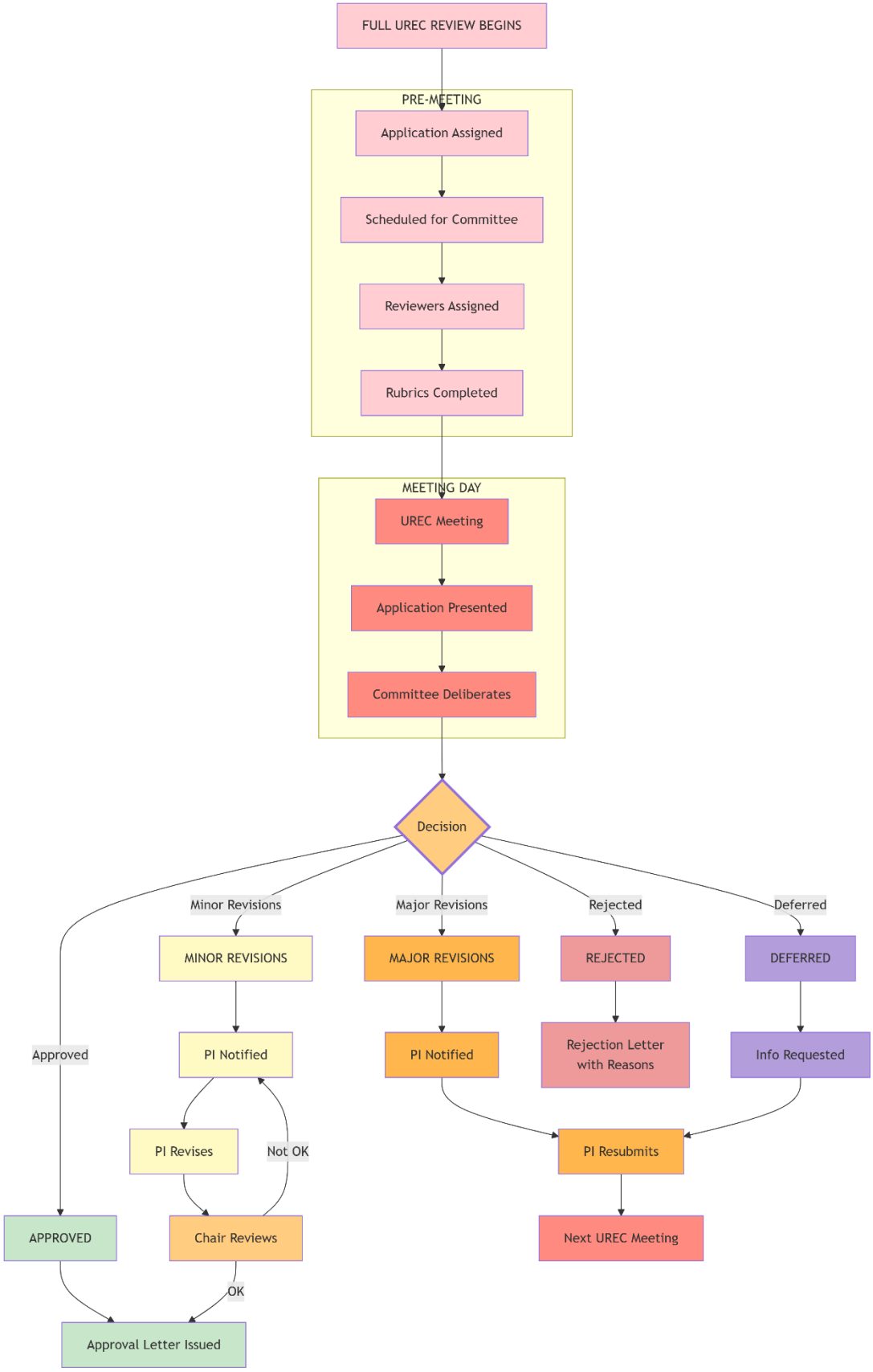
Fast-Track Decision Categories

Decision	Meaning	What Happens Next
Approved	No changes needed	Approval letter sent within 5 days
Minor Revisions	Small, clarifying changes required	PI has 10 working days to resubmit
Major Revisions Required	Significant issues identified	Transferred to Full UREC Review

The following diagram explains the process of Fast-Track review process:



On the other hand, the following diagram shows the Full UREC Review Process (Step-by-Step):


FULL UREC REVIEW BEGINS
PRE-MEETING
Application Assigned
Scheduled for Committee
Reviewers Assigned
Rubrics Completed
MEETING DAY
UREC Meeting
Application Presented
Committee Deliberates
Decision
Approved
Minor Revisions
Major Revisions
Rejected
Deferred
MINOR REVISIONS
MAJOR REVISIONS
REJECTED
DEFERRED
PI Notified
PI Notified
Rejection Letter with Reasons
Info Requested
PI Revises
Not OK
PI Resubmits
APPROVED
Chair Reviews
Next UREC Meeting
OK
Approval Letter Issued

UREC Decision Categories Explained

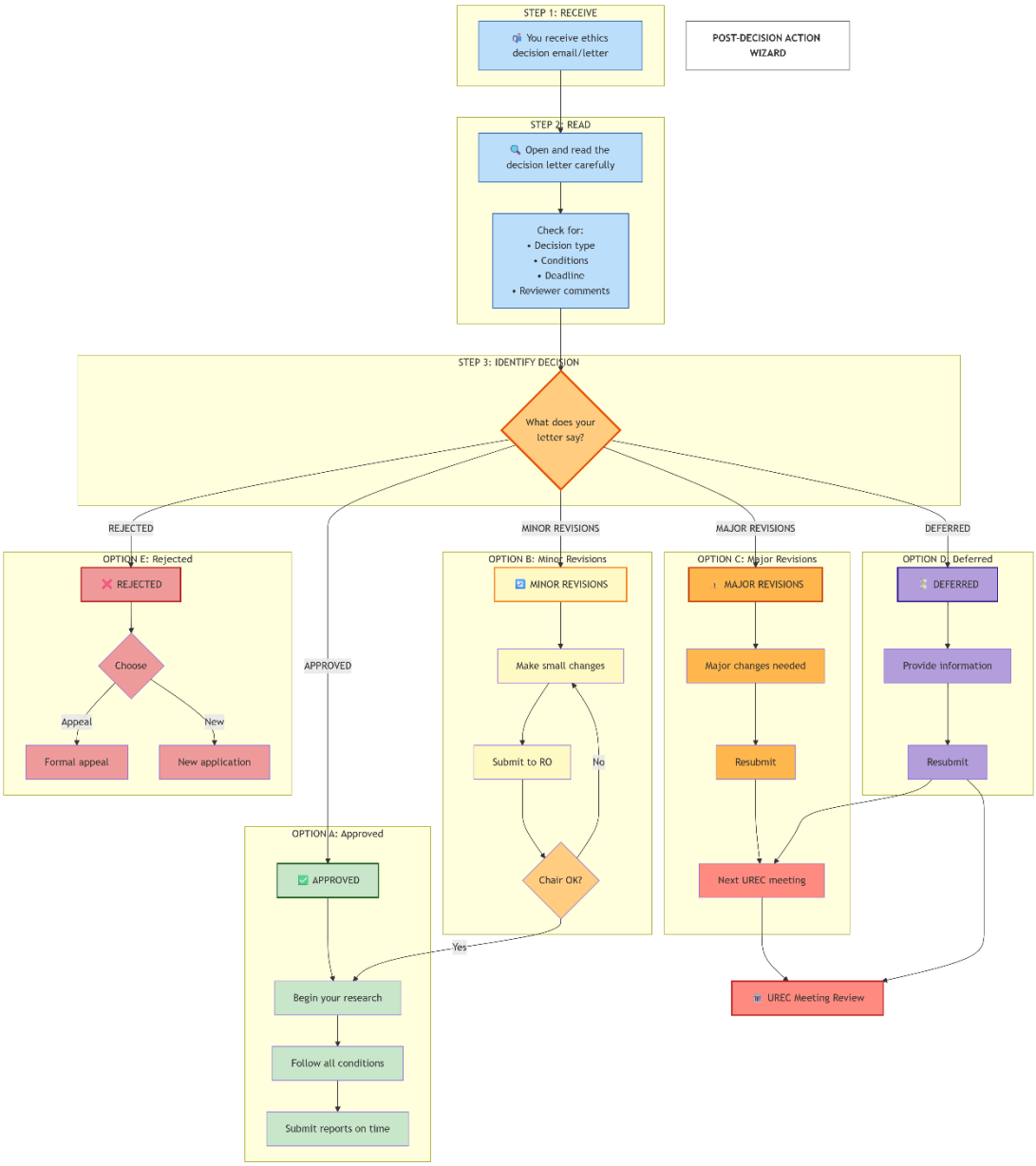
Decision	Definition	Implications	Resubmission Path
Approved	Application meets all ethical requirements	Research can commence immediately	N/A
Approved with Minor Revisions	Minor changes needed (typos, clarifications)	Chair can approve; no need for full committee	5 working days
Major Revisions Required	Significant changes needed to methodology or ethics	Must return to full committee	Next meeting cycle
Deferred	Insufficient information to make decision	Additional information requested	Next meeting cycle
Rejected	Application fails ethical standards	Cannot proceed; new application required	New submission only

Comparison: Fast-Track vs. Full UREC Review – in a glance

Aspect	Fast-Track Review	Full UREC Review
Who Reviews	Chair/Deputy + 1 member	Full committee (12-15 members)
Meeting Required	No - conducted electronically	Yes - scheduled committee meeting
Timeline	10 working days	15-21 days (meeting cycle dependent)
Decision Makers	Chair + 1 reviewer	Committee consensus/vote
Appeals Path	Can request Full Review if declined	Final decision (appeal to University)
Complexity Level	Low to moderate	High
Risk Level	Minimal	Low to high

Post-Decision Pathways

The following diagram shows the action required by the researcher once received the decision letter.



3.3 Communication of Decisions

- Decisions are communicated in writing via the Research Office within five working days of the review meeting.
- Approval letters include the UREC reference number, approval period, and mandatory reporting requirements.

4. Ethics And Data Protection

4.1 Legal Framework

All research data protection at Oryx University is governed by:

- The State of Qatar's Personal Data Privacy Law (PDPL).
- Mandatory compliance with relevant regulations from LJMU as the partner institution.
- **Data Residency:** No personal data classified as sensitive shall be stored, processed, or transferred outside the State of Qatar without explicit written approval from both UREC and the University Legal Counsel.

4.2 Data Protection Principles

Research involving personal data must adhere to the principles of Lawfulness, Fairness, Transparency, Purpose Limitation, Data Minimization, Accuracy, Storage Limitation, Integrity and Confidentiality, and Accountability.

4.3 Monitoring and Adverse Event Reporting

UREC monitors approved research through:

- Annual progress reports (for studies >12 months).
- Adverse Event Reports (AERs) and Protocol Deviation Reports (PDRs) submitted by the PI. **Reporting timelines are strictly enforced** as per **`RKEO-TOR-UREC-V1.0`** (Section 6.2).
- Random and For-Cause Audits.

5. Roles And Responsibilities

5.1 UREC Members

Review and make ethical decisions, attend meetings regularly, and complete required ethics training.

5.2 Principal Investigators (PIs)

Ensure full compliance with ethical standards and data protection laws. Submit complete and accurate applications. Report any adverse events, amendments, or non-compliance immediately to UREC.

5.3 Research Support Staff (Research Office)

Provide administrative support to UREC, manage application submissions, conduct completeness checks, maintain records, and issue formal decision letters.

6. Training And Development

6.1 Training Requirements

All researchers involved in projects subject to ethics review must complete:

- Initial ethics training prior to commencing research.
- Annual refresher training to stay updated on ethical and legal standards.

7. Documentation And Record Keeping

7.1 Document Control

All documents related to research ethics must be controlled, including application forms, approval letters, meeting minutes, and training records.

7.2 Record Retention

Records must be retained for a minimum of **ten years** post-completion or as specified by the relevant regulator or funder, whichever is longer.

7.3 Confidentiality

All UREC members and researchers must maintain strict confidentiality regarding applications and committee discussions.

8. Reporting

8.1 Internal Reporting

- **End-of-Project Report:** A mandatory **End-of-Project Report** must be submitted by the PI within three months of the project's completion to formally close the ethics file.
- UREC reports to the President/RKEO Director via Quarterly Summaries and an Annual Report (as detailed in **`RKEO-TOR-UREC-V1.0`**).

8.2 External Reporting

UREC reports to external bodies, including funding agencies and regulatory authorities, as legally required.

9. Compliance And Enforcement

9.1 Non-Compliance Procedures

Any instances of non-compliance with this SOP will be addressed as per the **Research Integrity Policy (`RKEO-POL-Research Integrity Policy`)**, including investigation by the UREC or a formally appointed panel, and possible suspension of research activities.

9.2 Consequences of Non-Compliance

Consequences may include withdrawal of ethics approval, mandated additional ethics training, or formal disciplinary action.

10. Review And Amendment of SOPs

This SOP will be reviewed annually or more frequently if changes in regulations, University policy, or best practices occur. Amendments require review and approval by UREC and the University President.

11. Institutional Sponsorship

Oryx University acts as the **Sponsor** for all research conducted under its auspices, assuming primary legal and ethical responsibility for the design, management, and reporting of the research.

- For joint degree programs (e.g., with LJMU), Oryx University serves as the primary local sponsor, working with the partner institution to define co-sponsorship agreements and ensure compliance with all applicable jurisdictions.
- The PI must confirm sponsorship status during the ethics application process.

12. External Representation & Activities

This section outlines the mandatory governance workflows for staff engagement in external activities, ensuring alignment with Oryx University's strategic goals, reputational standards, and financial policies.

12.1: Conference Attendance/Presentation

Purpose: To ensure that staff presenting externally uphold the university's academic standards and that travel funds are utilized strategically.

Workflow:

1. **Submission:** The staff member must complete **`RKEO-FRM-External Presentation & Travel Approval-V1.0`** at least **45 days** prior to the event.
2. **Departmental Review:** The Dean reviews the academic merit of the paper/presentation and confirms budget availability (if any).
3. **RKEO Compliance Check:** The form is submitted to RKEO to verify:
    - **IP Clearance:** Ensuring no patentable/sensitive IP is prematurely disclosed.
    - **Affiliation Check:** Ensuring the author's affiliation is correctly listed as "Oryx University."
4. **Approval:** Final approval is granted by the Faculty Dean (or designee). Bookings are processed only after this approval.

12.2: Hosting Distinguished Guests/Speakers

Purpose: To manage the prestige and protocol associated with inviting high-profile external speakers.

Workflow:

1. **Proposal:** The host staff member submits **`RKEO-FRM-Distinguished Speaker Request-V1.0`** to the RKEO **30 days** in advance.
2. **Strategic Review:** The Dean reviews the proposal for alignment with faculty research priorities and budget.
3. **Vetting & Protocol:** RKEO (in coordination with Public Relations) conducts necessary due diligence on the speaker and advises on appropriate protocol (e.g., VIP handling, media coverage).
4. **Formal Invitation:** Only after RKEO approval can the formal invitation be issued on University letterhead.

12.3: External Partner Collaboration Initiation

Purpose: To manage legal, financial, and reputational risks associated with formal institutional partnerships.

Workflow:

1. **Initiation:** Any staff member seeking to formalize a relationship (e.g., MOU, Joint Research, Student Exchange) must submit **`RKEO-FRM-Collaboration Review Initiation-V1.0`**.
2. **Due Diligence:** RKEO conducts a partner background check (financial health, reputational history).
3. **Governance & Legal Review:**
    - **Data Sharing:** If data transfer is involved, compliance with Qatar Law No. 13 (Data Residency) is verified.
    - **IP Rights:** Ownership of potential IP is defined.
4. **Agreement Drafting:** RKEO/Legal Counsel drafts the agreement. **Staff are prohibited from signing contracts or MOUs directly.**
5. **Signing Authority:** Agreements are signed by the President or authorized signatory based on the Delegation of Authority policy.

12.4: Internal Events and Seminars

Purpose: To coordinate the university's events calendar and ensure resource optimization.

Workflow:

1. **Registration:** The organizer submits **`RKEO-FRM-Event & Activity Registration-V1.0`** to RKEO **30 days** prior.
2. **Logistics Review:** RKEO checks for calendar conflicts with other major university events and validates room/venue requirements.
3. **Confirmation:** The event is confirmed and then added to the institutional Research Calendar.

Appendices

- Appendix A: DPIA Template (**`RKEO-TMP-DPIA-V1.0`**)
- Appendix B: UREC Terms of Reference (**`RKEO-TOR-UREC-V1.0`**)
- Appendix C: Conflict of Interest Declaration (**`RKEO-FRM-Conflict of Interest Declaration-V1.0`**)
- Appendix D: Reviewer Checklist and Rubric (**`RKEO-FRM-UREC Reviewer Rubric-V1.0`**)
- Appendix E**:** External Activity Forms **(Section 12)**