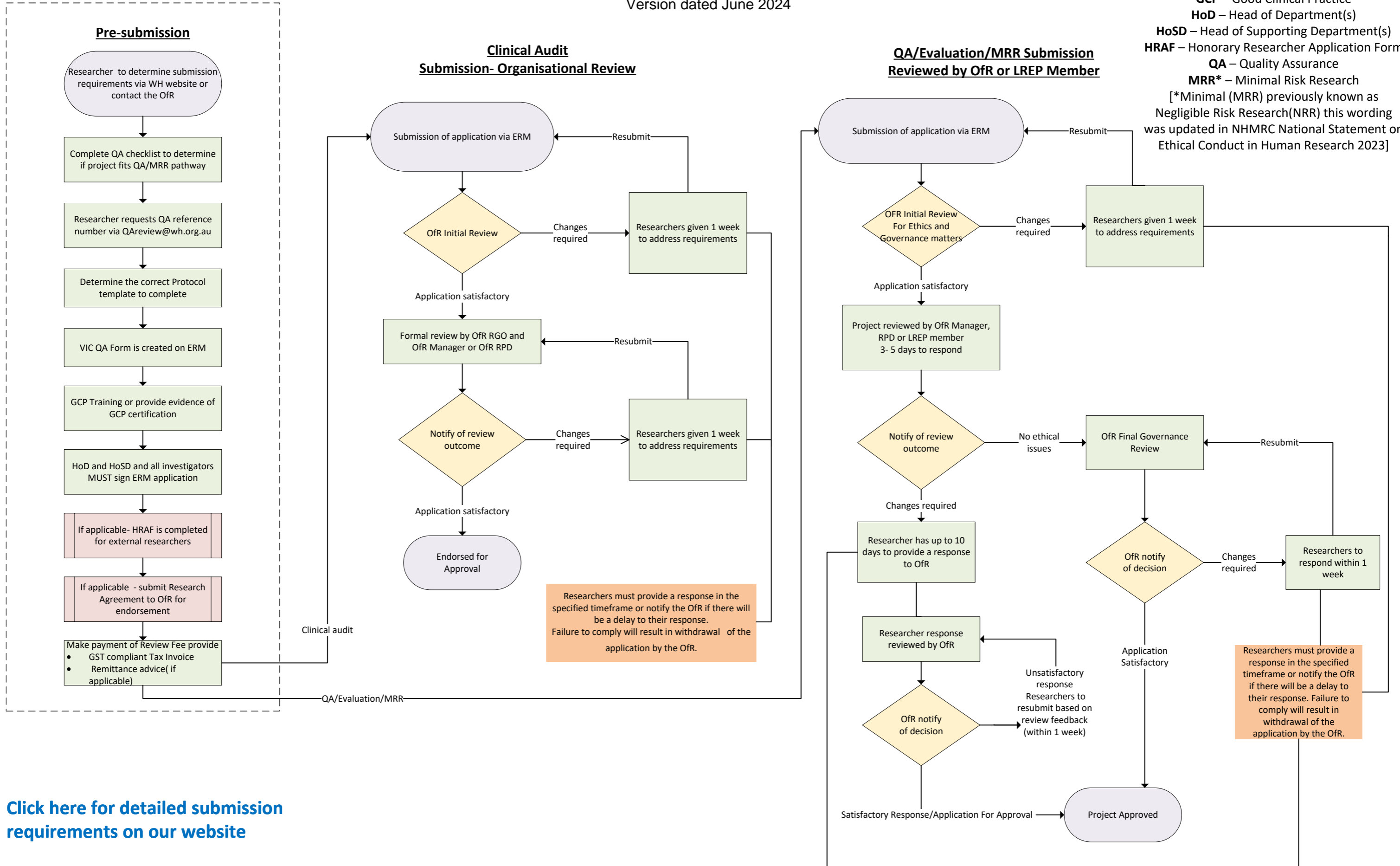# Western Health

Office for Research
Quality Assurance/Clinical Audit/Minimal* Risk
Ethics Review Process Map
Version dated June 2024

Abbreviations
ERM- Ethics Review Manager
OfR – Office for Research
RPD – Research Program Director
LREP – Low Risk Ethics Panel
GCP – Good Clinical Practice
HoD – Head of Department(s)
HoSD – Head of Supporting Department(s)
HRAF – Honorary Researcher Application Form
QA – Quality Assurance
MRR* – Minimal Risk Research
[*Minimal (MRR) previously known as Negligible Risk Research(NRR) this wording was updated in NHMRC National Statement on Ethical Conduct in Human Research 2023]

Pre-submission

- Researcher to determine submission requirements via WH website or contact the OfR
- Complete QA checklist to determine if project fits QA/MRR pathway
- Researcher requests QA reference number via QAreview@wh.org.au
- Determine the correct Protocol template to complete
- VIC QA Form is created on ERM
- GCP Training or provide evidence of GCP certification
- HoD and HoSD and all investigators MUST sign ERM application
- If applicable- HRAF is completed for external researchers
- If applicable - submit Research Agreement to OfR for endorsement
- Make payment of Review Fee provide
  - GST compliant Tax Invoice
  - Remittance advice(if applicable)

Clinical audit

QA/Evaluation/MRR

Clinical Audit
Submission- Organisational Review

- Submission of application via ERM
- OfR Initial Review → Changes required → Researchers given 1 week to address requirements → Resubmit
- Application satisfactory
- Formal review by OfR RGO and OfR Manager or OfR RPD ← Resubmit
- Notify of review outcome → Changes required → Researchers given 1 week to address requirements
- Application satisfactory
- Endorsed for Approval

Researchers must provide a response in the specified timeframe or notify the OfR if there will be a delay to their response.
Failure to comply will result in withdrawal of the application by the OfR.

QA/Evaluation/MRR Submission
Reviewed by OfR or LREP Member

- Submission of application via ERM ← Resubmit
- OFR Initial Review For Ethics and Governance matters → Changes required → Researchers given 1 week to address requirements
- Application satisfactory
- Project reviewed by OfR Manager, RPD or LREP member 3- 5 days to respond
- Notify of review outcome → No ethical issues → OfR Final Governance Review ← Resubmit
- Changes required
- Researcher has up to 10 days to provide a response to OfR
- Researcher response reviewed by OfR ← Unsatisfactory response Researchers to resubmit based on review feedback (within 1 week)
- OfR notify of decision → Satisfactory Response/Application For Approval → Project Approved
- OfR notify of decision → Changes required → Researchers to respond within 1 week
- Application Satisfactory → Project Approved

Researchers must provide a response in the specified timeframe or notify the OfR if there will be a delay to their response. Failure to comply will result in withdrawal of the application by the OfR.

Click here for detailed submission requirements on our website