

GREATER THAN LOW RISK	LOW RISK	NEGLIGIBLE RISK
Risk Profiling		
Researchers use the risk checklists to categorise their research. Projects categorised as negligible risk, low risk or high (i.e. greater than low) risk based on definitions in the National Statement.		
↓	↓	↓
Application Completed Protocol (CEBU & CRDO services available) & Patient Information finalised Plain Language Advisor (PLA) review (or concurrent to Scientific Assessment)		Short Application Completed Protocol & Patient Information finalised PLA review (if necessary)
↓	↓	↓
Peer Review		
Researchers obtain a peer review of their project using the Review Proforma & Guidelines. Once the review is received researchers address all queries and update relevant documents.		
↓	↓	↓
Line Manager Sign-off Nominated Line Manager (LM) signs-off that the proposed form and source of scientific review is appropriate, that they assume responsibility for PI conduct, the budget is appropriate and funds available.		Line Manager Sign-off Project is negligible risk (in addition to left)
		Executive Director Sign-off: Project is negligible risk
SUBMIT TO ETHICS OFFICE		
Scientific Assessment TOR: Review protocol & project documentation for scientific merit & integrity Composition: Drug Trials Subcommittee or Expert reviewers picked from pool Output: Approved protocol and summary of key issues for HREC or Chair attention		
↓	↓	↓
Full HREC (ethical review) Includes Information Statement content	HREC Chair (ethical review) Includes Information Statement content check	
↓	↓	↓
Ethics & Research Department Check (May occur at any stage in the process before approval is granted)		
<ul style="list-style-type: none"> • HREC application is complete • Appropriate scientific review received and protocol approved • All required sign-offs received • Governance check (Regulatory Documents) • Site specific assessment 		
↓	↓	↓
Final Approval		
Scientific & Ethical (& Legal where applicable) review complete. All queries responded answered. Regulatory & site specific documents in place. Notify PI (& Study Contact where applicable) & Line Manager of approval		
↓	↓	↓