



Signature requirements and delegations for research projects

Type of Project	Required Documents to be signed	Delegated authority for signing
Quality Assurance	QA Checklist & Site Specific Form	Must be signed by: <ul style="list-style-type: none"> Principal Investigator (PI) Associate Investigator/s (AI) Head of Department (HoD) Where the Head of Department is the PI the Divisional Director is to sign all relevant documents
	Statement of Approval Form	<ul style="list-style-type: none"> Head of Supporting Department Where the Head of Department is the PI the Divisional Director is to sign all relevant documents <ul style="list-style-type: none"> PI signature
	WH Curriculum Vitae Template & WH Research Code of Conduct	Individual CVs To be signed and dated by all investigators. Updated CV required every 2 years
	Research Agreements <ul style="list-style-type: none"> Memorandum of Understanding (MOU) Research Collaboration Agreements (RCA) Melbourne Academic Centre for Health (MACH) 	Depending on the nature of the study signatories vary: <p>MOU</p> <ul style="list-style-type: none"> WH PI Collaborating PI <p>RCA</p> <ul style="list-style-type: none"> WH Director of Research/Research Program Director/Chief Medical Officer Collaborator approving authority <p>MACH</p> <ul style="list-style-type: none"> Sponsor/Initiating Party WH Director of Research/Research Program Director/Chief Medical Officer
	LREP Amendment Request Form	<ul style="list-style-type: none"> Sign off from PI Sign off declaration by new personnel or personnel with change in roles If change involves a change in PI, then HoD is require to sign off
	LREP Change of Personnel Form	<ul style="list-style-type: none"> Sign off from PI or delegate. Delegate can only sign if formally delegated (delegation log authority to sign)
	LREP Progress Report & Self – Audit Form	<ul style="list-style-type: none"> Sign off from PI or delegate. Delegate can only sign if formally delegated (delegation log authority to sign)
	LREP Protocol Deviation/Violation Form	<ul style="list-style-type: none"> Sign off from PI or delegate. Delegate can only sign if formally delegated (delegation log authority to sign)



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	LREP AE/SAE Report Form	<ul style="list-style-type: none"> Sign off from PI or delegate. Delegate can only sign if formally delegated (delegation log authority to sign)
Low & Negligible Risk	Cover Letter & Checklist	Sign off from PI or Applicant/Contact person
	Human Research Ethics Application (HREA) Form	Signed and dated by PI Signed and dated by AIs Signed and dated by HoD Signed and dated by Head of Supporting Departments
	Victorian Specific Module	If word version completed, to be signed by PI
	WH LREP Site Specific Form	Sign off from PI
	Statement of Approval Form	<ul style="list-style-type: none"> Head of Supporting Department Where the Head of Department is the PI the Divisional Director is to sign all relevant documents PI signature
	WH Curriculum Vitae Template & WH Research Code of Conduct	Individual CVs To be signed and dated by all investigators. Updated CV required every 2 years
	Budget	If the project is funded. Itemised budget is to be signed by the Principal Investigator and approved/endorsed by the departmental Business Analyst (signature on budget/email confirmation is acceptable)
	Research Agreements <ul style="list-style-type: none"> Memorandum of Understanding (MOU) Research Collaboration Agreements (RCA) Melbourne Academic Centre for Health (MACH) 	Depending on the nature of the study signatories vary: MOU <ul style="list-style-type: none"> WH PI Collaborating PI RCA <ul style="list-style-type: none"> WH Director of Research/Research Program Director/Chief Medical Officer Collaborator approving authority MACH <ul style="list-style-type: none"> Sponsor/Initiating Party WH Director of Research/Research Program Director/Chief Medical Officer
	LREP Amendment Request Form	<ul style="list-style-type: none"> Sign off from PI Sign off declaration by new personnel or personnel with change in roles If change involves a change in PI, then HoD is require to sign off
	LREP Change of Personnel Form	<ul style="list-style-type: none"> Sign off from PI or delegate. Delegate can only sign if formally delegated (delegation log authority to sign)
LREP Progress Report & Self –	<ul style="list-style-type: none"> Sign off from PI or delegate. 	



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	Audit Form	Delegate can only sign if formally delegated (delegation log authority to sign)
	LREP Protocol Deviation/Violation Form	<ul style="list-style-type: none"> • Sign off from PI or delegate. Delegate can only sign if formally delegated (delegation log authority to sign)
	LREP AE/SAE Report Form	<ul style="list-style-type: none"> • Sign off from PI or delegate. Delegate can only sign if formally delegated (delegation log authority to sign)
Site Specific Assessment	Research Governance Cover Letter and Checklist	Sign off from PI or applicant
	Site Specific Assessment (SSA) Form	<ul style="list-style-type: none"> • Research Personnel Declarations <ul style="list-style-type: none"> ○ WH site Specific Investigator Declaration Signature Form can be used instead of generating fields within the SSA form • HoD to sign. Where the HoD is the PI the Divisional Director is to sign all relevant documents • Head of Supporting Departments. Where the HoD is the PI the Divisional Director is to sign all relevant documents <ul style="list-style-type: none"> ○ WH Statement of Approval Form could be signed instead of SSA Head of Supporting Department sign offs.
	Statement of Approval Form	<ul style="list-style-type: none"> • Head of Supporting Department Where the Head of Department is the PI the Divisional Director is to sign all relevant documents • PI signature
	Pathology Approval	<ul style="list-style-type: none"> • Sign off from PI • Sign off from HoD • Sign off from Pathology & Medical Imaging Operations Manager
	Medical Imaging Approval	<ul style="list-style-type: none"> • Sign off from PI • Sign off from Director of Radiology
	Victorian Specific Module	If word version completed, to be signed by Coordinating PI (CPI) as reviewed and approved by the Reviewing HREC
	WH Curriculum Vitae Template & WH Research Code of Conduct	Individual CVs To be signed and dated by all investigators. Updated CV required every 2 years



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	Budget	If the project is funded. Itemised budget is to be signed by the Principal Investigator and approved/endorsed by the departmental Business Analyst (signature on budget/email confirmation is acceptable)
	Research Agreements <ul style="list-style-type: none"> • Clinical Trial Research Agreements (CTRA) • Research Collaboration Agreements (RCA) • Melbourne Academic Centre for Health (MACH) 	Depending on the nature of the study signatories vary: <u>CTRA</u> <ul style="list-style-type: none"> • Sponsor/CRO • Principal Investigator • WH Director of Research/Research Program Director/Chief Medical Officer <u>RCA</u> <ul style="list-style-type: none"> • WH Director of Research/Research Program Director/Chief Medical Officer • Collaborator approving authority <u>MACH</u> <ul style="list-style-type: none"> • Sponsor/Initiating Party • WH Director of Research/Research Program Director/Chief Medical Officer
	Medicines Australia Standard Form of Indemnity	<ul style="list-style-type: none"> • Signed by Sponsor/CRO • WH Director of Research/Research Program Director/Chief Medical Officer
	Change of Personnel Form	<ul style="list-style-type: none"> • Sign off from PI or delegate. • Delegate can only sign if formally delegated (delegation log authority to sign)
	Progress & Final Reports	<u>Progress Report – Project Form (HREC)</u> <ul style="list-style-type: none"> • Signed by Sponsor/CRO or the (CPI) <u>Progress Report – Site Form (RGO)</u> <ul style="list-style-type: none"> • Signed by PI <u>WH Self Audit Form</u> <ul style="list-style-type: none"> • Sign off from PI or delegate. Delegate can only sign if formally delegated (delegation log authority to sign)
	Safety Report	<ul style="list-style-type: none"> • Signed by PI/CPI
	Annual Safety Report	<ul style="list-style-type: none"> • Signed by Sponsor/CRO or CPI
	Study Breaches	<u>Non Serious Breach – Deviation Report</u> <ul style="list-style-type: none"> • Signed by Sponsor/CRO or Site PI <u>Serious Breach Report Form (Sponsor)</u> <ul style="list-style-type: none"> • Signed by Sponsor/CRO or Site PI <u>Suspected Breach Report Form (Third Party)</u> <ul style="list-style-type: none"> • Signed by reporter