



Review Pathways – Cheat Sheet

	Timeframe	Review	Minimum Submission Requirements via RGS
<p>Minimal Risk</p> <ul style="list-style-type: none"> • No risk of harm or discomfort • No foreseeable risk more than an inconvenience • Retrospective de-identified data • Prospective de-identified data of observational studies of healthy volunteers • De-identified questionnaires or surveys • WA Public Health Hospitals • Affiliation with WA Universities <i>(Data Transfer/Confidentiality Agreement (Students, Interns, Resident Medical Officers, Trainees/Registrars, Fellows, and Higher Degree Research))</i> • On site Data Scientists, Statisticians and Bio Statisticians. <i>(Some on site statisticians will have affiliation with WA Universities)</i> • Strong data management plan ensuring only de-identified data <i>(REDCap is a secure web application and the preferred WA Health data management tool supported by a governance structure)</i> • No financial burden on the institution 	<p>10 business days from submission to HREC * <i>(Does not need to be submitted to RGO)</i></p>	<p>Internal Panel Review</p>	<p>Forms:</p> <ul style="list-style-type: none"> • WAHEAF or • HREA and WASM <p>Documents:</p> <ul style="list-style-type: none"> • Minimal & Low Risk Coversheet • Protocol • Waiver of Consent, addressing Waiver Criteria <i>(retrospective project)</i> • PICF <i>(participant involvement)</i> • Data Management Plan • All other necessary document specific to the project

* Dependent on stop clock, time sitting with researcher





	Timeframe	Review	Minimum Submission Requirements via RGS
<p>Low Risk</p> <ul style="list-style-type: none"> • No risk of harm • No foreseeable risk more than discomfort • Retrospective de-identified data • Prospective de-identified data • Questionnaires or surveys • Participant involvement • External Sites <i>(Data Transfer Agreement)</i> • Affiliation with WA Universities <i>(Data Transfer/Confidentiality Agreement)</i> <i>(Students, Interns, Resident Medical Officers, Trainees/Registrars, Fellows, and Higher Degree Research)</i> • On site Data Scientists, Statisticians and Bio Statisticians. <i>(Some on site statisticians will have affiliation with WA Universities)</i> • Strong data management plan <i>(REDCap is a secure web application and the preferred WA Health data management tool supported by a governance structure)</i> • No financial burden on the institution 	<p>Up to 30 business days from submission to HREC and RGO *</p>	<p>Internal Panel or Out of Session Review <i>(Case by case basis)</i></p>	<p>Forms:</p> <ul style="list-style-type: none"> • WAHEAF or • HREA and WASM <p>Documents:</p> <ul style="list-style-type: none"> • Minimal & Low Risk Coversheet • Protocol • Waiver of Consent, addressing Waiver Criteria <i>(retrospective project)</i> • PICF <i>(participant involvement)</i> • Data Management Plan • All other necessary documents specific to the project

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	Timeframe	Review	Minimum Submission Requirements via RGS
<p>More than Low Risk</p> <ul style="list-style-type: none"> • Foreseeable risk is more than discomfort, harm, or significant harm • Interventions and therapies, including clinical and non-clinical trials • Innovations or new treatment modalities • Active concealment or planned deception of participants • Human genetics and stem cells • Research specifically targeting Aboriginal and/or Torres Strait Islander peoples • Women who are pregnant and the human foetus • Other forms of gaining consent (<i>People who are highly dependent on medical care, People who are highly dependent on medical care, or People with an intellectual disability or a mental illness</i>) • Includes all other criterion 	<p>60 business days from submission to HREC and RGO *</p>	<p>Full Committee Review</p>	<p>Forms:</p> <ul style="list-style-type: none"> • WAHEAF or • HREA and WASM <p>Documents:</p> <ul style="list-style-type: none"> • Protocol • Waiver of Consent, addressing Waiver Criteria (<i>retrospective project</i>) • <i>OptOut Consent, addressing OptOut Criteria</i> • PICF (<i>participant involvement</i>) • Data Management Plan • All other necessary documents specific to the project

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