EDITH COWAN UNIVERSITY
RESEARCH SERVICES

Edith Cowan University
Research Ethics Management System (REMS)

User Guide

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Contents

BEFORE YOU START

The ethical dimensions of a project are central to its overall success and as such, form an important part of the research design, conduct and reporting at ECU. This User Manual provides the background context to ECU's approach to human research ethics review and provides a step by step guide to seeking human research ethics approval for your project.

All human interaction, including the interaction involved in human research, has ethical dimensions. However, 'ethical conduct' is more than simply doing the right thing. It involves acting in the right spirit, out of an abiding respect and concern for one's fellow creatures.
National Statement on Ethical Conduct in Human Research

An introduction to the Research Ethics Management System

The Research Ethics Management System (REMS) at ECU is an online system which facilitates the end-to-end process of applying for, reviewing and approving all research being conducted with human and animal participants. The REMS is comprised of the following:

1. REMS Portal
2. Proportional Review Checklist;
3. Team Collaboration Spaces; and
4. Online Application Form.

The ***REMS Portal*** is the personalised landing page for all REMS related activities. When you log in to the Student or Staff Portal you will see a link to the REMS Portal in the list of *Easy Login's* to the left of the screen. When you enter this REMS Portal, you will see all of the research projects you are named on, including those where you are a supervisor or reviewer. You can review each application's status and application form/review feedback where appropriate. You can also commence a new application or view our helpful resources.

The ***Proportional Review Checklist*** (PRC) is the first step in the development of a new research ethics application that comprises a series of questions asked of a researcher to help determine if the proposed work requires human or animal research ethics review. The PRC has a secondary purpose of collating information relating to all research being undertaken at ECU, regardless of whether it requires human or animal ethics review. Responses to the PRC will determine if the proposed work is either out of scope of human or animal ethics review, exempt from human research ethics review or requires review as defined by the National Statement on Ethical Conduct in Human Research.

Once a project has been deemed to require human research ethics review, REMS automates the creation of a ***Team Collaboration Space*** (in Microsoft Teams) and populates this space with the relevant application form and supporting documentation to enable the research team to complete and submit their application for human research ethics review. The online ***Application Form*** is

accessible from your automated email, Microsoft Team site and REMS portal and can be edited and saved as often as required until submission.

In short, the REMS facilitates all aspects of an ECU researcher's submission of a research ethics application, its review, approval, monitoring and reporting.

Who needs to read this document?

Any active researcher, whether an ECU Staff member or Student must be familiar with the REMS to ensure that all research conducted is tested for its requirement to undergo review by a human research ethics committee.

Even where a researcher's work is known to not involve humans, the completion of the initial stages of the REMS enables the collation of important high-level data relating to the scope of research being conducted by ECU staff and students.

What you need to know before starting your application

Before you log in to the ECU REMS you should have read through this User Manual and be familiar with the types of questions to be asked. This will ensure you have all relevant information at hand to complete your application promptly.

AN OVERVIEW OF THE RESEARCH ETHICS MANAGEMENT SYSTEM (REMS)

ECU's Research Ethics Management System (REMS) is an integrated online approach to research ethics. The REMS encompasses the end-to-end process of applying for research ethics approval including the review and approval of research ethics applications, monitoring and reporting. Underpinning REMS is the *National Statement on Ethical Conduct in Human Research*.

Logging in to your Portal

To commence your new human or animal research ethics application or to access an existing application, you can log in to your REMS portal from the Student/Staff portal *Easy Logins* list to the left of the screen. Once in your portal you may start a new application, review an existing one or see the status of an application. Your portal is personalised so that any ethics application on which you are named as a chief investigator, investigator, supervisor or student will be visible to you.

Determining if an activity requires research ethics review in the Proportional Review Checklist

All research being undertaken at ECU is required to be tested in REMS via the Proportional Review Checklist to determine whether it requires research ethics review. In making this determination, ECU has developed the Proportional Review Checklist which, in accordance with the *National Statement* and other associated policies and guidelines, determines whether a proposed activity requires research ethics review. Completion of the Proportional Review Checklist will result in a researcher being advised their work falls within one of the following categories:

- Prior Review (multicentre project)
    - Projects which have been reviewed by another HREC
- Mandated for review by the Human Research Ethics Committee
- Out of Scope of Human Research Ethics Review
    - Including animal ethics review
- Exempt from Human Research Ethics Review
- Requires Human Research Ethics Review within one of three review pathways:
    - Negligible Risk Review;
    - Low Risk Review; or
    - Greater than Low Risk Review (HREC).

When a project is screened out of the Proportional Review Checklist (because the work is deemed out of scope or exempt), the researcher will receive an automated email notifying them of the decision, and after consideration of the specific advice relating to the nature of the research, researchers may move forward with their research without the need for further review.

Where a project requires research ethics review, a collaboration space will be established within Microsoft Teams with all required information and application forms necessary for the completion and submission of a research ethics application.

The diagram on the following page provides an illustrative overview of the Research Ethics Management System and the Proportional Review Checklist at ECU.

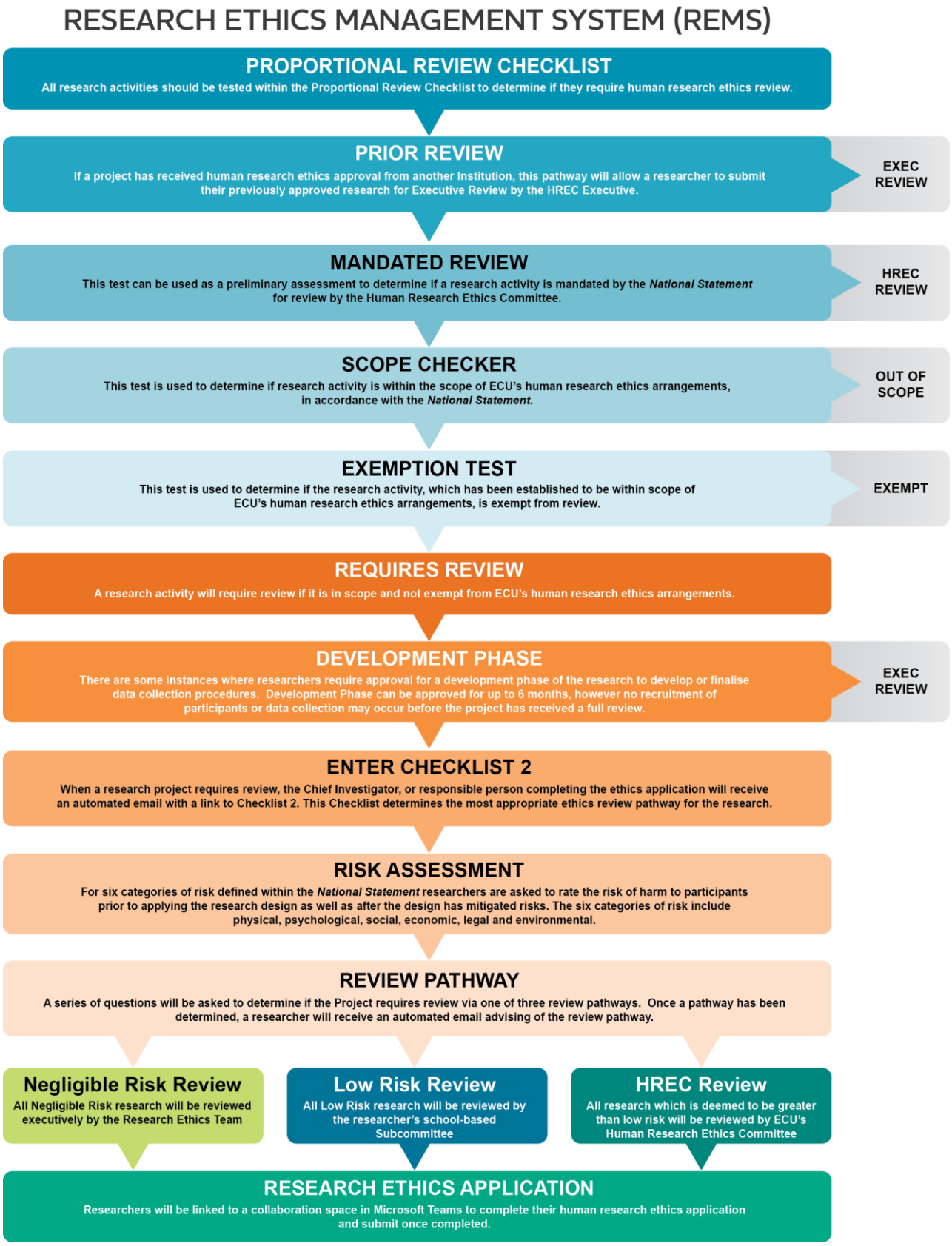


Figure 1: Research Ethics Management System (REMS)

Review of research ethics applications

There are five main pathways of research ethics review at ECU. These review pathways are aligned to the requirements for research ethics review as outlined in the *National Statement* and *Animal Code* and have been established to expedite the ethics review process based on each project's level of risk. The review pathways include:

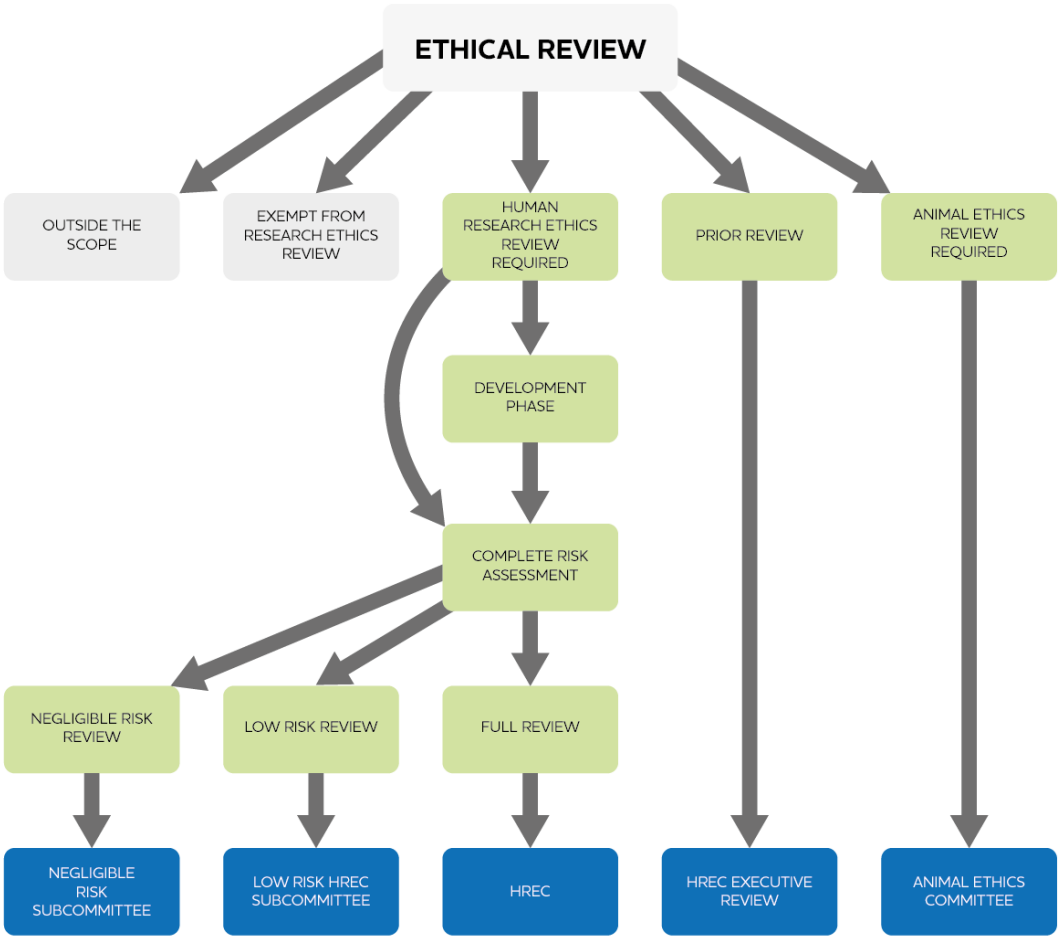


Figure 2: ECU's Ethical Review Pathways

Human Research Ethics Committee Review

The National Statement on Ethical Conduct in Human Research requires all research with more than a low level of risk to participants be considered by a meeting of the Human Research Ethics Committee (HREC).

Low Risk Review

Research which presents a low level of risk to participants may be considered by a delegated subcommittee of the HREC. At ECU, all low-risk research is considered by a relevant school-based Subcommittee.

Negligible Risk Review

All research that involves humans or their previously collected confidential data but contains no more than negligible risk, is reviewed administratively by the Research Ethics Team, with delegated authority from the HREC.

Review outcomes

Once a project is submitted for human research ethics review, it may move through a series of review outcomes, depending on the feedback received by the review committee. A project may move in and out of one or more of these outcomes prior to being approved. The typical review outcomes include:

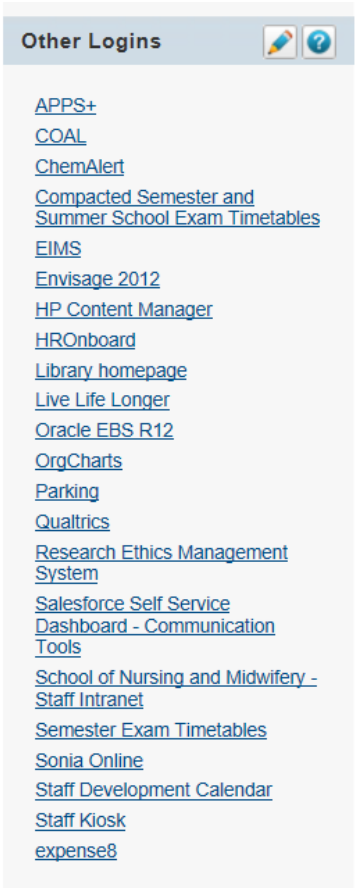
1. Approved;
2. Minor amendment or clarification needed. Further review not needed;
3. Additional information or clarification of project required. Further review needed;
4. Inadequate. Opportunity to re-submit offered;
5. Not applicable (e.g. no human participants); and
6. Not approved (e.g. research activities already conducted).

Monitoring and Reporting

All approved human research ethics projects require annual monitoring and reporting and the submission of a final report at the end of the project. For projects approved for more than 12 months, annual reports are also due. The REMS automatically calculates the due dates of these reports and sends reminder emails to the Chief Investigator.

LOGGING IN TO YOUR PORTAL

To commence a new application for review by a human or animal ethics committee, you must first log in to your REMS portal. This link can be found on the left-hand side of the Staff or Student portal in the 'Other Logins' List.



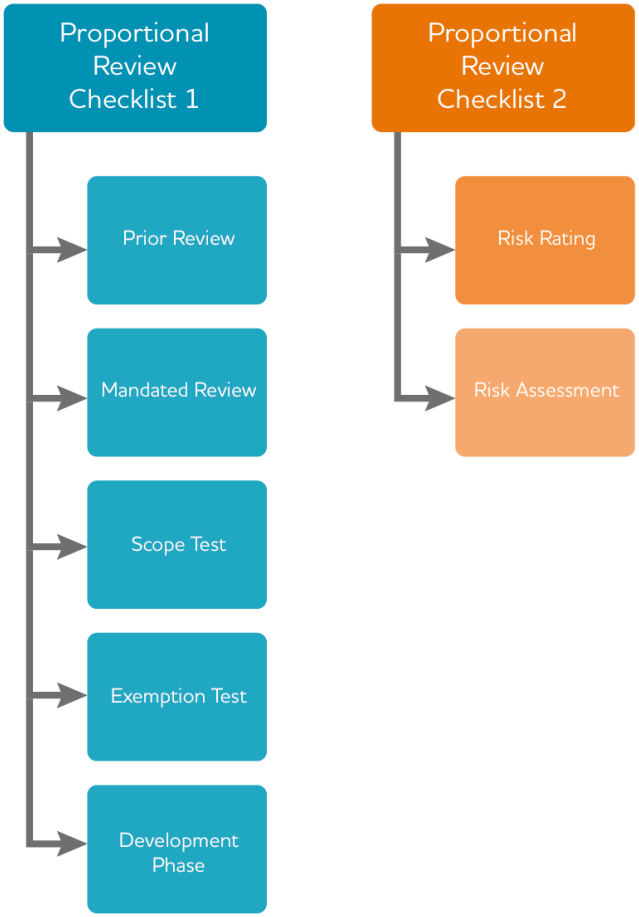
The REMS portal will list all of the applications that you are currently named on, either as an investigator, research assistant, supervisor or reviewer and will show the status of each of these projects and a quick link in to the application form. The portal also allows you to commence a new application or visit the helpful online resources.

USING THE REMS TO APPLY FOR RESEARCH ETHICS APPROVAL

The Research Ethics Management System has several steps as illustrated earlier in Figure 1 to assist researchers to submit a research ethics application for review. The first stage of the REMS is the completion of the Proportional Review Checklist. This Checklist is designed to determine whether a research project requires review, and if it does, the type of review required. To guide researchers through the first stage of the REMS, the Proportional Review Checklist, the following section details all questions contained within each of the steps in the Checklist. *Please note that not all researchers will be asked every question. The responses you provide guide the question logic specific to your project. Therefore, you will likely never see each of these questions in your application, however all are presented here for completeness.*

Once you have reached the end of the Checklist (this will differ depending on when the system knows which level of review you require) you will be asked for some brief project information and will be prompted to submit your Checklist. Upon submission you will receive an automated email providing you with further instructions. These instructions will vary depending on whether your project is out of scope, exempt or requires further review. In most cases, the automated email will direct you to your tailored application form.

The following provides detail of each of the questions asked within the seven sections of the Proportional Review Checklist:



Logging in

From the ECU Research Ethics Intranet page select the link to the *Proportional Review Checklist*, or log in to REMS from the staff portal 'Other Logins'. You will need an active ECU staff or student email address to complete the Checklist.

Prior Review

Upon logging in to the Proportional Review Checklist you will be asked if you wish to test whether your project has been reviewed previously by a research ethics committee at another Institution and subsequently provided with ethics approval. For most researchers, this will not be applicable and an answer of 'No' will take you to the next section, Mandated Review. If your work has been reviewed by another Institution and you are seeking ECU's approval for a multi-site project, completion of this brief section will lead you to a collaboration space where you will be asked to submit all relevant documentation from the prior review, for review by the Executive Committee of the Human Research Ethics Committee, comprising the Chair and Deputy Chair.

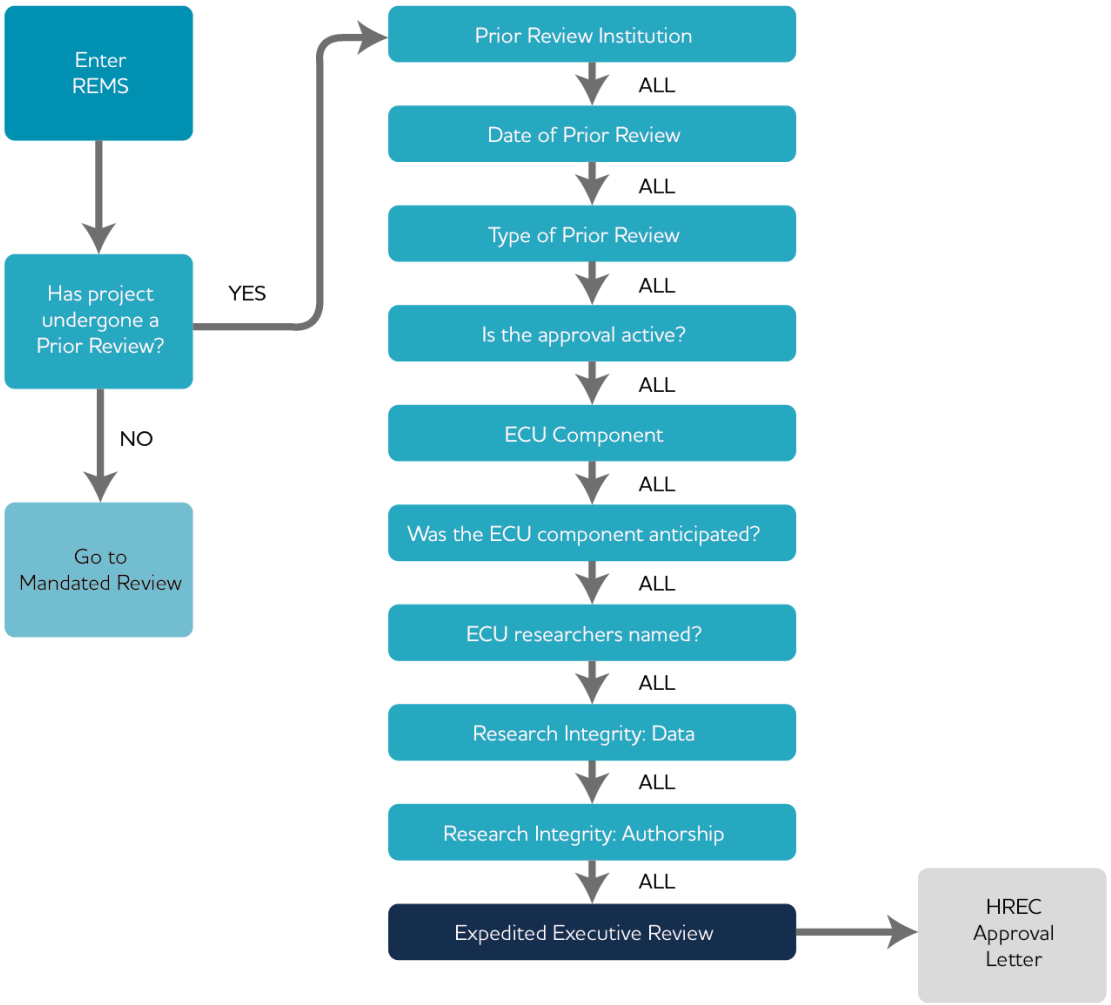


Figure 3: Prior Review Question Pathway

The following table follows the flow of the Prior Review Questions shown in Figure 1 above by providing detail of each of the questions asked. An answer of 'No' to the first question will automatically direct you to the next section, Mandated Review.

Table 1: Questions asked within the Prior Review section of the Proportional Review Checklist

Prior Review Category	Question
Prior Review Test	Has this project been reviewed by another research ethics committee?
Who conducted the prior review?	What is the name of the review body that conducted the prior review?
	On what date was the prior review approved?
	What type of review of the work was conducted previously?
Status	Is the prior review of this project active?
ECU Component	What is the ECU component of the project?
	Was the ECU component of the project anticipated in the prior review?
	Were the ECU researchers named in the prior review?
Research Integrity	Has an agreement been reached with regards to ownership, control, and for access / use of the data?
	Has an agreement been reached with regards to authorship and research outputs arising from the work?
Outcome	**Complete Prior Review Application Form**

Mandated Review

In this section, researchers can complete a quick test to determine if their planned research activity is, in accordance with the *National Statement*, mandated for review by a HREC due to the high-risk nature of the research. All researchers must complete this section prior to moving to the next section, Scope Checker.

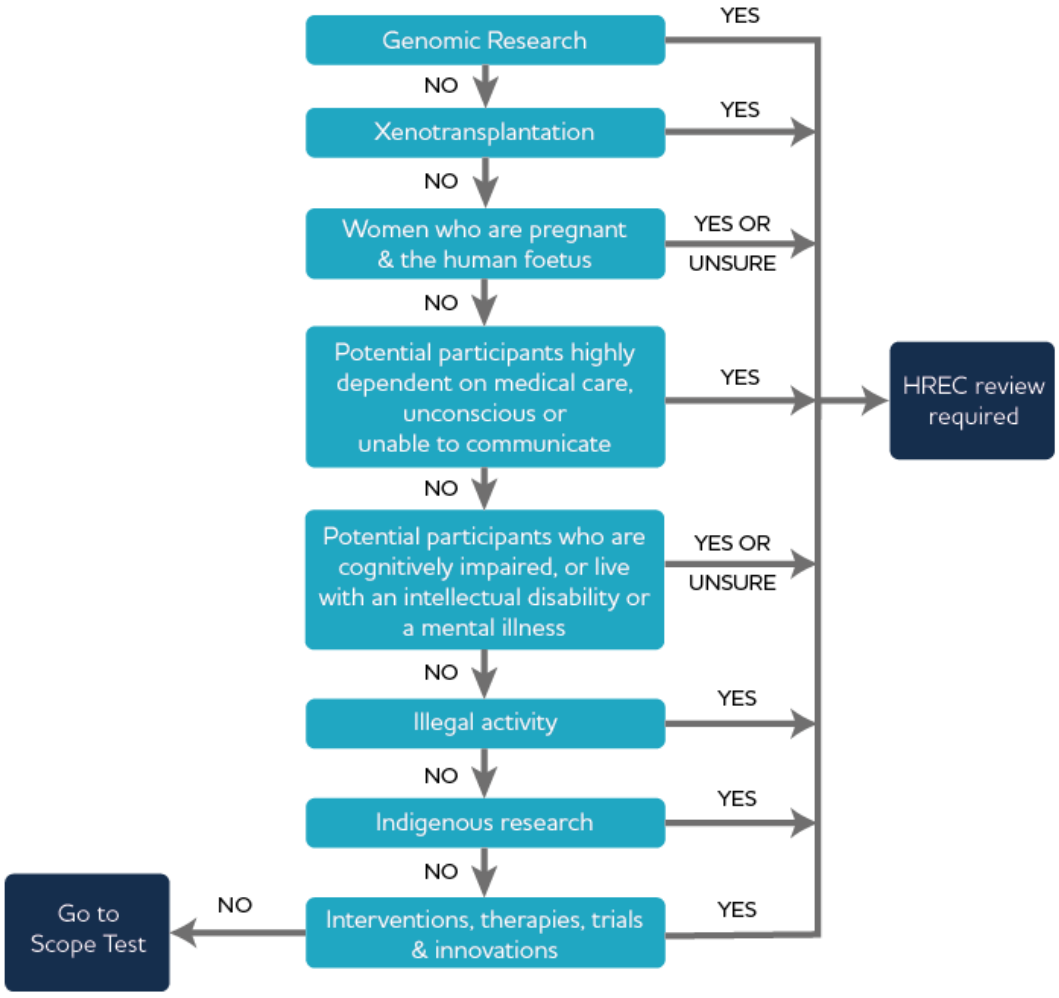


Figure 4: Mandated Question Pathway

The following table follows the flow of the Mandated Review Question Pathway shown in Figure 2 above by providing detail of each of the questions asked.

Areas shaded in the Mandated section below indicate a response that will trigger an automatic HREC review. An empty box means you will be directed to another question in this section. As there are multiple pathways within this section depending on your previous responses, only an answer that triggers a Mandated HREC Review condition are highlighted. If you reach the end of this section without being advised your project requires review, or your responses indicate you need to move to the next section (Scope Checker), you will be directed to the Scope Checker.

Table 2: Questions asked within the Mandated Review section of the Proportional Review Checklist

Mandated HREC Review Category	Question	HREC Review Required (shaded) Yes	No
Mandated HREC review test	Do you wish to test if the planned work is mandated for HREC review?		Scope Checker
Genomic Research	Does the project involve genomic research?		
	Will the researchers use information that can identify an individual?		
	Does the research involve linkage of data?		
Xenotransplantation	Does the project involve animal-to-human xenotransplantation?		
Risk to pregnant woman, pregnancy and / or foetus	Could the research be a source of risk to a pregnancy or foetus?		
Potential participants who are highly dependent on medical care, unconscious or otherwise unable to communicate	Could the participant pool include persons who are highly dependent on medical care, unconscious or otherwise unable to communicate?		
	Is the research limited to only work with non-identifiable data?		
	Does the research involve more than negligible risk?		
Potential participants who are cognitively impaired, or live with an intellectual disability or a mental illness	Could the participant pool include persons who are cognitively impaired, or live with an intellectual disability or with a mental illness		
	Given the specifics of this project and nature of the impairment, disability or illness limit does this raise a question as to the capacity of individuals to provide consent for their participation?		

Mandated HREC Review Category	Question	HREC Review Required (shaded) Yes	No
	Is the research limited to only work with non-identifiable data?		
	Does the research involve more than negligible risk?		
Illegal activity	Is the research intended to study or expose illegal activity or that is likely to discover it?		
	Will the participant pool be limited to regulators, investigators, enforcement officers, educators or others who have a professional role?		
	Is the research limited to only work with non-identifiable data?		
	Does the research involve more than negligible risk?		
Indigenous research	Does the research involve the purposive recruitment of Aboriginal or Torres Strait Islander people, or because of the nature of the research, the highly probable, greater than the normal population, incidental recruitment of Aboriginal or Torres Strait Islander people?		
Interventions, therapies, trials, and innovations	Is the research a clinical health intervention or therapy (including clinical and non-clinical trials), or treatment innovation?		
	Is the research a clinical trial?		
	Is the research a clinical intervention, therapy or innovation?		Scope Checker

Scope Checker

This section of the Proportional Review Checklist uses the *National Statement* to determine if a project is outside the scope of human research ethics review. If certain conditions are met, in some instances the proposed activity is not considered to be human research. If you know your work will require human research ethics review, you can skip through this section by answering 'No' to the first question, otherwise all researchers are encouraged to complete this section.

If you move through the Scope Checker to the Exemption test, this indicates your activity is within the scope of ECU's human research ethics arrangements.

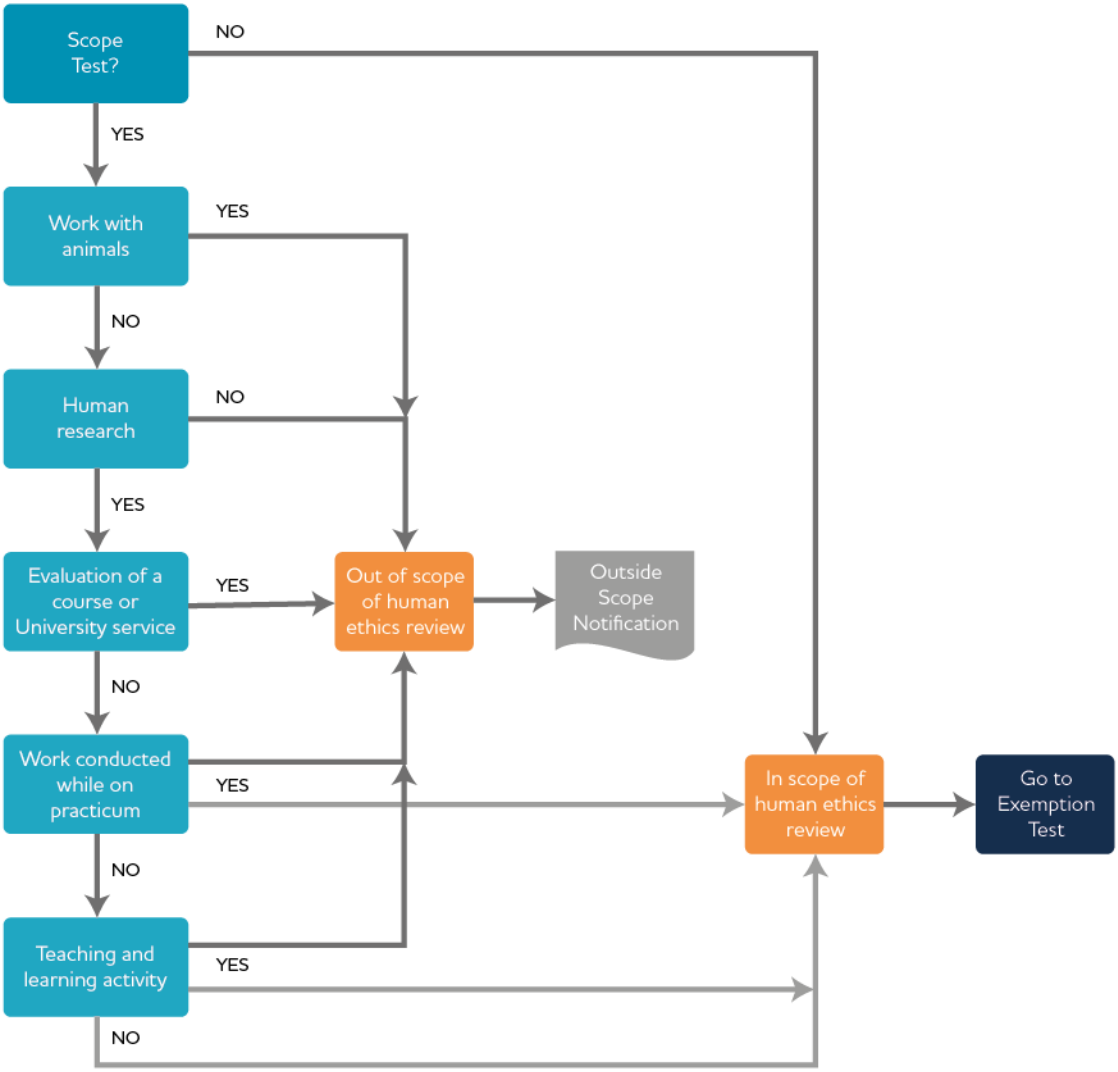


Figure 5: Scope Checker Question Pathway

The following table follows the flow of the Scope Checker Question Pathway shown in Figure 4 by providing detail of each of the questions asked. Shaded areas in the table below indicate a response that will trigger an *Out of Scope* notification email. An empty box means you will be directed to another question in this section. If you reach the end of this section without being advised your project is *Out of Scope*, or your responses indicate you need to move to the next section (Exemption Test), you will be directed to the Exemption Test.

Table 3: Questions asked within the Scope Checker section of the Proportional Review Checklist

Scope Checker Category	Question	Out of Scope	
		Yes	No
Scope test	Do you wish to test if the planned work falls outside the scope of the University's research ethics arrangements?		Exemption Test
Work with animals	Does the activity only involve work with animals as defined in the Australian code for the care and use of animals for scientific purposes?	Animal Ethics Required	
	Does the activity only involve the use of invertebrate animals (excluding cephalopods)?		
Human research	Does the proposed research involve working with humans or their data (as defined below)?		
Evaluation of course or University service	Is the primary purpose for the collection of data to evaluate an ECU course or a University service?		
Work conducted while on practicum	Is this work to be conducted while on a practicum placement with an industry or community partner?		
	Is the work to be conducted under the auspices of an industry or community partner?		Exemption Test
	Will the work be described to potential participants as an ECU research project?	Exemption Test	
	Will the industry / community party own the data?		Exemption Test
	Will there be a research output (e.g. publication) that can be claimed as an ECU research activity?	Exemption Test	
Teaching and learning activity	Is the activity being conducted solely for a teaching & learning purpose?		Exemption Test
	Is the work a practical exercise or test conducted for teaching purposes?		

Scope Checker Category	Question	Out of Scope	
		Yes	No
	Is the work a routine experiment or procedure conducted for teaching purposes		
	Is the work / data collection conducted by a student only for teaching / learning purposes?		Exemption Test
	Will the results be published / presented in any way other than a paper / produced purely for assessment purposes?	Exemption Test	

Exemption Test

This final test determines if activities that are within the scope of human research ethics review are exempt from review. If certain conditions are met, in these instances, the proposed activity is exempt from human research ethics review. If you know your work will require human research ethics review, you can skip through this section by answering 'No' to the first question.

If you move through the Exemption Test section without being told your work is exempt, your research activity is considered to be in scope and not exempt from human research ethics review at ECU.

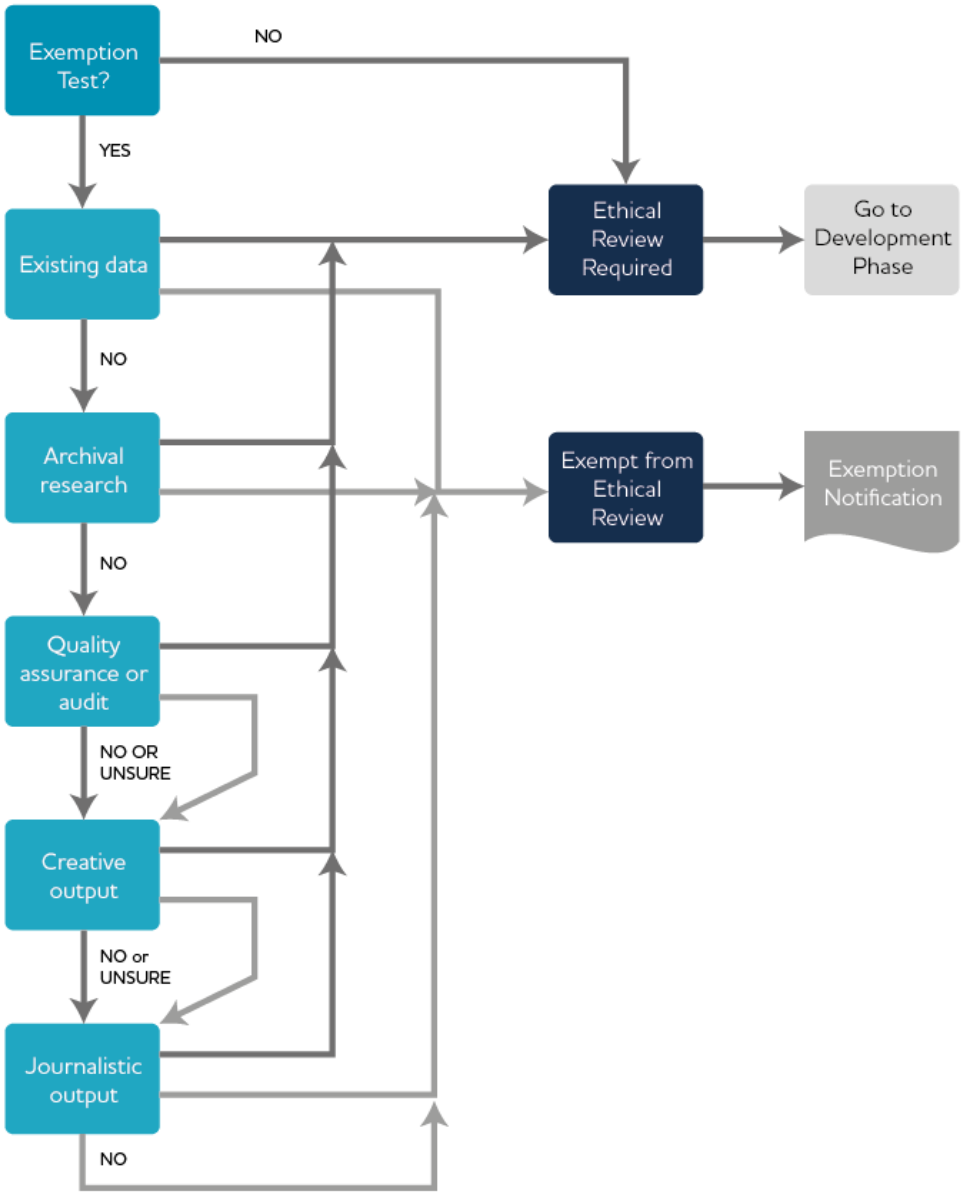


Figure 6: Exemption Test Question Pathway

The following table follows the flow of the Exemption Test Question Pathway shown in Figure 5 above by providing detail of each of the questions asked. Shaded areas in the table below indicate a response that will trigger an *Exemption* notification email. An empty box means you will be directed to another question in this section. If you reach the end of this section without being advised your project requires review, or your responses indicate you need to move to the next section (PRP Risk Assessment), you will be directed to the Proportional Review Pathway – Risk Assessment.

Table 4: Questions asked within the Exemption Test section of the Proportional Review Checklist

Exemption Test Category	Question	Exempt (shaded) Yes	No
Exemption test	Do you wish to test if the planned work is exempt from ethical review?		PRC Risk Assessment
Existing data	Will the work involve only the analysis of existing data?		
	Will the data be accessed in a non-identifiable form?		
	Is the data already in the public domain?		
	Was consent obtained for the potential reuse of the data?		PRC Risk Assessment
	Does the research involve only negligible risk?		
Archival research	Will the work involve only the analysis of existing documents?		
	Are the documents available to the public?		
	Is some form of approval required before a person can access the documents?		
	Has approval already been obtained, or will it be obtained?		PRC Risk Assessment
	Does the research involve more than negligible risk?		
Quality assurance or audit?	Should the work be characterised as quality assurance or an audit		

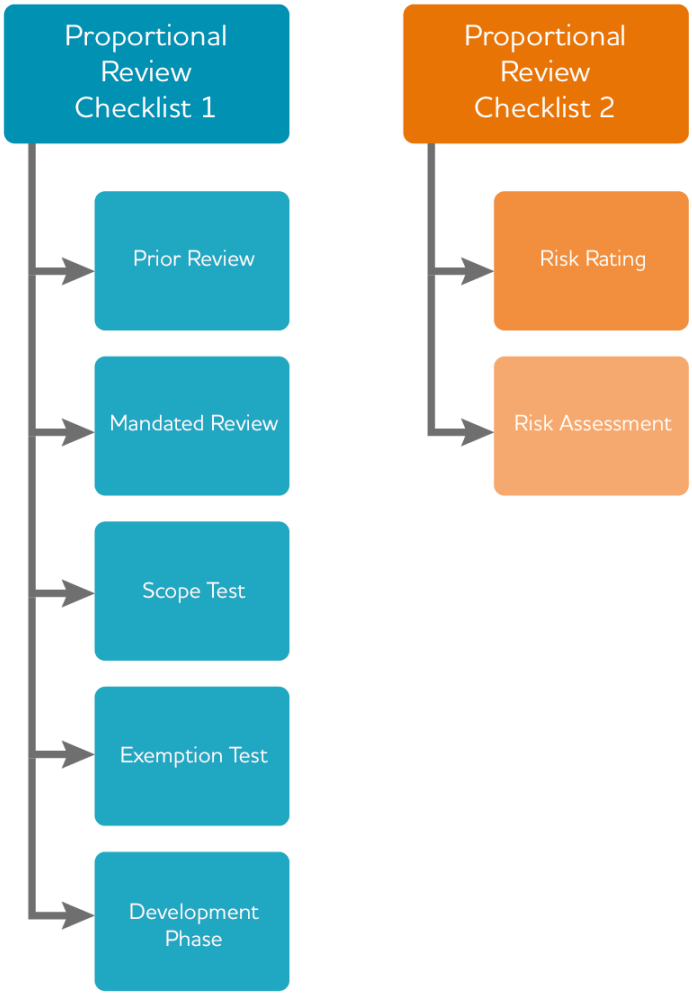
	Has or will the work be approved by the organisation responsible for the area, team or activity that is subject to the quality assurance or audit?		PRC Risk Assessment
	Will an academic publication of other research output arise from the work?	PRC Risk Assessment	
	Could participants or known third parties suffer any harm (physical, mental, psychological, economic, spiritual or social) associated with the work?	PRC Risk Assessment	
Creative output	Will the final output of the research be creative (eg photographic exhibition, theatrical or music performance, novel)?		
	Will the work include interviews, surveys or focus groups?	PRC Risk Assessment	
	Will the informed consent of participants be obtained?		PRC Risk Assessment
	Could participants be identified by third parties (including other participants)?		
	Will participants consent to being identifiable?		PRC Risk Assessment
	Is there more than a negligible risk of harms (physical, psychological, social, economic, legal etc.) to participants, the researchers or known third parties?	PRC Risk Assessment	
Journalistic output	Will the final output of the research be journalistic (e.g. a news story or a documentary)?		
	Will the informed consent of participants be obtained?		PRC Risk Assessment
	Could participants be identified by third parties (including other participants)?		
	Will participants consent to being identifiable?		PRC Risk Assessment

Development Phase

If your project is deemed to be in Scope and not Exempt you will be asked if you would like to apply for a Development Phase interim approval for your work. Development phase approval is typically only granted for six months and allows a research team to develop or finalise data collection procedures and instruments for research projects. No recruitment of participants or data collection can occur during Development Phase before full approval has been granted by the HREC or its subcommittees.

If you would like to apply for Development Phase you will be prompted for some project details, then sent an automated email with a link to a Microsoft Team site for collaboration and a link to your tailored application form.

If you do not wish to apply for a Development Phase approval, you will be asked to submit the form and an automated email will direct you to the Proportional Review Checklist – Part 2.



Proportional Review Checklist – Risk Assessment

Once you have completed the first five sections of the Proportional Review Checklist and you have not been told that your work is Out of Scope or Exempt, you will be directed to Part 2 of the Checklist. This Checklist determines the review level required for all research that has been deemed to require human research ethics review. The three levels of review include:

1. Negligible Risk Review;
2. Low Risk Review; and
3. Greater than Low Risk Review (HREC)

Part 2 of this Checklist uses two distinct sections to calculate the review pathway for each research project. The two sections of Part 2 include a Risk Rating and specific Risk Assessment.

Risk Rating

The first component of Checklist Park 2 explores the risk associated with the research across six areas of physical; social, psychological, economic, legal and environmental. Researchers will be required to answer three questions relating to each type of risk as follows:

Initial Risk Rating: Using the risk matrix provided, what is the initial risk rating for this particular risk category, prior to the introduction of activities to avoid or minimise the risk exposure?

Mitigation Approach: Describe any activities that will be undertaken prior to or during the research project to avoid or minimise the risk exposure.

Residual Risk Rating: Using the provided risk matrix, what is the residual rating for this particular risk category, AFTER the introduction of the aforementioned mitigation activities?

Impact	Greater	LR	LR	LR	HREC
	Low	NR	LR	LR	LR
	Negligible	NR	NR	NR	LR
	None	NR	NR	NR	NR
		None	Negligible	Low	Greater
		Chance of risk occurring			

Figure 7: Risk Matrix

For each question a researcher will need to decide what the chance of the risk occurring is, and the impact the risk might have on participants. For example, for physical risks, a researcher will need to decide what the chance of physical risk occurring is (no chance, negligible chance, low chance or greater than low chance) and the impact of this risk (no impact, negligible impact, low impact and greater than low impact). If the chance was negligible but the impact was low, then the research would be considered within the 'Low Risk' review pathway. Therefore, these initial six areas of risk are used in the 'back-end' of the REMS in combination with the responses to the second part of this Checklist to determine the most appropriate review pathway based on the risk level and type.

Risk Assessment

The second part of this Checklist assesses 13 broad areas of specific risks to human research participants including:

- Third party identification;
- Participation of minors;
- Unequal relationships;
- Indigenous research;
- Participant exposures to substances;
- Tissue extraction or invasive procedures;
- Ionising radiation;
- Sensitive personal information;
- Incentives;
- Limited disclosure;
- Existing personal information;
- Research outside of Australia; and
- Human biospecimens.

Within each of the 13 risk areas two levels of questions are asked to determine if the research activity has negligible levels of this risk, low levels, or levels which are greater than low risk and as such, require full research ethics review by the HREC. In Table 5 to follow, questions starting with a 6 represent negligible risk research. Those starting with 7 indicate the research involves greater than low risk.

Therefore, as an outcome of the Proportional Review Checklist Part 2 you will either be stopped part of the way as the Checklist has determined you require HREC review or you will move through all 13 areas of the Checklist. To qualify for the Negligible Risk pathway, you must only have answered questions from the table below starting with a 6. Projects requiring Low Risk review will have at some point been directed to answer a question starting with 7.

Table 5: Questions asked within the Review Pathway section of the Proportional Review Checklist

Category	Question Number	Question	Outcomes (shading indicates LR)	
			Yes	No
Third party identification	6.1	Could third parties identify participants from the disseminated results of the research?	6.1.1	6.2
	6.1.1	Will prior and express consent for any identification be obtained from the participant?	6.2	7.1
	7.1	Could identification be a source of new, or compounded, risk?	HREC Review	6.2
Participation of minors	6.2	Is the target pool of the proposed research under the age of 18?	6.2.1	6.3
	6.2.1	Will the participation of the young people (persons aged under 18) occur outside a standard educational context (eg as part of a standard school activity)?	7.2	6.3
	7.2	Does the research involve activities, as part of the research process, that are illegal, unsafe or otherwise inappropriate for minors?	HREC Review	7.2.1
	7.2.1	Will a parent, or appropriate guardian, consent to the participation of the child / young person (aged under 18)?	6.3	7.2.1.1
	7.2.1.1	Is it possible to justify seeking primary consent from only the young person?	6.3	HREC Review
Unequal relationship	6.3	Is there a direct and current unequal relationship between the potential participants and a member of the research team, or with the perceived sponsor of the research?	6.3.1	6.4

Category	Question Number	Question	Outcomes (shading indicates LR) Yes	No
	6.3.1	Will the person(s) in the authority position know the participatory status of individuals?	7.3.1	6.4
	7.3.1	Should the unequal relationship be described as a captive one?	HREC Review	7.3.2
	7.3.2	Are there strategies in place to safeguard the voluntary nature of participation, and to manage any risks arising from the unequal relationship?	6.4	HREC Review
Indigenous research	6.4	Does the research involve the purposive recruitment of Aboriginal or Torres Strait Islander people, or because of the nature of the research, the highly probable, greater than the normal population, incidental recruitment of Aboriginal or Torres Strait Islander people?	7.4	6.5
	7.4	Is your target population or research topic related to Aboriginal and Torres Strait Islander peoples?	7.4.1	6.5
	7.4.1	Is a member of the research team Indigenous?	7.4.2	7.4.2
	7.4.2	Does the research team have access to relevant cultural knowledge for the successful and respectful design and conduct of this project?	7.4.3	7.4.3
	7.4.3	Will the results of the research and any benefits of the research flow back to Aboriginal and Torres Strait Islander People?	7.4.4	7.4.4
	7.4.4	In the reporting of the results of the research, will there be acknowledgement of advisers, any reference group, participants or others, in terms of the cultural knowledge and other contributions to the design and conduct of the research?	HREC Review	HREC Review

Category	Question Number	Question	Outcomes (shading indicates LR) Yes	No
Participant exposure to substances	6.5	Does the project involve participant exposure to potentially harmful substances or procedures or exposure to ordinary substances at levels or in a manner that are beyond the normal everyday experience	6.5.1	6.6
	6.5.1	Does the project involve participant exposure to a therapeutic agent or substance outside of the registered indication, purpose or dose?	7.5	6.5.2
	6.5.2	Does the project involve participant exposure to a substance beyond that which is considered to be normal safe levels for your population?	HREC Review	6.6
	7.5	Has the design of the protocol been informed by appropriate pharmacological expertise?	7.5.1	HREC Review
	7.5.1	Is there some sort of safety monitoring and advisory process?	6.6	HREC Review
Tissue extraction or invasive procedures	6.6	Does the research involve the extraction of human tissues/biospecimens?	6.6.1	6.7
	6.6.1	Is it necessary to break the skin or physically insert anything (e.g. an indwelling catheter) to collect the specimens?	7.6	6.7
	7.6	Is the procedure limited only to the extraction of blood?	7.6.1	HREC Review
	7.6.1	Will the blood be extracted by a person with appropriate training and expertise?	7.6.2	HREC Review
	7.6.2	Will the standard biosafety precautions for needles and for the handling of blood be adhered to?	6.7	HREC Review

Category	Question Number	Question	Outcomes (shading indicates LR) Yes	No
Ionising radiation	6.7	Does the research involve the exposure of humans to ionising radiation?	7.7	6.8
	7.7	Are participants being exposed to ionising radiation?	7.7.1	6.8
	7.7.1	Is it for research purposes only?	7.7.1.1.	HREC Review
	7.7.1.1	Is it in line with ECU's Standard Operating Procedures?	6.8	HREC Review
Sensitive personal information	6.8	Will sensitive personal information be disclosed, or made available, to the research team?	6.8.1	6.9
	6.8.1	Will the researcher(s) know the identity of the individual to whom the sensitive personal information relates?	7.8	6.9
	7.8	Are potential participants Informed that they will be asked to disclose sensitive personal information?	6.9	HREC Review
	7.8.1	Is there any legal, contractual, professional or moral obligation that might compel the researchers to disclose sensitive information to third parties?	HREC Review	6.9
Incentive	6.9	Will participants be offered an incentive, as opposed to a reimbursement?	6.9.1	6.10
	6.9.1	Could the incentive have a coercive impact, especially with regards to an individual's weighing of the risks / burdens of participation?	7.9	6.10

Category	Question Number	Question	Outcomes (shading indicates LR) Yes	No
	7.9	With reference to Booklet 21 of the ECU Research Ethics Manual, is it possible to justify the value of the incentive and why it should not be considered coercive or manipulative?	7.10	HREC Review
Limited disclosure	6.10	Will potential participants not be fully informed about the project, will they be covertly observed, or deceived?	6.10.1	6.11
	6.10.1	Will participants be deceived?	HREC Review	6.10.2
	6.10.2	Will participants be covertly observed?	7.10	6.11
	7.10	Could the observed behaviour include illegal activities or other sensitive matters?	HREC Review	6.11
Existing personal information	6.11	Will the research involve access to existing identified personal information?	6.11.1	6.12
	6.11.1	Is the identified information subject to privacy regulation?	6.11.1.1	6.12
	6.11.1.1	Will consent be obtained prior to the researchers having access to the identified information?	6.12	HREC Review
Research Outside Australia	6.12	Will the research be conducted outside Australia?	6.12.1	6.13
	6.12.1	Is there currently a DFAT Travel Advisory that is of importance to the design and / or conduct of this research?	HREC Review	6.12.2

Category	Question Number	Question	Outcomes (shading indicates LR) Yes	No
	6.12.2	Could the research be perceived as being critical of an oppressive regime?	HREC Review	6.13
Human Biospecimens	6.13	Does the project involve human biospecimens in laboratory-based research	7.13.1	Negligible Risk Review
	7.13.1	Does the project involve human embryos and gametes, including the derivation of human embryonic stem cell lines?	HREC Review	7.13.2
	7.13.2	Does the project involve the prospective collection of human biospecimens for research?	HREC Review	7.13.3
	7.13.3	Does the project involve the use of stored human biospecimens for research?	7.13.3.1	Low Risk Review
	7.13.3.1	Will the research involve any risks to the donors, their relatives or their community that are more serious than discomfort?	HREC Review	7.13.3.2
	7.13.3.2	Will the research give rise to information that may be important for the health of the donors, their relatives or their community where the identity of the donors will be know to, or can reasonably be ascertained by, those conducting the research or with access to health or research data or information related to donors?	HREC Review	7.13.3.3
	7.13.3.3	Will the project involve human biospecimens obtained for clinical purposes?	7.13.3.3.1	7.13.3.4
	7.13.3.3.1	Will the researcher know the identity of the donor of the human biospecimen?	HREC Review	7.13.3.4
	7.13.3.4	Will the project involve the importation and/or the exportation of human biospecimens for research?	HREC Review	7.13.3.5

Category	Question Number	Question	Outcomes (shading indicates LR) Yes	No
	7.13.3.5	Will the proposed research involve the use of human biospecimens that have been obtained without specific consent for their use in research, or where the proposed research is not consistent with the scope of the original consent?	HREC Review	Low Risk Review

Submission of an application for human research ethics review

After submitting your Proportional Review Checklist, you will be sent an automated email with further instructions. Should your project require human research ethics review, your automated email will contain two links to facilitate the completion of your ethics application. The first is a link to a Microsoft Team that has been created specifically for your project where you can collaborate with the other Investigators or project Personnel you nominate, in preparing your research ethics application. The second link in your email is a link to your personalised application form. You can also access your application at any time by logging in to your REMS portal (link available from the ethics intranet page or from the staff portal 'Other logins' section).