**Human Research Ethics Application Form**

*Please complete this form once you have received notification from the Research Ethics Management System that your project requires review by the Human Research Ethics Committee.*

*Please refer to the reviewer checklist to become familiar with the detail reviewers are looking for as well as Chapter 3 of the National Statement on Ethical Conduct in Human Research.*

1. **PROJECT DETAILS**

**Chief Investigator**

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| Title |  |
| First Name |  |
| Last Name |  |

**Project Title**

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**Research Ethics Management System (REMS) Number**

*This is the number allocated to your application at the time of completing the Proportional Review Checklist online. It is also quoted in all correspondence to you from the REMS system.*

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1. **QUALIFICATIONS, EXPERTISE AND/OR EXPERIENCE OF RESEARCH TEAM**

Please list the relevant qualifications, experiences and/or skills of the research team which equip them to conduct this research. In the case of student research, the response to this question must also discuss the expertise of the supervisory team and any situations where the student will need extra training and/or support.

*The National Statement indicates it is important to establish the degree to which the researchers have training and experience to safely and appropriately conduct the research. In practice, during the ethical review of a proposed project, the reviewers will need to be satisfied that the persons conducting the research have the necessary skills and expertise. This might relate to the conduct of a particular test or procedures, working with specific populations, the handling of specific risks, or other matters where specific expertise is required.*

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1. **ELEMENT 1: RESEARCH SCOPE, AIMS, THEMES, QUESTIONS AND METHODS**

Please define your research questions or aim, the benefit of exploring these research questions, your project’s methods and how these will achieve your project’s aims. Your responses should include a description of the research questions that would make sense to non-researchers and people without expertise in your area.

Your responses should also be made with reference to the population you are working with. Please refer to Section 4 of the National Statement when working with: women who are pregnant and the human fetus; children and young people; people in dependent relationships; people highly dependent on medical care; people with a cognitive impairment; people involved in illegal activities, Aboriginal and Torres Strait Islander peoples; or people in other countries.

*See Section 3, Guidelines 3.1.1 to 3.1.11 of the National Statement and Section 4.*

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| ***Aims or Questions*** |
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| ***Benefit of exploring these research questions*** |
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| ***Brief research methods and any legal and regulatory requirements*** |
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| ***How the planned methods achieve the aim or research questions*** |
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| ***For Biospecimen research, please discuss any additional information as per the National Statement Chapter 3.2.1 to 3.2.3*** |
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| ***For Genomic research, please discuss any additional information as per the National Statement Chapter 3.3.1 to 3.3.3*** |
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| ***For Animal-to-Human Xenotransplantation research, please discuss any additional information as per the National Statement Chapter 3.4.1 to 3.4.5*** |
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1. **ELEMENT 2: RECRUITMENT**

Please provide details in relation to the potential participant pool including: the target participant group; identification of potential participants; any screening mechanisms used; the initial contact method and recruitment method. Please also attach your recruitment documents (eg: advertisements, letters, flyers and emails).

Your responses should also be made with reference to the population you are working with. Please refer to Section 4 of the National Statement when working with: women who are pregnant and the human fetus; children and young people; people in dependent relationships; people highly dependent on medical care; people with a cognitive impairment; people involved in illegal activities, Aboriginal and Torres Strait Islander peoples; or people in other countries.

*See Section 3, Guidelines 3.1.12 to 3.1.22 of the National Statement and refer to Booklet 21 of the ECU Research Ethics Manual for more about the ethical issues associated with recruitment of participants.*

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| ***Nature of the potential participant pool (eg: who are they?)*** |
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| ***How will participants be identified and initially contacted including screening processes?*** |
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| ***How will formal recruitment of potential participants be conducted?*** |
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| ***Please provide a response to any ethical issues and concerns raised by the recruitment process such as the relationship between researchers and participants, risks associated with recruitment strategy and the nature of the population being examined.*** |
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| ***For Biospecimen research, please discuss any additional information as per the National Statement Chapter 3.2.4 to 3.2.10*** |
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| ***For Genomic research, please discuss any additional information as per the National Statement Chapter 3.3.4 to 3.3.9*** |
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| ***For Animal-to-Human Xenotransplantation research, please discuss any additional information as per the National Statement Chapter 3.4.6*** |
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1. **element 3: CONSENT**

Please provide details of the appropriate informed consent procedure and attach a copy of the informed consent materials (including a research project information sheet). If you are applying for a Waiver of Consent, please provide the basis upon which you are seeking this Waiver. Please also describe any deception of participants and the debriefing process to be used, if appropriate.

Your responses should also be made with reference to the population you are working with. Please refer to Section 4 of the National Statement when working with: women who are pregnant and the human fetus; children and young people; people in dependent relationships; people highly dependent on medical care; people with a cognitive impairment; people involved in illegal activities, Aboriginal and Torres Strait Islander peoples; or people in other countries.

*See Chapter 3, Guidelines 3.1.23 to 3.1.39 of the National Statement and refer to Booklet 22 of the ECU Research Ethics Manual for more about the ethical issues associated with consent, waiver of consent and deception.*

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| ***Informed consent procedure (including justification for a Waiver of Consent, opt out consent or deception strategies)*** |
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| ***Are there project-specific matters that warrant specific attention (eg: re-use of data; results of significance to participants; third party knowledge of participants etc).*** |
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| ***For Biospecimen research, please discuss any additional information as per the National Statement Chapter 3.2.11 to 3.2.14*** |
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| ***For Genomic research, please discuss any additional information as per the National Statement Chapter 3.3.10 to 3.3.17*** |
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| ***For Animal-to-Human Xenotransplantation research, please discuss any additional information as per the National Statement Chapter 3.4.7 to 3.4.8*** |
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1. **element 4: collection, use and management of data and information**

Please provide details in relation to the data collection: method, location, duration and analysis. Include also details about the degree of identifiability of data, data storage and disposal. Attach to your application a copy of any surveys, interview questions or testing protocols.

Your responses should also be made with reference to the population you are working with. Please refer to Section 4 of the National Statement when working with: women who are pregnant and the human foetus; children and young people; people in dependent relationships; people highly dependent on medical care; people with a cognitive impairment; people involved in illegal activities, Aboriginal and Torres Strait Islander peoples; or people in other countries.

*The response to this question should provide sufficient information about data collection. The level of information should be proportional to the level of risk and sensitivity of the proposed research. Information about identifiability can be found in Booklet 23 of the ECU Research Ethics Manual and Chapter 3, Guidelines 3.1.40 to 3.1.62 of the National Statement.*

*If using potential teratogens or carcinogens; Recombinant DNA molecules; Ionising radiation / radioactive substances e.g. DEXA, X-rays; Chemical hazard (toxic or corrosive); or Infectious material, please clearly describe the procedures to be used*

*In Western Australia, research data retention periods are stipulated in the Western Australian University Sector Disposal Authority* ([WAUSDA](http://www.sro.wa.gov.au/sites/default/files/western-australian-university-sector-disposal-authority_-_revised_edition_-_approved_6_dec_2013.pdf)). *At ECU, the researcher needs to* ***ensure*** *that all data supporting the findings of the research is made available to Information Management and Archive Services (IMAS) who manage data retention on behalf of the university. To find out more about data retention please contact IMAS on (6304 2915,* records@ecu.edu.au)*.*

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| ***Data collection method and location including who will be responsible for the data collection*** |
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| ***Data collection duration*** |
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| ***Identifiability of the data, and management of risks associated with the collection, use and management of data or information*** |
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| ***Describe any future use of the data*** |
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| ***Retention of Data*** |
| *Please indicate the minimum length of time the data for this project will need to be retained (according to WAUSDA). Only one option should be selected.* |
| ***Research Description*** | ***Retention*** | ***Select (X)*** |
| Research involving humans or animals that utilise high risk material (teratogens, carcinogens, ionising radiation or dangerous drugs). | 50 Years |  |
| Research involving clinical trials. | 25 Years |  |
| Research involving children under the age of 18 years old must be kept until the children have reached 25 years of age\*. | Birth:Retention: |  |
| All other research | 7 Years |  |
| ***According to WAUSDA, research data retention starts at the conclusion of the project or at the date of publication whichever is later. Please provide an estimate of when you think your data may be ready for retention.*** |
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| ***If any project agreements stipulate any non-WAUSDA compliant retention and disposal instructions, please indicate the agreement and the stipulation below*** |
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| ***For Genomic research, please discuss any additional information as per the National Statement Chapter 3.3.18 to 3.3.25*** |
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\* *Please provide the birth year of the youngest participant in your study and your calculation of the year when retention ends.*

1. **element 5, 6, 7: communication of research findings or results to partcipants; dissemination of project outputs and outcomes; after the project**

Please tick all the mechanisms by which the results of the research will be communicated, reported, published or disseminated?

Your responses should also be made with reference to the population you are working with. Please refer to Section 4 of the National Statement when working with: women who are pregnant and the human foetus; children and young people; people in dependent relationships; people highly dependent on medical care; people with a cognitive impairment; people involved in illegal activities, Aboriginal and Torres Strait Islander peoples; or people in other countries.

*In nearly all cases, a research project cannot be considered complete until the results of the work are appropriately disseminated – irrespective of whether those results are what we had expected and/or hoped to see. This sharing of results, and its contribution to the professional or other body of knowledge, may be an important part of the benefits of the work. See Chapter 3, Guidelines 3.1.65 to 3.1.74 of the National Statement and refer to Booklets 9, 31 and 38 of the ECU Research Ethics Manual for more about communication of research findings and dissemination of outcomes.*

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| ***Dissemination*** | ***Yes*** |
| Final Report / Report to Funding Body |  |
| Peer Reviewed Publication |  |
| Lay person summary (eg: Brochure / Report) |  |
| Public presentation |  |
| Media release |  |
| Summary provided to participants |  |
| Conference presentation |  |
| Debriefing of participants |  |
| Other |  |
| ***Please indicate if there are any arrangements regarding intellectual property and copyright related to the outputs of the research*** |
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| ***For Biospecimen research, please discuss any additional information as per the National Statement Chapter 3.2.15*** |
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| ***For Genomic research, please discuss any additional information as per the National Statement Chapter 3.3.26 to 3.3.35*** |
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1. **Risk**

For each of the risk categories given below, please describe the specific risks to participants and the activities that will be undertaken prior to or during the research project to avoid or minimise each risk exposure. If there are no risks, please state that there are no risks. If your project involves the use of the following substances, please also address risks specific to the use of them.

* Potential teratogens or carcinogens;
* Recombinant DNA molecules;
* Ionising radiation / radioactive substances e.g. DEXA, X-rays;
* Chemical hazard (toxic or corrosive); or
* Infectious material.

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| ***Physical Risks*** |
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| ***Psychological Risks*** |
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| ***Social Risks*** |
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| ***Economic Risks*** |
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| ***Legal Risks*** |
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| ***Environmental Risks*** |
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1. **Ethically defensible plan**

**For research involving the use of genomics or human biospecimens** which may reveal information that may be important for the health of the donor, their blood relatives or their community (whether incidental or anticipated), please attach your *Ethically Defensible Plan for the Potential Return of the Findings and Individual Results from Genomic Research.* According to Chapter 3.3 of the *National Statement*, any researcher working with genomic information must prepare and follow an ethically defensible plan to manage the disclosure or non-disclosure of genomic information. This plan must be approved by the HREC.

Please use the following headings to develop your ethically defensible plan, in consultation with Chapter 3.2 and 3.3 of the *National Statement*.

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| ***The Nature of the Research Findings (3.3.38 – 3.3.40)*** |
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| ***STEP 1: Determination of Whether Findings Will Be Returned (3.3.41 – 3.3.44)*** |
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| ***STEP 2: Validation and Assessment of Findings (3.3.45 – 3.3.46)*** |
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| ***STEP 3: Consent to Disclosure of Findings and Notification Requirements (3.3.47 -3.3.57)*** |
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| ***Privacy Issues Specific to Genetic Information (3.3.58 – 3.3.61)*** |
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1. **privacy act considerations**

Personal Information includes names, addresses or information / opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information. It also includes health information (e.g. health opinions, organ donation or genetic information).

These questions relate to the collection, use or disclosure of personal or health information about individuals, which is either identifiable or potentially identifiable, without their consent.

If this research only involves the collection, use or disclosure of non-identifiable personal or health information, or involves the collection, use or disclosure of identifiable or potentially identifiable personal or health information WITH CONSENT of the individuals, this section does not need to be completed.

**If the project involves the collection, use or disclosure of personal information from Commonwealth departments or agencies or private sector organisations, please provide the following information:**

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| ***Name of the Department or Agency*** |
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| ***The data needed and how it will be analysed*** |
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| ***The number of records to be accessed*** |
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| ***A general description of the records to be accessed*** |
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| ***Why is it necessary for the records to be accessed?*** | ***Tick*** |
| Final Report / Report to Funding Body |  |
| Peer Reviewed Publication |  |
| Lay person summary (eg: Brochure / Report) |  |
| ***Why is it necessary for the information to be identifiable or potentially identifiable?*** |
| Research project involves the linkage of data |  |
| Scientific defects would result if deidentified information was used |  |
| Other |  |
| ***Why is it not possible to obtain the consent of the individuals?*** |
| The nature of any existing consent with respect to the collection, use or disclosure of the information |  |
| It would be impossible or difficult to obtain consent due to the age of the records or lack of up to date contact details |  |
| The proposed research will be minimally intrusive on the privacy and wellbeing of the individuals involved |  |
| The research project is an extension of, or closely related to a previously approved research project |  |
| Other | Please explain |
| ***The public interest in the proposed research must substantially outweigh the public interest in respecting individual privacy. Please explain why the collection, use or disclosure of the information is in the public interest and why the public interest in the project substantially outweighs the public interest in the protection of privacy?*** |
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1. **ATTACHMENTS**

Please upload all relevant attachments to this page. You can click the Attach file button, or drag and drop over the button.

A maximum of 100 attachments is allowed. If you have more than 100, please zip your attachments before uploading.

**12 SUBMISSION**