

SECTION 1 – Introduction

Please **DO NOT** use this form to apply for ethical review of human research projects.

This form is only designed as a guide/help resource to assist you with submitting a full human ethics application.

## SECTION 2 – Investigators

<b>1</b>	<b>Chief Investigator</b>		
The chief investigator <b>must be a Curtin staff member</b> . If this application is for a student project the chief investigator must be one of the student's supervisors.			
<b>Name (include title)</b>		<b>Staff ID</b>	
<b>School/Area</b>			
<b>Telephone</b>		<b>Email</b>	
<b>In the space below, explain how the researcher has sufficient skills and experience to conduct the proposed research (<a href="#">NS 3.3.5</a>):</b>			

<b>1a</b>	<b>Co-investigator 1</b>		
<b>Name (include title)</b>		<b>Curtin ID</b>	
<b>School/Area</b>		<b>Role</b>	
<b>Telephone</b>		<b>Email</b>	
<b>In the space below, explain how the researcher has sufficient skills and experience to conduct the proposed research (<a href="#">NS 3.3.5</a>):</b>			

<b>1b</b>	<b>Co-investigator 2</b>		
<b>Name (include title)</b>		<b>Curtin ID</b>	
<b>School/Area</b>		<b>Role</b>	
<b>Telephone</b>		<b>Email</b>	
<b>In the space below, explain how the researcher has sufficient skills and experience to conduct the proposed research (<a href="#">NS 3.3.5</a>):</b>			

<b>1c Co-investigator 3</b>			
Name (include title)		Curtin ID	
School/Area		Role (Co-inv, supervisor, student)	
Telephone		Email	
In the space below, explain how the researcher has sufficient skills and experience to conduct the proposed research ( <a href="#">NS 3.3.5</a> ):			

<b>1d Co-investigator 4</b>			
Name (include title)		Curtin ID	
School/Area		Role (Co-inv, supervisor, student)	
Telephone		Email	
In the space below, explain how the researcher has sufficient skills and experience to conduct the proposed research ( <a href="#">NS 3.3.5</a> ):			

<b>1e Co-investigator 5</b>			
Name (include title)		Curtin ID	
School/Area		Role (Co-inv, supervisor, student)	
Telephone		Email	
In the space below, explain how the researcher has sufficient skills and experience to conduct the proposed research ( <a href="#">NS 3.3.5</a> ):			

**SECTION 3 – General information**

<b>2 Does the research project have a SCRIPT project ID?</b>			
<input type="checkbox"/>	<b>No</b>		
<input type="checkbox"/>	<b>Yes</b> - indicate the funding source below:		
Script ID:			
Source :		Name of source:	
Funding start date:		Funding end date:	

<b>3 Please indicate the type of project</b>	
	If other specify:

<b>4 Has this project been peer reviewed?</b> <i>Peer reviewed means accepted by a granting body that uses a peer review process (e.g. NH&amp;MRC) or if the project has been approved through the candidacy process at Curtin.</i>	
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> – please provide the acceptance/candidacy letter.

<b>5 Does this research involve any of the researchers going overseas?</b>	
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> – please refer to the <a href="#">Curtin Travel Policy</a>

<b>6 Does this research involve any students going overseas? (<a href="#">NS4.8.8</a>, <a href="#">NS4.8.18</a>), <a href="#">Curtin WiL</a></b>	
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> – describe how supervision of the student is to be effected so that due respect and protection will be accorded to participants; and describe any considerations for researcher safety:

<b>7 List the locations research will be conducted. If the research is being conducted on a Curtin University campus please specify the building and room number/s.</b>	

**8**

**Provide a lay summary of your project. Include background, aims and hypothesis, methods and anticipated outcomes in your summary.**

*For assistance in writing in lay language please refer to the [Tips for Writing in Plain English](#).*

**9**

**Describe how your research will have an impact on the community.**

**10**

**Outline the potential risks to participants. If potential risks are identified, explain how this research justifies the burden and risk to participants (NS 2.1).**

*Consider illness or injury, potential side effects, but also include potential embarrassment, economic loss, exposure to prosecution, anything stressful, noxious or unpleasant, and complaints. Ensure you address these in your Participant Information Statement. Some examples of risks/expected adverse events may include:*

- *For a drug-intervention clinical trial there will be side effects of the drug.*
- *For psychological based studies risks may be psychological stress due to the assessment; there may be a potential for increased risk of suicidality or self-harm; there may be a potential for worsening of psychological disorder etc.*

*For data collected off Curtin campus there may be a risk that participant privacy and confidentiality may be breached if data are not transferred correctly (e.g. if not going directly from site to Curtin campus there is a risk that consent forms may be stolen).*

**11**

**If you identified risks in the previous question, outline how you will mitigate the risks identified above and your plan of action for expected adverse events and other identified risks.**

*Please outline how you will mitigate the risks identified above and your plan of action for expected adverse events and other identified risks. Please also outline your plan of action for unexpected adverse events. The Human Research Ethics Office will use this information and follow this procedure should an event or complaint occur.*

## 12 Outline the potential harm or risk to researchers.

Outline the potential harm or risk this research exposes to the research team, and if identified how these will be mitigated and your plan of action should these risks occur.

You may complete the [HSEM generic risk assessment form](#) to help identify and mitigate any potential risks this research exposes to the research team. For assistance with completing the assessment, contact the [Health, Safety and Emergency Management department](#) Some examples are:

- Dangers to personal safety
- Research located overseas

## 13 Outline the potential risk to the University and the research.

Identify the risks this research exposes to The University and to the research and how these risks may be mitigated. Some examples are:

- Reputational risk to The University if the study is a controversial topic;
- Loss of data due to inadequate back-up procedures;
- Unable to recruit expected numbers.

**SECTION 5 – Participant Recruitment and Consent**

<b>14</b>	<b>Are you recruiting participants?</b>
<input type="checkbox"/>	<b>No</b> – in the space below provide information on how you will gain access to participant information, where the information is held and who are the data custodians. If participants have provided, or will provide, consent for their information to be used please describe in the space below. If participants are not providing consent for their information to be accessed, please address points (a) to (i) in section <a href="#">2.3.10</a> of the National Statement so a waiver of consent may be applied.
<input type="checkbox"/>	<b>Yes</b>

If you are **NOT** recruiting participants, please skip to Question 23.

<b>15</b>	<b>Does your research involve staff and students from Curtin University?</b>
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> – <a href="#">Approvals to Access Curtin Students and Staff for Research Purposes</a> must be obtained before ethics submission.

<b>16</b>	<b>Describe your target population and sample size.</b>

<b>17</b>	<b>Select how you are going to recruit participants (select all that apply).</b>		
<input type="checkbox"/>	Database/medical records	<i>Describe the source:</i>	
<input type="checkbox"/>	Social media including Facebook, Yammer, LinkedIn, Twitter etc.	<i>List:</i>	
<input type="checkbox"/>	Classroom or hospital or clinic or community groups etc.	<i>List sources:</i>	
<input type="checkbox"/>	Snowball recruitment or word of mouth etc.	<i>List:</i>	
<input type="checkbox"/>	Print media including flyers, newspapers, newsletters, etc.	<i>List sources:</i>	
<input type="checkbox"/>	Radio/television	<i>List sources:</i>	
<input type="checkbox"/>	Other	<i>Describe:</i>	



<b>18</b>	<b>Describe your recruitment process.</b>
<p><i>When you are describing your recruitment processes please indicate who is going to talk to the potential participants, how they contact the researcher or the researcher contacts them etc. If you are using telephone calls, flyers, social media, radio announcements etc., please provide a copy of the information and/or a transcript. If you are using any form of print media (e.g. flyers, newsletters, social media etc.) you need to put the ethics approval number and the Curtin logo on the document. Please refer to the <a href="#">Curtin Brand website</a> for information on advertising.</i></p>	

<b>19</b>	<b>Will participants receive anything in exchange for participating in research? (<a href="#">NS 2.2.10</a> - <a href="#">2.2.11</a>)</b>
<p><i>Include in your answer anything the participant may receive from taking part in research including cash, vouchers, entry into a prize draw, stationery, access to a study drug once the study has concluded, other goods including chocolate bars etc.</i></p> <p><i>References to what the participant will receive should be in the participant information statement. It is discouraged to add this information to recruitment materials.</i></p> <p><i>Refer to the <a href="#">Payments in Research guidelines</a>.</i></p> <p><i>If a prize is used please indicate the prize and the chances of winning this prize in the space below and in the Participant Information Statement. Please refer to the <a href="#">Competitions Toolkit</a> for further guidance on prizes. Please refer to the Payments to Participants in Research guidelines available on the ethics website.</i></p>	
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> – <i>in the space below detail what the participant will receive, what the value is, and when it will be received.</i>

## Participant consent

<b>20</b>	<b>Will participants provide consent? (<a href="#">NS 2.2</a>, <a href="#">NS 2.3</a>)</b>
<input type="checkbox"/>	<b>No</b> – <i>In the space below provide a reason as to why consent will not be obtained and how privacy and confidentiality will be maintained (<a href="#">NS 2.3</a>)</i>
<input type="checkbox"/>	<b>Yes</b> – <i>describe the process of how you will obtain consent:</i>

<b>21</b>	<b>Is there the potential for the participant to be subject to coercion or pressure, including perceived position of power or people in dependent or unequal relationships? (<a href="#">NS 2.2.9</a> and <a href="#">NS 4.3</a>)</b>
<p><i>For example, will principals or teachers at schools be recruiting or seeking consent from students, will lecturers at Curtin be recruiting and seeking consent from their students, will primary treating physicians be recruiting and seeking consent from patients?</i></p>	
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> - <i>describe the dependent relationship between the participants and the researcher and how it will be addressed.</i>

<b>22</b>	<b>Does the research use deception, concealment, incomplete disclosure, limited disclosure, an opt-out approach, or use of information, samples, health information etc., without the specified consent from those persons? (<a href="#">NS 2.3</a>)</b>
<i>Limited disclosure/deception/concealment/incomplete disclosure is defined as not fully disclosing or describing the aims or methods of observational research in public contexts, all the way to actively concealing information and planning deception of participants. An opt-out approach is where information is provided to the potential participant regarding the research and their involvement and their participation is presumed unless they take action to decline to participate.</i>	
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> - describe the method, why it is essential and how participants will be informed after the study:

## Commonwealth agencies

<b>23</b>	<b>Will you collect or use IDENTIFIED <u>health</u> information held by Commonwealth agencies <u>without consent</u>?</b>
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> - where identified health data are being used a waiver of consent will need to be granted. Only a HREC may grant a waiver of consent which can be done at their next scheduled meeting. Read the <a href="#">Guidelines Under Section 95 of the Privacy Act 1988</a> , answer the following questions and address section 2.4 (g, k, l, m, n(i) and n(ii)) of this Act:
	<b>The agency from which the information will be sought:</b>
	<b>The data items sought from the agency:</b>
	<b>The number of records involved:</b>
	<b>Which <a href="#">Information Privacy Principles</a> would be breached, or likely to be breached (please number):</b>

## Private sector

<b>24</b>	<b>Will you collect or use IDENTIFIED <u>health</u> information from the private sector <u>without consent</u>?</b>
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> - where identified health data are being used a waiver of consent will need to be granted. Only a HREC may grant a waiver of consent which can be done at their next scheduled meeting Read the <a href="#">Guidelines Under Section 95A of the Privacy Act 1988</a> , answer the following questions and address the relevant section/s of this Act (e.g. A2.6, A3.6, B2.6, B3.6, C2.6).
	<b>The organization(s) from which the information will be sought:</b>
	<b>The data items sought from the organization(s):</b>
	<b>The number of records involved:</b>
	<b>Which <a href="#">Information Privacy Principles</a> would be breached, or likely to be breached (please number):</b>
	<b>Indicate which kind of research your study is:</b>

**25** Describe your research methods clearly outlining your study protocol and what each participant will be required to do for the research study ([NS 3.1](#) and [NS 3.4](#)).  
*You may want to attach a flow chart or Standard Operating Procedure.*

**26** Does your research involve withholding from one group specific treatments or methods of learning, from which they may “benefit” (e.g. in medicine or teaching)?

No

Yes

**27** Does your research include invasive physical procedures, collection of body fluid, tissue sampling, infliction of pain, psychological interventions, treatments, administration of drugs or other substances or use of a medical intervention device?

No

Yes

**28** Does your research use medical records where participants can be identified or linked?

No

Yes

**29** Briefly explain your research outcomes and how do you plan to analyse the data.  
*Provide sufficient detail in this section to describe the data you collect, how you will analyse it and what the outcomes of the research will be.*

<b>30</b>	<b>Does your research involve exposing participants to radiation?</b> <i>Eg. radioisotopes, lasers, x-rays, microwaves, ultra-violet radiation</i>
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> - You will need to contact the Radiation Safety Officer at <a href="http://radsafetycurtin.edu.au">radsafetycurtin.edu.au</a> and receive approval prior to submitting ethics.

<b>31</b>	<b>Does your research use health information (including biospecimens) that may reveal information that may be important for the health or future health of the donor(s), their blood relatives or their community? (NS 3.4.10, 3.5.1 and 3.5.2)</b>
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> – indicate how you will address the management of any proposed disclosure or non-disclosure of that information:

<b>32</b>	<b>Does your research involve human genetics? (NS 3.5)</b>
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> – address the parts of Section 3.5 of the National Statement that are relevant to this project:

**33 Is your study a clinical trial? (NS 3.3)**

Curtin University Ethics Office uses the WHO / ICMJE 2008 definition of a clinical trial. That is, any research study that prospectively assigns human participants or groups of humans to one or more health related interventions to evaluate the effects on health outcomes. 'Intervention' refers to manipulation of the participants or the participants' environment for the purpose of modifying one or more of the study outcomes. The intervention may be a drug, medical device, surgical procedure, diagnostic or screening procedure, a health service change, or a psychological, educational or behavioural strategy. Interventional studies characteristically involve comparison of one or more interventional groups with a control group.

If you need help completing this section contact the Clinical Trials Monitor at [ORD-clinicaltrials@curtin.edu.au](mailto:ORD-clinicaltrials@curtin.edu.au).

**No** – skip to Section 8.

**Yes** - All clinical trials need to have institutional approval prior to commencing the study.  
Please contact [ORD-clinicaltrials@curtin.edu.au](mailto:ORD-clinicaltrials@curtin.edu.au)

If your study is **NOT** a clinical trial, skip to Section 8.

**33a**

Are you using any medicine, biological or device not entered in the [Australian Register of Therapeutic Goods](#), including any new formulation of an existing product or any new route of administration; or

A marketed medicine, biological or device beyond the conditions of its marketing approval including new indications extending the use of the product to a new patient group and the extension of doses or duration of treatments outside the approved range?

**No**

**Yes** - Attach a copy of the CTN

**33b**

Will a placebo/non-treatment group be used? ([NS 3.3.10](#))

**No** - outline why a placebo or non-treatment group will not be used:

**Yes** - describe why a placebo or non-treatment group is the best comparator:

**33c**

Describe the randomisation and blinding process.

**33d**

Has this trial been registered? ([NS 3.3.12](#))

**No** - please register this trial on a publically accessible register (e.g. ANZCTR) prior to recruitment of participants.

**Yes** – in the space below provide the registration number and the name of the trial registry:

<b>33e</b>	Are there arrangements (business, financial or other similar association) between a researcher and supplier of a drug or surgical or other device to be used in the trial? <a href="#">(NS 3.3.4)</a>
<input type="checkbox"/>	Not applicable
<input type="checkbox"/>	No
<input type="checkbox"/>	Yes

<b>33f</b>	Are there any restrictions on publications? <a href="#">(NS 3.3.4)</a>
<input type="checkbox"/>	No
<input type="checkbox"/>	Yes – enter the details in brief:

<b>33g</b>	Is funding sufficient to conduct and complete the trial as designed? <a href="#">(NS 3.3.2 and 3.3.18)</a>
<input type="checkbox"/>	No – in the space below indicate how you will address this:
<input type="checkbox"/>	Yes

<b>33h</b>	Are payments to researcher, participants or the institution likely to influence the design, conduct, findings or publications of the research? <a href="#">(NS 3.3.2 and 3.3.18)</a>
<input type="checkbox"/>	No
<input type="checkbox"/>	Yes – in the space below indicate how you will address this:

<b>33i</b>	Are the facilities, expertise and experience available sufficient for the trial to be conducted safely? <a href="#">(NS 3.3.5)</a>
<input type="checkbox"/>	No – in the space below indicate how you will address this:
<input type="checkbox"/>	Yes

<b>33j</b>	Does your Participant Information Statement make clear to the participant whether they will have continued access after the trial to treatment they have received during the trial, and on what terms? <a href="#">(NS 3.3.18)</a>
<input type="checkbox"/>	No – please update your Participant Information Statement to include this information
<input type="checkbox"/>	Yes

<b>34</b>	<b>Does your research involve games and/or embryos?</b>
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b>

<b>35</b>	<b>Does your research involve women who are pregnant and/or the human fetus?</b>
<input type="checkbox"/>	<b>No</b> – skip to Section 9.
<input type="checkbox"/>	<b>Yes</b> – please respond to the questions below.

If your study **DOES NOT** involve women who are pregnant and/or the human fetus, skip to Section 9.

<b>35a</b>	<b>Will steps be taken to ensure that the well-being and care of the woman who is pregnant, and her fetus takes precedence over the aims of the research? (<a href="#">NS 4.1.1</a>)</b>
<input type="checkbox"/>	<b>No</b> – in the space below justify why:
<input type="checkbox"/>	<b>Yes</b> – outline the procedures in the space below:

<b>35b</b>	<b>Will access to counselling be offered to the participant? (<a href="#">NS 4.1.14</a> and <a href="#">4.1.17</a>)</b>
<input type="checkbox"/>	<b>No</b> – in the space below justify why there is no counselling available:
<input type="checkbox"/>	<b>Yes</b> – describe the counselling process in the space below:

<b>35c</b>	<b>Will the women be asked whether they wish to involve others for whom the research may have implications? (<a href="#">NS 4.1.5</a> and <a href="#">4.1.15</a>)</b>
<input type="checkbox"/>	<b>No</b> – in the space below justify why they will not be offered to involve others.
<input type="checkbox"/>	<b>Yes</b>

<b>35d</b>	<b>Will the information about research be separate from information about routine clinical care? (<a href="#">NS 4.1.6</a>)</b>
<input type="checkbox"/>	<b>No</b> – in the space below justify why the information will not be provided separately to the participant.
<input type="checkbox"/>	<b>Yes</b>

<b>35e</b>	<b>Is the research on the fetus <i>in utero</i>?</b>	
<input type="checkbox"/>	<b>No</b> – skip to Question 35f.	
<input type="checkbox"/>	<b>Yes</b> – please answer the sub-questions below.	
	<b>No</b>	<b>Yes</b>
		<b>Question 35e sub-questions</b>
<input type="checkbox"/>	<input type="checkbox"/>	<b>Has the research been designed to minimize pain or distress for the fetus?</b>
<input type="checkbox"/>	<input type="checkbox"/>	<b>Will action be taken to monitor for signs of fetal pain or distress?</b>
<input type="checkbox"/>	<input type="checkbox"/>	<b>Will steps be taken for suspending or ceasing the research to prevent pain or distress to the fetus?</b>
<i>If you answered <b>NO</b> to any of the above questions please provide a justification below.</i>		

<b>35f</b>	<b>Does the research involve the human fetus <i>ex utero</i> or fetal tissue after separation or termination?</b>	
<input type="checkbox"/>	<b>No</b> – skip to Question 36.	
<input type="checkbox"/>	<b>Yes</b> – please answer the sub-questions below.	
	<b>No</b>	<b>Yes</b>
		<b>Question 35f sub-questions</b>
<input type="checkbox"/>	<input type="checkbox"/>	<b>Do any of those conducting the research have any financial or legal relationships, or is involved in the clinical care of the woman? (<a href="#">NS 4.1.11</a>,</b>
<input type="checkbox"/>	<input type="checkbox"/>	<b>Will the research involve the removal of organs or tissues from a fetus delivered dead? (<a href="#">NS 4.1.22</a>)</b>
<i>If you answered <b>YES</b> to any of the above questions please provide a justification below.</i>		



**SECTION 9 – Aboriginal and Torres Strait Islanders**

<b>36</b>	<b>Does your research involve Aboriginal and Torres Strait Islanders? <a href="#">(NS 4.7)</a></b>
<i>Note: If your research will incidentally involve Aboriginal and Torres Strait Islanders because your study is on the general population you do not need to fill in this section. Complete this section if you are specifically targeting recruitment of Aboriginal and Torres Strait Islanders, or there is a potential for a high number of Aboriginal and Torres Strait Islanders to be recruited.</i>	
<input type="checkbox"/>	<b>No</b> – skip to Section 10.
<input type="checkbox"/>	<b>Yes</b>

If your study **DOES NOT** involve Aboriginal and Torres Strait Islanders, skip to Section 10.

<b>36a</b>	<b>What is the estimated proportion of Aboriginal and Torres Strait Islanders in the population from which the participants will be recruited?</b>

<b>36b</b>	<b>Has there been a process of consultation and negotiation with Aboriginal and Torres Strait Islanders in the development of the research?</b>
<input type="checkbox"/>	<b>No</b> – in the space below justify why:
<input type="checkbox"/>	<p><b>Yes</b> – describe this process of consultation and negotiation in the space below. Include, as appropriate:</p> <ul style="list-style-type: none"> <li>▪ how the consultation process and the research proposal demonstrates the integrity of the researcher,</li> <li>▪ negotiation of the aims, anticipated outcomes and priorities of the research,</li> <li>▪ consultation regarding community and individual consent to participation in the research,</li> <li>▪ the process for negotiating ongoing advice as the research progresses, to monitor ethical standards and minimise unintended consequences,</li> <li>▪ how the processes show engagement with the values and processes of participating communities, and</li> <li>▪ the process of negotiating access to, and /or control of the results of the research.</li> </ul>

<b>36c</b>	<b>Is there a role for Aboriginal and Torres Strait Islanders in the implementation of the research?</b>
<input type="checkbox"/>	<b>No</b> – in the space below justify why:
<input type="checkbox"/>	<b>Yes</b> – describe the role of Aboriginal and Torres Strait Islanders in the development and or implementation of the research. Include, as appropriate: <ul style="list-style-type: none"> <li>▪ whether any or all of the researchers are of Aboriginal and/or Torres Strait Islander descent,</li> <li>▪ how Aboriginal and Torres Strait Islanders from the community involved in, or affected by, the research have collaborated in the development of the research,</li> <li>▪ whether the participating communities have expressed satisfaction with the research agreement, potential benefits and their distribution,</li> <li>▪ the extent to which reciprocal obligations, responsibilities and benefits is demonstrated between the</li> </ul>

<b>36d</b>	<b>Is the project related to health research?</b>
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b>

<b>36e</b>	<b>Describe how the research will provide benefits to Aboriginal and Torres Strait Islanders.</b>
Include, as appropriate: <ul style="list-style-type: none"> <li>▪ a description of how the research relates to the health priorities and needs of participant communities,</li> <li>▪ a description of benefits for participants and the communities, including establishment and/or enhancement of capacities, opportunities and outcomes beyond the project,</li> <li>▪ a description of how the research shows an intent to contribute to the advancement of the health and well-being of participants and their communities</li> </ul>	

<b>36f</b>	<b>Describe how the proposal responds to the diversity between communities.</b>
<p><i>Research in Indigenous studies must recognise the diversity of Indigenous peoples, including their different languages, cultures, histories and perspectives. It is also important to recognise the diversity of individuals and groups within communities. For more information refer to the <a href="#">Guidelines for Ethics Research in Australian Indigenous Studies Principle 1</a>.</i></p>	

<b>36g</b>	<b>Justify how the research respects the values based expectations, and protects and promotes cultural distinctiveness of Aboriginal and Torres Strait Islander participants.</b>
<p><i>Outline how your research demonstrates the six values the Spirit and Integrity, Reciprocity, Respect, Equality, Survival and Protection, and Responsibility. For more details on these values please refer to <a href="#">Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research</a>.</i></p>	

<b>36h</b>	<b>Describe the researchers' competencies for carrying out research in Aboriginal and Torres Strait Islanders and their community.</b>
<p><i>Demonstrate your community positioning and current relationship with guardians of Aboriginal knowledge ie. Elders and Boards of Community controlled organisations or key individuals who are can be justified to hold significant knowledge. Suitability/competency must be acknowledged in writing by at least one community controlled organisation in the location of where the research will be conducted and if possible, a written acknowledgement signed by community elders that they acknowledge the researcher as being ethical and able to ensure cultural safety for participants.</i></p>	

## Children and young people

<b>37</b>	<b>Does your research involve children and young people?</b> <a href="#">(NS 4.2)</a>
<i>Mature minors are defined as a child under the age of 18 years who is assessed as being competent to consent by virtue of the fact that they fully comprehend the nature, consequences and risks of the proposed research. Refer to section 4.2.8 and 4.2.9 of the National Statement.</i>	
<input type="checkbox"/>	<b>No</b> – skip to question 38.
<input type="checkbox"/>	<p><b>Yes mature minors</b> - Refer to the <i>Working with Children Check for Researchers</i> to determine if your research requires staff and/or students to have a <a href="#">working with children check</a>.</p> <p>In the space below please describe:</p> <ul style="list-style-type: none"> <li>• Why these participants are considered mature minors and why parental consent is not required; and</li> <li>• Address why participation of children or young people is indispensable to this research; and how this study has been designed to be appropriate for children or young people:</li> </ul>
<input type="checkbox"/>	<p><b>Yes children not considered mature minors</b> – Refer to the <i>Working with Children Check for Researchers</i> to determine if your research requires staff and/or students to have a <a href="#">working with children check</a>.</p> <p>In the space below address why participation of children or young people is indispensable to this research; and how this study has been designed to be appropriate for children or young people.</p>

## Highly Dependent on Medical Care

<b>38</b>	<b>Does your research involve people highly dependent on medical care who may be unable to give consent?</b> <a href="#">(NS 4.4)</a>
<i>People who are highly dependent on medical care refer to those who may be unable to give consent. This may be people who are patients in the emergency department or intensive care, unconscious people or people in terminal care.</i>	
<input type="checkbox"/>	<b>No</b> – skip to question 39.
<input type="checkbox"/>	<b>Yes</b> - Describe how participation in research is in the best interest of the participant.

## Cognitive Impairment, Intellectual Disability, Mental Illness

<b>39</b>	<b>Does your research involve people with a cognitive impairment, an intellectual disability, or a mental illness?</b> <a href="#">(NS 4.5)</a>
<i>Refer to the <a href="#">Diagnostic and Statistical Manual of Mental Disorders, 5th Edition: DSM-5</a>, and <a href="#">Tables for the Assessment of Work Related Impairment for Disability Support Pension</a></i>	
<input type="checkbox"/>	<b>No</b> – skip to question 40.
<input type="checkbox"/>	<b>Yes</b> - describe the nature of the intellectual or mental impairment e.g. permanent, temporary or fluctuating:

# Illegal Activities

<b>40</b>	<b>Does your research involve people who may be involved in illegal activities?</b> <a href="#">(NS 4.6)</a>
<p>Research may in some instances discover illegal activity (including notifiable activity) by participants or others, or may discover information indicating future illegal activity. Such research may:</p> <ul style="list-style-type: none"> <li>▪ be intended to study, and perhaps to expose, illegal activity;</li> <li>▪ be not specifically intended to discover illegal activity, but likely to do so;</li> <li>▪ discover illegal activity inadvertently and unexpectedly.</li> </ul>	
<input type="checkbox"/>	<b>No</b> – skip to question 41.
<input type="checkbox"/>	<b>Yes</b> - justify how the risk of discovery of illegal activities is justified by the benefits of the research:

# Research involving participants in other countries

<b>41</b>	<b>Does your research involve participants in other countries?</b> <a href="#">(NS 4.8)</a>
<input type="checkbox"/>	<b>No</b> – skip to question 42.
<input type="checkbox"/>	<b>Yes</b> – please respond to the questions below.

<b>41a</b>	<b>Is there an ethics approval process in the country you intend to do the research?</b> <a href="#">(NS 4.8.4)</a>
<input type="checkbox"/>	<b>No</b>
<input type="checkbox"/>	<b>Yes</b> – in the space below describe if these processes are mandatory (as opposed to voluntary); how they function, what are the values and principles on which they rely and do they require reporting of the Australian review body approval? <a href="#">(NS 4.8.4)</a>

<b>41b</b>	<b>Is a local, readily accessible contact available to participants to receive responses, questions and complaints about the research?</b> <a href="#">(NS 4.8.16)</a>
<input type="checkbox"/>	<b>No</b> - justify why a local contact will not be available to participants to receive responses, questions and complaints about the research:
<input type="checkbox"/>	<b>Yes</b> – describe:

<b>41c</b>	<b>Address any cultural sensitivities that need to be taken into account in designing and implementing the research.</b>

## Research involving non-English speakers

<b>42</b>	<b>Does your research involve participants whose primary language is not English?</b>
<input type="checkbox"/>	<b>No</b> – skip to question 43
<input type="checkbox"/>	<b>Yes</b> – in the space below describe what steps will be taken to ensure the participants provide informed consent, and that they fully understand the study requirements and their rights.

SECTION 11 – Conflicts of interest

**43** Are there any potential conflicts of interest?

Refer to the Curtin University [Conflict of Interest Procedures](#).

Specific to researchers, conflict of interests may include:

- the research is sponsored by another person or entity with which the researcher has an affiliation or a financial involvement.
- the researcher may benefit, directly or indirectly, from any inappropriate dissemination of research results (including any delay in or restriction upon publication of such results).
- the researcher may personally benefit, directly or indirectly, from the use of University resources in conducting University research.
- the researcher conducts a clinical trial which is sponsored by any person or organisation with a significant interest in the results of the trial.
- private benefits or significant personal or professional advantage are dependent on a **researcher's** research outcomes.
- in relation to the commercialisation of research, substantial benefits for a researcher arise from collaborations and relationships with industry in the licensing and marketing of research discoveries and in the creation of spin-off companies.

**No**

**Yes** – in the space below describe the potential conflicts of interest.

## SECTION 12 – Attachments

Please use the checklist below for attachments you may be required to include as part of your application:

Item	N/A	No	Yes	Version	Date
Peer review documents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Protocol/research proposal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Participant Information statement and consent form/s	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Parent Information statement and consent form/s	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Child Information statement and assent form/s	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Questionnaires/survey instruments (list below)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Translations where languages other than English are used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Recruitment materials (list below)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Approval from the Radiation Safety Officer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
CTN/CTX (drug or device clinical trials only)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Investigator brochure or Product Information (for drug intervention studies)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Research Data Management Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Working with Children's Card	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
SOL Research Integrity Professional Development Program training certificate/s. <i>Staff can access certificates from iPerform. Students can take a screen capture of completion in blackboard.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

### NOTES

1. In the footer of all your documents (e.g. protocol, recruitment material, information statements and consent forms, questionnaires etc) you should include:
  - Name of the document
  - Version number
  - Date
  
2. Refer to the guidelines for Participant Information Statements and Consent Forms. Remember to include a phrase similar to the following:  
 Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number XX/XXXX). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.
  
3. Refer to the [Curtin Brand website](#) for information on advertising for recruitment. All forms of print media must contain the HREC approval number.