Human Research Ethics Office



Application for Ethical Approval for a Research Project Involving Humans

Use this form to apply for ethical review of human research projects by Curtin University staff or students. Ethical review of research is a necessary pre-requisite for research involving humans. This includes research that studies people, their data and tissues, and observation of people.

Throughout this document you will find hyperlinks to the relevant sections of the <u>National Statement on Ethical Conduct in Human Research</u> and other relevant documents.

INSTRUCTIONS FOR THE PRINCIPAL INVESTIGATOR

Completing the Form

Answer all questions. Please keep your answers concise, but informative and written in lay language. Based on the questions answered in the "Assessment of applications for ethics triage" your project will be categorised as either "Low Risk" or "Non-low Risk". "Low Risk" projects are assessed at the faculty level, "Non-low Risk" projects are assessed by the Human Research Ethics Committee at the next monthly meeting. You will be informed of the triage decision.

Submitting the Application

Submit the completed and signed application, and any attachments, to the Ethics Support Officer for your faculty:

- Business: ORD-ethicscbs@curtin.edu.au
- Health Sciences: ORD-ethicshs@curtin.edu.au
- Humanities: <u>ORD-ethicshum@curtin.edu.au</u>
- Science and Engineering: <u>ORD-ethicssae@curtin.edu.au</u>

To submit the application

Option 1: Attach the application, all the emails from the Co-investigators which serve as their signature (see Section 7 – upload these as a pdf) and all other necessary documents to an email. The Principal Investigator forwards the email with all attachments and the application form onto the Head of School/Area. The HOS/A then approves by forwarding the email trail (which shows it was sent by the PI), with attachments to the appropriate Ethics Support Officer.

Option 2: Obtain original signatures from the PI and HOS/A. You can either obtain original signatures from the CI, or you can attach an email from the CI which serves as their signature (see Section 7). Submit one single-sided copy of all documents with no staples, to the Ethics Office, Room 108, Building 100.

Need help completing this form?

Contact your Ethics Support Officer or the Ethics Office via email at hrec@curtin.edu.au or go to the Research Integrity section of the Office of Research Development contact page.

Do not commence research until written approval has been received from the Human Ethics Office

Assessment of applications for ethics triage

The following questions are a guide as to whether you project may be considered low risk and therefore go through the low risk approval system. Fill in this section before moving onto Section 1.

Does your research involve recruiting participants:	No	Yes
Who are/have been a patient at a hospital or health department?	Continue to the questions below	STOP You need ethics approval from the relevant Department of Health authority FIRST.
Who are/have been a patient at a hospital or health department AND Aboriginal and Torres Strait Islanders?	Continue to the questions below	STOP You need ethics approval from the WAHEC FIRST.
From a school or education facility?	Continue to the questions below	STOP You need a letter of support from the principal/s FIRST. Approval from the education department/s can be applied for after Curtin HREC approval.

can be applied for after editin Title approval.				
Does the study include any of the ten following types of research and/or participants?	No	Yes		
According to section 5.1.6 (b) of the National Statement if your study involves any of the following groups the project National Statement if your study involves any of the following groups the project National Statement if your study involves any of the following groups the project National Statement if your study involves any of the following groups the project National Statement if your study involves any of the following groups the project National Statement if your study involves any of the following groups the project National Statement if your study involves any of the following groups the project National Statement in your study involves any of the following groups the project National Statement in your study involves any of the following groups the project National Statement in your study involves and your study involves are not your study involves and your study involves	1UST b	е		
Interventions and therapies, including clinical and non-clinical trials (NS 3.3)	\boxtimes			
Human genetics (NS 3.5)	\boxtimes			
Women who are pregnant and/or the human fetus (NS 4.1)	\boxtimes			
People who are highly dependent on medical care who may be unable to give consent (NS 4.3 and 4.4)	\boxtimes			
People with a cognitive impairment, intellectual disability or a mental illness (NS 4.5)	\boxtimes			
Research specifically targeting Aboriginal or Torres Strait Islanders (NS 4.7)	\boxtimes			
People who may be involved in illegal activities (NS 4.6)	\boxtimes			
Are any of the following topics covered in part or in whole?	No	Yes		
Research about parenting issues	\boxtimes			
Research investigating sensitive personal issues	\boxtimes			

Are any of the following topics covered in part or in whole?	No	Yes
Research about parenting issues	\boxtimes	
Research investigating sensitive personal issues	\boxtimes	
Research investigating sensitive cultural issues	\boxtimes	
Explorations of grief, death or serious/traumatic loss	\boxtimes	
Illicit drug use	\boxtimes	
Substance abuse (prescribed or over the counter)	\boxtimes	
Self-report of criminal behaviour	\boxtimes	
Suicide risks	\boxtimes	
Gender identity	\boxtimes	
Sexuality	\boxtimes	
Race or ethnic identity	\boxtimes	
Fertility	\boxtimes	
Termination of pregnancy	\boxtimes	

Are any of the following procedures to be employed?		
Use of personal data obtained from Commonwealth or State Government Department/Agency	\boxtimes	
Deception of participants or concealing the purposes of the research	\boxtimes	
Covert observation (or minimal disclosure)	\boxtimes	
Audio or visual recording without consent	\boxtimes	

Are any of the following procedures to be employed (continued)?	No	Yes
Withholding from one group specific treatments or methods of learning, from which they may "benefit" (e.g. in medicine or teaching)	\boxtimes	
Psychological interventions or treatments	\boxtimes	
Invasive physical procedures	\boxtimes	
Infliction of pain	\boxtimes	
Administration of drugs or other substances	\boxtimes	
Use of devices	\boxtimes	
Exposure to ionising radiation	\boxtimes	
Tissue sampling or blood for pathological or genetic testing	\boxtimes	
Collecting body fluid (eg. saliva)	\boxtimes	
Use of medical records where participants can be identified or linked	\boxtimes	

Select the categories that are targeted or likely to be included as participants in this research study.	No	Yes
Suffers from a disease or health problem	\boxtimes	
Suffers from a psychiatric / psychological disorder / emotional impairment	\boxtimes	
Suffering a physical disability or medical condition	\boxtimes	
Participants are aged less than 18 years	\boxtimes	
Children and/or young people without parental or guardian consent	\boxtimes	
Resident of a custodial institution	\boxtimes	
Unable to give freely an informed consent because of difficulties in understanding information provided (eg. Language difficulties, primary language is not English)	\boxtimes	
Members of a socially identifiable group with special cultural or religious beliefs or political vulnerabilities	\boxtimes	
Participants specifically targeted belong to a cultural/minority group or any other collective	\boxtimes	
Those in a dependent relationship with the researchers (eg. Lecturer/student, doctor/patient, teacher/pupil and professional/client)		\boxtimes
Participants are identifiable or re-identifiable	\boxtimes	
Participants are identifiable in the final report when specific consent for release has not been given	\boxtimes	

A "yes" response to any of the above questions would normally indicate your project is **not eligible** for a Low or Negligible Risk review. However, a "Yes" answer does not necessarily, automatically, preclude the research from being reviewed through a low risk review process. If you answered "yes" to any of the above questions and you think your study should be reviewed through the low risk process please justify why in the space below.

Whilst the proposed research involves Curtin students, and two of the investigators are the unit coordinators and teach in the unit the dependent relationship will be managed/mitigated by:

- 1. Most of the data is readily available to the principal investigator as part of their role as the unit coordinator (eVALUate data, learning analytics from Blackboard, student attendance in tutorials, and plagiarism rates).
- 2. Recruitment of student participants for the in class online questionnaire will be anonymous and carried out by the team of tutors for each class [Appendix E]. None of the tutors are part of the research team. Students will be provided with an information sheet and participation will be voluntary. As the questionnaire will be entirely about the student experience in the unit, and it will be anonymous it poses minimal risk. To ensure tutors follow ethical recruitment processes training will be provided in one of the normal tutor meetings prior to data collection. For the tutorials where the investigators teach, the co-tutor will facilitate the questionnaire whilst the researcher leaves the room.
- 3. Recruitment of student participants for the end of semester in-class online questionnaire will be carried out by the same tutors who will have undergone training and students will be able to opt out of their feedback being

	part of the data and by tipking a boy (Appendix E). For the tytorials where the investigators tooch, the actuary
	part of the data set by ticking a box (Appendix F). For the tutorials where the investigators teach, the co-tutor
	will facilitate the questionnaire whilst the researcher leaves the room.
4.	The proposed end of semester focus group will be conducted by AI 1 and recruitment and participation
	conducted in accordance with ethical standards. The questions will be about the tutors' experience of student
	learning in the unit and is a normal part of quality processes conducted in the unit (see Appendix G).
	End of Assessment of applications for ethics triage

			SECTION 1 – Genera	l info	ormation		
1	Project Ti	itle					
'Flipping'	the classroo	om: are students eng	aged?				
2	Provide up to six keywords (not included in the project title) below						
Flipped cl	assroom, s	tudent engagement					
3	Please in	dicate the type of p	roject				
Staff proje	ect				If other spe	ecify:	
4	Peer reviewe approved the	rough the candidacy proce	ranting body that uses a pe			H&MRC) or if the p	project has been
5	Please in	dicate the funding s	source				
Source :	Universi	ty	Name of sour		TASS		
Funding s	start date:	Jan, 2016	Funding end date:	31 st 2016	December,	Script ID:	NA
6	Does this	research involve a	ny of the researcher	s goi	ing overseas?		
\boxtimes	No						
	Yes – plea	se refer to the Curtin Trav	el Policy				
7	Please 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						
8	Project S Give a conci	-	in plain language, of the s	tudy in	each of the section	s below.	
i		I					

8a

Background

(No more than 200 words).

The flipped classroom (or inverted classroom) is receiving increased attention although it is not a new approach (Watters, 2012). Flipped learning is a pedagogical approach that requires students to do background reading/preparation (often involving elearning resources) prior to attending the face-to-face component of a course where the tutor facilitates learning through applied activities and discussion to foster deep learning (Davis, 2013). This approach, acknowledges that the role of the academic or teacher is changing from "sage on the stage" to "meddler in the middle" as information is readily available to learners through the internet (McWilliam, 2009); in other words, how do academics add value when they are no longer the holder of knowledge and the information typically delivered through lectures is easily accessible elsewhere? Although an increasing number of publications are exploring the flipped learning model there is a lack of evidence to determine whether the approach works with all cohorts and, indeed, what the key elements are that support student engagement to ensure they come to the class prepared.

8b

Aims and hypothesis

The aim of this research project is to determine whether the flipped classroom model is engaging first year students in their learning. The research aims to explore the following research questions:

- 1. Does the flipped/new unit structure engage students in their learning?
- 2. What elements of the unit design support engagement in the flipped model?
- 3. What improvements to the unit would enhance engagement?

8c

Methods

(No more than 200 words)

A mixed methods approach will be used to address the research questions.

- 1. Blackboard© data on student access to online material. (quantitative)
- 2. Incidents of plagiarism (including a comparison with 2014 data, where the unit was not utilizing a flipped approach). (quantitative)
- 3. Student attendance for the workshop. (quantitative)
- 4. In week 5 of the semester a 5 minute online anonymous "stop, start and continue" exercise to determine what is working/not working in support of student learning (see Appendix E). (qualitative)
- 5. At the end of semester an anonymous online questionnaire (the validated measure) the Flipped Classroom Student Engagement Questionnaire Version 2.2 (Kynn, Taylor, & Cole, 2015) (see Appendix F) to explore students' experience of the flipped approach will be administered. (quantitative and qualitative)
- 6. À focus group with tutors to explore their perceptions of whether students were engaged, prepared, and if the flipped approach supported student learning (Appendix G). (qualitative)

8d

Anticipated outcomes

(No more than 100 words)

The research data collected will, primarily, be used to improve the student experience in the unit. However, given the emergent field of research into flipped learning the findings will be published and of relevance to higher education through providing an evidence base to inform flipped or inverted learning approaches. Specifically, the findings will provide information about what supports students' engagement within a large, flipped, first year unit.

8e

Significance

(No more than 100 words)

Although the 'flipped classroom' model is increasing in popularity in higher education through technological advances, increased student numbers, decreased funding and the knowledge economy, there is only a relatively small and emergent body of literature (Mok, 2014). This project aims to expand knowledge in the field by determining the impact of the flipped model on student engagement. The student cohort provides a unique opportunity to explore how best to engage students within a unit of this nature.

9	Principal Investion The principal investigation one of the student's su	ator mu	ust be a Curtin staff member. If	this applica	ntion is i	for a s	student projed	et the principal inve	estigator must be
Name (in	clude title)	PI Staff ID 123456A							
School,	Centre or Area	[Sc	:hool name]						
Telephor	ne	X12	234	Email	1234	456A	@curtin.e	du.au	
	SOL Research Integrity Professional Development Program training complete (NOTE: this is a requirement of approval) Yes – certificate attached						tificate attached		
10	approved before an et	pages hics a	for more co-investigators. If ca pplication is submitted. NOTE: Program training – this is a requ	All Curtin s	staff and	d stua	lents MUST c	omplete the SOL I	Research Integrity
N	ame (include title)		School, Centre, Area, University or Institution	Staff II Studen	-		Role supervisor, student)	Candidacy approved	Research Integrity training complete
Al 1			[school name]	234567	3	Co-ir	nvestigator		\boxtimes
Al 2			[school name]	7894560	;	Co-ir	vestigator		\boxtimes
						Choo	se an item.		
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						Choo	se an item.		
						Choo	se an item.		
11	Contact Person								
		estiga	ators details – go to ques	tion 12.					
	clude title)						Staff ID		
`	Centre or Area								
Telephor				Email					
12	Team Expertise		am has sufficient skills and exp					1 (110 0 0 5)	
their emp	unit coordinator for t bloyment to undertal research projects, h	the u ke the as be	nit and is a Teaching Foo e Scholarship of Teaching een successful with seven Teaching Focused acade	cused aca g and Lear al Office	ademi arning for Le	c sta g. Al earni	ff member 1 has work ng and Tea	who is require led on numerou aching national	us teaching and

SECTION 2 - Themes in research ethics: Risk and benefit, consent

Potential harm or risk to participants

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

13

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 (See Adverse Event Guidelines for more information) 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.

There is minimal risk or potential harm to participants.

Risk management strategy

If you identified risks in Question 13, 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. Please refer to Adverse Event Guidelines for more information.

Potential harm or risk to researchers

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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.

Some examples are:

- Dangers to personal safety
- Research located overseas

There is no foreseen potential harm or risk to the research team.

Potential risk to The University and the research

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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.

There are minimal risks to the University through this research project as it aims to provide evidence to improve student learning in the unit under investigation. Asking students to complete the online questionnaires in class will assist with recruitment, and data will be stored in accordance with the data management plan provided.

17	7	Will participan	ts be given financial or non-fi	nancia	al incentives? (NS 2	2.2.10 - 2.2.11)			
]	No							
\boxtimes		Yes — please provide details below. 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 <u>Competitions Toolkit</u> for further guidance on prizes. Details of the incentives should not be detailed on the recruitment material; however this information may be included in the Participants Information Statement.							
			our TASS grant we will pay sessi						
			for staff who are paid by the holded financial or non-financial ince			igoing contracts).			
Otaat	onto	Will flot be provid		OTTER OC	o to participate.				
18	3	When you are desc contact the researc announcements et newsletters, social	recruitment process. cribing your recruitment processes please ther or the researcher contacts them etc., please provide a copy of the information.	se indica . If you a tion and	te who is going to talk to are using telephone calls or a transcript. If you are				
\boxtimes	reco	se describe the	Learning Management System: Blackboard. eVALUate data gathered as normal University business.		Snowball recruitment or word of mouth etc. (please list):				
	Face Linke	al media including book, Yammer, edIn, Twitter etc. se list):			Print media including flyers, newspapers, newsletters etc. (please list sources):				
\boxtimes	or cli grou	sroom or hospital nic or community ps etc. see list sources):	Students enrolled internally in the unit.		Radio/television (please list sources):				
	Othe (plea	r ese describe):							
ensu have	re the	ey do not coerce option of opting o	students to participate. Student	s will i	eceive an information. The questionnair	e will be accessed via iPads. Each			

19

Please describe your target population and sample size.

Please include a description of your target population, including inclusion/exclusion criteria if appropriate. Please justify the sample size e.g., through a power calculation, a sample size calculation or previous studies (provide reference)

The target participant group is students enrolled internally in the unit. All students enrolled and present in the workshops in week 5 and week 14 will be invited to participate. As the online questionnaires (which should only take 5-10 minutes) will be done in class the response rate should be high, however, we are aiming for a minimum of a 25% response rate.

There are 10 tutors teaching in semester 1, 2016. They will be invited to participate in the end of semester focus group by PI 1.

20	Does your research involve staff and students from Curtin University?						
	No						
\boxtimes	Yes – please refer to the <u>Approvals to Access Curtin Students and Staff for Research Purposes</u> .						
21	Will participants provide consent? (NS 2.2, NS 2.3) Please provide a copy of the Participant Information Statement and Consent Forms. If you are recruiting children provide a Parent Information Statement and Consent Form, and a Child Information Statement and Assent Form if appropriate. If you are using secondary data and therefore consent is not required, select "no" and provide an explanation in the space below.						
	No — please address section 2.3 of the National Statement below AND answer questions 21a/b.						
\boxtimes	Yes – please describe below how you will obtain consent and go to question 22.						
	g supplied with an information sheet (Appendix B) consent will be assumed if participants complete the aire/s or sign a consent form (tutor focus groups) (Appendices C and D).						
	21a Will you collect or use IDENTIFIED information held by Commonwealth agencies?						

21a	Will you collect or use IDENTIFIED information held	d by Commonwealth agencies?	
\boxtimes	No – go to question 21b		
	Yes — read the <u>Guidelines Under Section 95 of the Privacy Act 198</u> section 2.4 (g, k, l, m, n(i) and n(ii)) of this Act in the space below.	Yes — read the <u>Guidelines Under Section 95 of the Privacy Act 1988</u> , answer the following questions and address section 2.4 (g, k, l, m, n(i) and n(ii))of this Act in the space below.	
	The agency from which the information will be sought:		
	The data items sought from the agency:		
	The number of records involved:		
	Which Information Privacy Principles would be breached, or likely to be breached (please number):		

21b	b Will you collect or use IDENTIFIED information from the private sector?	
\boxtimes	No – go to question 22	
	Yes — read the <u>Guidelines Under Section 95A of the Privacy Act 1988</u> , 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) in the space below.	

	The organisation(s) from which health information is sought:	
	The data items sought from the organization(s):	
	The number of records involved:	
	Which National Privacy Principles would be breached, or likely to be breached (please number):	
	Indicate which kind of research your study is (tick one only):	 ☐ Research relevant to public health or safety ☐ The compilation or analysis of statistics relevant to public health or safety ☐ The management, funding or monitoring of a health service
00	Is there the potential for the participant to be sub position of power? (NS 2.2.9)	ject to coercion or pressure, including perceived
22	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 physical No	icians be recruiting and seeking consent from patients?
$\overline{\boxtimes}$	Yes – please describe below how you will address this.	
For the in questionn be provide for the tut the focus	ne of the tutors are on the research team. vestigators' classes where they are tutors, they will lead aires. Participation will be assumed if the students cored. Both questionnaires should take no more than 10 in	nplete the questionnaires and an information sheet will ninutes each to complete. The proposed focus group ement relationship to the tutors. Any identifying data in
23	Does the research use deception, concealment, i out approach, or use of information, samples, he from those persons? (NS 2.3)	ncomplete disclosure, limited disclosure, an optalth information etc., without the specified consent
\boxtimes	No	
	Yes — please detail the methods below. Please describe how this be de-briefed after the study.	s method is essential to the research aims and how participants will
	End of secti	on 2

SECTION 3 – Ethical considerations specific to research methods or fields

Describe your research methods. (NS 3.1 and NS 3.4)

24

Please explain the research methods below clearly outlining your study protocol and what each participant will be required to do for the research study. Ensure you explain storage of this material in question 25b. Ensure you advise of this in your Participant Information Statement. Please address any cultural issues if applicable For example, does your research explore sensitive topics that may involve emotional risks and other risks; are you using research methods that may be culturally sensitive (e.g. photographs, video, audio recordings etc.). You may want to include a flow chart, reference to your protocol, or Standard Operating Procedures here.

Students of the unit will be invited in class to participate in the online questionnaires, and their participation will be entirely voluntary. An information sheet will be provided to the students explaining the study. Both questionnaires (week 5 and 14) will take between 5-10 minutes to complete. Both questionnaires will be anonymous.

Tutors teaching in the unit will be invited to participate in the focus group via email by PI 1, who has no line management authority for the tutors. At that time they will be provided with an information sheet and signed consent forms will be completed prior to the focus group. PI 1 and an external transcriber will have access to the data prior to the removal of any identifying information. Once de-identified the data will be shared with the other investigators.

25

What are your research outcomes and how do you plan to analyse the data?

For example, inflammatory markers between treatment groups will be compared using a t-test.

Proposed analysis

Qualitative

Qualitative data from the online questionnaires and the focus group will first be prepared for thematic analysis by the researchers familiarising themselves with the data set and cleaning/organising the data (e.g. the focus group transcription will be cross-checked with the audio file by the researcher who facilitated the session). An inductive process will be used to identify themes, following a preliminary exploratory analysis (Creswell, 2012). As recommended in the literature, a reflexive dialogue between researchers will be entered into to explore the process, and decisions, associated with identifying themes (Braun & Clarke, 2006).

Quantitative

The outcome measures which are assessed on a continuous scale (eVALUate scores, student marks, number of cases of plagiarism) will be compared between the two time points (2015 and 2016) using the Student's t-test. The student attendance records will be compared between years using a repeated measures analysis (and treated as a continuous variable to examine the total attendance at each class). The attendance may be expected to be related to the week number through the semester.

The responses to the Flipped Classroom Student Engagement Questionnaire Version 2.2 (delivered online only once, in 2016) will be summarised using standard descriptive statistics (frequencies and percentages for the Likert response questions). These will provide a measure of support (or otherwise) for the flipped classroom format.

All analyses will be performed using the SPSS v22 statistical software, and, following convention, a p-value<0.05 will be taken to indicate a statistically significant association in all tests.

26	Does your research make use of, create, or add to a databank? (NS 3.2 and Guidelines for human biobanks. genetic research databases and associated data) Databanks include information (e.g. data collected from questionnaires) stored in a database as well as information derived from human tissue such as blood, bone, muscle and urine, and the storage of the biospecimens.
	No – please skip to question 27
\boxtimes	Yes — please answer Question 26 subsections below. Please address in your Participant Information Statement how data (including participant samples) will be collected, stored, used and disclosed.

26a	Will data, including biospecimens, be sent overseas? (NS 3.4.15)
\boxtimes	No
	Yes — please indicate in the space below where it will be sent, in what format and how patient privacy according to the <u>Australian Privacy Principles</u> (see APP #8 for Cross-border disclosure of information) will be maintained.

How long will data, including biospecimens, be stored? (WAUSDA – Research starts at Section 14)

Please indicate in the space below how long data will be stored for.

26b

• Research = 7 years after date of publication or completion of project, whichever is later;

Here are some examples, but see WAUSDA for further guidance:

- Research involving humans that use high risk material (e.g. teratogens, carcinogens, ionizing radiation, dangerous drugs) = 50 years after date of publication or completion of project whichever is later;
- Clinical trials = 25 years after date of publication or completion of project whichever is later;
- Research involving children = 7 years after date of publication or completion of project, or subjects have reached 25 years of age whichever is later.

26c	How will your data be stored? (NS 3.2 and 3.5.14)	
	Individually identifiable – the identity of a specific individual can reasonably be ascertained (e.g. name).	
	Re-identifiable – identifiers have been removed and replaced by a code, but it is possible to re-identify an individual.	
\boxtimes	Non-identifiable – data which has never been labelled with individual identifiers.	

	26 d	Please submit your data management plan Go to the Research Data Management webpage and complete a research data management plan using the Research Data Management Planning Tool and attach it to this application
	\boxtimes	Data management plan attached
27	A clinical tria study the ca intervention process-of-o	tudy a clinical trial? (NS 3.3) al is defined as any research project that prospectively assigns human subjects to intervention and comparison groups to buse-and-effect relationship between a medical intervention and a health outcome. Medical intervention means any used to modify a health outcome This definition includes, drugs, surgical procedures, devices, behavioral treatments, care change etc. If you need help completing this section contact the Clinical Trials Monitor at ORD- @curtin.edu.au.
\boxtimes	No – pleas	re skip to question 28
	Yes – plea	se answer Question 27 subsections below.
	27a	Are you using any medicine, biological or device not entered in the <u>Australian Register of Therapeutic Goods</u> , 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 — please attach a CTN or a CTX
	27b	Will a placebo/non-treatment group be used? (NS 3.3.10)
		No - please outline why a placebo or non-treatment group will not be used.
		Yes – please describe why a placebo or non-treatment group is the best comparator.
	27c	Describe the randomisation and blinding process.
	27d	Has this trial been registered? (NS 3.3.12)
		No
		Yes – please provide the registration number and the name of the trial registry in the space below.
	27e	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? (NS 3.3.4)
		Not applicable
		No
		Yes – please enter the details in brief below. This needs to be declared in the Participant Information Statement.

27 f	Are there any possible conflicts of interest or any restrictions on publications? (NS 3.3.4)
	No
	Yes – please enter the details in brief below.
27g	Is funding sufficient to conduct and complete the trial as designed? (NS 3.3.2 and 3.3.18)
	No – please indicate how you will address this in the space below.
	Yes
27h	Are payments to researcher, participants or the institution likely to influence the design, conduct, findings or publications of the research? (NS 3.3.2 and 3.3.18)
	No
	Yes – please indicate how you will address this in the space below.
27 i	Are the facilities, expertise and experience available sufficient for the trial to be conducted safely? (NS 3.3.5)
	No - please indicate how you will address this in the space below.
	Yes
27j	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? (NS 3.3.18)
	No No
	Yes
-	ur research involve exposing participants to radiation? topes, lasers, x-rays, microwaves, ultra-violet radiation
No	
Yes – you	will need to contact the Radiation Safety Officer at radsafety@curtin.edu.au and receive approval prior to submitting

 \boxtimes

29	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)
\boxtimes	No
	Yes – indicate below how you will address the management of any proposed disclosure or non-disclosure of that information.
	Does your research involve human genetics? (NS 3.5)
30	Specific requirements for research involving fetal tissue are detailed in Chapter 4.1 of the National Statement. Research involving human embryos and gametes, including the derivation of human embryonic stem cell lines, is separately governed by the Research Involving Human Embryos Act 2002 (Cth) and the Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research (2007). Please refer to Chapter 3.5 of the National Statement for more information.
\boxtimes	No
	Yes – please address in the space below the parts of Section 3.5 of the National Statement that are relevant to this project.

	ur research involve women who are pregnant and/or the human fetus?
No – pleas	se skip to question 32.
Yes – plea	ase answer Question 31 subsections below.
31a	Will steps be taken to ensure that the well-being and care of the woman who is and her fetus takes precedence over the aims of the research? (NS 4.1.1)
	No – please justify why below.
	Yes – please outline the procedures below.
31b	Will the possibility of providing access to counselling be included in the discurelated to consent to participant in the research? (NS 4.1.14 and 4.1.17)
	Telated to consent to participant in the research: (NS 4.1.14 and 4.1.17)
	No - please justify why there is no counselling available in the space below.
240	No — please justify why there is no counselling available in the space below. Yes — please describe the counselling process below.
31c	No — please justify why there is no counselling available in the space below. Yes — please describe the counselling process below. Will the women be asked whether they wish to involve others for whom the reshave implications? (NS 4.1.5 and 4.1.15)
31c	No — please justify why there is no counselling available in the space below. Yes — please describe the counselling process below. Will the women be asked whether they wish to involve others for whom the res
31c	No — please justify why there is no counselling available in the space below. Yes — please describe the counselling process below. Will the women be asked whether they wish to involve others for whom the reshave implications? (NS 4.1.5 and 4.1.15)
31c	No — please justify why there is no counselling available in the space below. Yes — please describe the counselling process below. Will the women be asked whether they wish to involve others for whom the reshave implications? (NS 4.1.5 and 4.1.15) No — please justify why they will not be offered to involve others below.
31c	No — please justify why there is no counselling available in the space below. Yes — please describe the counselling process below. Will the women be asked whether they wish to involve others for whom the reshave implications? (NS 4.1.5 and 4.1.15) No — please justify why they will not be offered to involve others below.
31c	No — please justify why there is no counselling available in the space below. Yes — please describe the counselling process below. Will the women be asked whether they wish to involve others for whom the reshave implications? (NS 4.1.5 and 4.1.15) No — please justify why they will not be offered to involve others below.
31c	No – please justify why there is no counselling available in the space below. Yes – please describe the counselling process below. Will the women be asked whether they wish to involve others for whom the reshave implications? (NS 4.1.5 and 4.1.15) No – please justify why they will not be offered to involve others below. Yes Will the information about research be separate from information about routing
	No — please justify why there is no counselling available in the space below. Yes — please describe the counselling process below. Will the women be asked whether they wish to involve others for whom the reshave implications? (NS 4.1.5 and 4.1.15) No — please justify why they will not be offered to involve others below. Yes
	No – please justify why there is no counselling available in the space below. Yes – please describe the counselling process below. Will the women be asked whether they wish to involve others for whom the reshave implications? (NS 4.1.5 and 4.1.15) No – please justify why they will not be offered to involve others below. Yes Will the information about research be separate from information about routine care

31e	Is the re	esearch	on the fetus in utero?
	No – plea	ase skip to	question 31f.
	Yes – ple	ease answ	ver the sub-questions below.
	No	Yes	Question 30e sub-questions
			Has the research been designed to minimize pain or distress for the fetus?
			Will action be taken to monitor for signs of fetal pain or distress?
			Will steps be taken for suspending or ceasing the research to prevent pain or distress to the fetus?
	If you ans	wered NO	to any of the above questions please provide a justification below.
31f			rch involve the human fetus ex utero or fetal tissue after separation or
	termination? No – please skip to question 32.		
			question 32.
	No – plea	ase skip to	o question 32. ver the sub-questions below.
	No – plea	ase skip to ease answ	
	No - plea Yes - pla	ase skip to ease answ	ver the sub-questions below.
	No - plea Yes - pla	ase skip to ease answ	Question 31f sub-questions Do any of those conducting the research have any involvement in the clinical care of the women
	No - plea Yes - pla	ase skip to ease answ	Question 31f sub-questions Do any of those conducting the research have any involvement in the clinical care of the women from whom the fetus or fetal tissue will be derived? (NS 4.1.11, 4.1.16) Do any of those conducting the research have a financial relationship with those who will provide
	No - plea Yes - pla	ase skip to ease answ	Question 31f sub-questions Do any of those conducting the research have any involvement in the clinical care of the women from whom the fetus or fetal tissue will be derived? (NS 4.1.11, 4.1.16) Do any of those conducting the research have a financial relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Do any of those conducting the research have any legal relationship with those who will provide
	No – plea Yes – pla No	Yes	Question 31f sub-questions Do any of those conducting the research have any involvement in the clinical care of the women from whom the fetus or fetal tissue will be derived? (NS 4.1.11, 4.1.16) Do any of those conducting the research have a financial relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Do any of those conducting the research have any legal relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Will the research involve the removal of organs or tissues from a fetus delivered dead? (NS)
	No – plea Yes – pla No	Yes	Do any of those conducting the research have any involvement in the clinical care of the women from whom the fetus or fetal tissue will be derived? (NS 4.1.11, 4.1.16) Do any of those conducting the research have a financial relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Do any of those conducting the research have any legal relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Will the research involve the removal of organs or tissues from a fetus delivered dead? (NS 4.1.22).
	No – plea	Yes	Do any of those conducting the research have any involvement in the clinical care of the women from whom the fetus or fetal tissue will be derived? (NS 4.1.11, 4.1.16) Do any of those conducting the research have a financial relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Do any of those conducting the research have any legal relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Will the research involve the removal of organs or tissues from a fetus delivered dead? (NS 4.1.22).
	No – plea	Yes	Do any of those conducting the research have any involvement in the clinical care of the women from whom the fetus or fetal tissue will be derived? (NS 4.1.11, 4.1.16) Do any of those conducting the research have a financial relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Do any of those conducting the research have any legal relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Will the research involve the removal of organs or tissues from a fetus delivered dead? (NS 4.1.22).
	No – plea	Yes	Do any of those conducting the research have any involvement in the clinical care of the women from whom the fetus or fetal tissue will be derived? (NS 4.1.11, 4.1.16) Do any of those conducting the research have a financial relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Do any of those conducting the research have any legal relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Will the research involve the removal of organs or tissues from a fetus delivered dead? (NS 4.1.22).
	No – plea	Yes	Do any of those conducting the research have any involvement in the clinical care of the women from whom the fetus or fetal tissue will be derived? (NS 4.1.11, 4.1.16) Do any of those conducting the research have a financial relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Do any of those conducting the research have any legal relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Will the research involve the removal of organs or tissues from a fetus delivered dead? (NS 4.1.22).
	No – plea	Yes	Do any of those conducting the research have any involvement in the clinical care of the women from whom the fetus or fetal tissue will be derived? (NS 4.1.11, 4.1.16) Do any of those conducting the research have a financial relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Do any of those conducting the research have any legal relationship with those who will provide the clinical care of the women from the fetus or fetal tissue will be derived? Will the research involve the removal of organs or tissues from a fetus delivered dead? (NS 4.1.22).

32	Does you	ur research involve children and young people? (NS 4.2)
\boxtimes	No – pleas	se skip to question 33.
		ne space below address why participation of children or young people is indispensable to this research; and how this study esigned to be appropriate for children or young people.
	32a	Do you have a Working With Children's (WWC) card?
		No — it is a legal requirement to have a WWC's card. Please arrange to submit your WWC application and provide a receipt or a have a card BEFORE you submit this ethics application. Ethics approval will not be given without a WWC.
		Yes — please attach a copy to your application.
33	Does you	ur research involve people in dependent or unequal relationships? (NS 4.3)
<u> </u>		e: teachers and their students, health care professionals and their patients, employers and their employees.
		se skip to question 34. The space below describe the dependent relationship between the participants and the researcher, members of the research
\boxtimes	team and/or dependent i dependent i	r any person involved in the recruitment/consent process; how will the process of obtaining consent enable persons in relationships to give voluntary consent; if a participant choose to withdraw from the research, how will the ongoing relationship with the participant be maintained?
Please se	ee pages 3	and 4 (why this project should be assessed as Low Risk) and questions 18, 22, and 24.
34	Does you consent?	ur research involve people highly dependent on medical care who may be unable to give ? (NS 4.4)
		e: patients in the emergency department or intensive care, unconscious people, terminal care.
		se skip to question 35. The space below describe the recruitment/consent process; and how participation in research is in the best interest of the
	participant?	

35	mental illness? (NS 4.5)				
\boxtimes	No — please skip to question 36.				
	Yes – in the space below describe the nature of the intellectual or mental impairment e.g. permanent, temporary or fluctuating; describe how the consent process will take into account the nature of the impairment.				
36	Does you	ur research involve people who may be involved in illegal activities? (NS 4.6)			
\boxtimes	No – pleas	re skip to question 37.			
	Yes – in th	ne space below please justify how the risk of discovery of illegal activities is justified by the benefits of the research.			
37	Does your research involve Aboriginal and Torres Strait Islanders? (NS 4.7) Note: If your research will incidentally involve Aboriginal and Torres Strait Islanders because your study is on the general population				
<u> </u>	you do not n	need to fill in this section. Complete this section if you are specifically targeting recruitment of Aboriginal and Torres Strait rthere is a potential for a high number of Aboriginal and Torres Strait Islanders to be recruited.			
\boxtimes	No – pleas	re skip to question 38.			
	Yes – plea	ase answer Question 37 subsections below.			
	37a	What is the estimated proportion of Aboriginal and Torres Strait Islanders in the			
	0.0	population from which the participants will be recruited?			
	37b	Will Aboriginal and Torres Strait Islander status of participants be recorded?			
		No - please justify why below.			
		Yes – please justify why below.			

37c	Will there be or has there been a process of consultation and negotiation between Aboriginal and Torres Strait Islanders and the researchers regarding the proposed research?		
	No - please justify why below.		
	Yes — Describe this process of consultation and negotiation. Include, as appropriate: - how the consultation process and the research proposal demonstrates the integrity of the researcher, - negotiation of the aims, anticipated outcomes and priorities of the research, - consultation regarding community and individual consent to participation in the research, - the process for negotiating ongoing advice as the research progresses, to monitor ethical standards and minimise unintended consequences, - how the processes show engagement with the values and processes of participating communities, and - the process of negotiating access to, and /or control of the results of the research.		
37d	Has there been a role for Aboriginal and Torres Strait Islanders in the development of the research and/or will there be a role for Aboriginal and Torres Strait Islanders in the implementation of the research proposal?		
	No - please justify why below.		
	Yes — Describe the role of Aboriginal and Torres Strait Islanders in the development and or implementation of the research. Include, as appropriate: - whether any or all of the researchers are of Aboriginal and/or Torres Strait Islander descent, - how Aboriginal and Torres Strait Islanders from the community involved in, or affected by, the research have collaborated in the development of the research, - whether the participating communities have expressed satisfaction with the research agreement, potential benefits and their distribution, - the extent to which reciprocal obligations, responsibilities and benefits is demonstrated between the researchers and the community.		
37e	Describe how the research will provide benefits to the Aboriginal and Torres Strait Islanders. Include, as appropriate: - a description of how the research relates to the health priorities and needs of participant communities, - a description of benefits for participants and the communities, including establishment and/or enhancement of capacities, opportunities and outcomes beyond the project, - 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		
37f	Describe how the proposal responds to the diversity between communities E.g. Different languages, cultures, histories, decision-making and perspectives (refer to Chapter 4.7 of the National Statement, Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, and the AIATSIS Guidelines for Ethical Research in Indigenous Studies).		

	Justify how the research respects the values based expectations, and protects and promotes culture distinctiveness of Aboriginal and Torres Strait Islander participants.				
38	Does you	ur research involve people in other countries? (NS 4.8)			
\boxtimes	No — please skip to question 39.				
	Yes — please answer Question 38 subsections below.				
	38a	Is there an ethics approval process in the country you intend to do the research? (NS 4.8.4)			
		No/Not applicable			
		Yes — please describe in the space below 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? (NS 4.8.4)			
	38b	Is the research being conducted by a student who will be located overseas for the project? (NS 4.8.8)			
		No/Not applicable			
		Yes — please describe in the space below how that supervision is to be effected so that due respect and protection will be accorded to participants			
	38c	Is a local, readily accessible contact available to participants to receive responses, questions and complaints about the research? (NS 4.8.16)			
		No/Not applicable – please justify why in the space below.			
		Yes – please describe in the space below.			
20	_				
39		ur research involve people whose primary language is other than English?			
\boxtimes	No — please skip to the next section.				
	Yes — given that the person's primary language is one other than English, in the space below describe what steps will be taken to ensure each participant's free and voluntary consent is obtained.				
		End of section 4			

SECTION 5 – Processes of research governance and ethical review

40	Are there any potential conflicts of interest?
\boxtimes	No – please skip to the next section.
	Yes – please describe in the space below.

SECTION 6 – 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	\boxtimes	\boxtimes			
Protocol/research proposal			\boxtimes	V1	17/3/16
Recruitment material	\boxtimes				
Participant Information statement and consent form/s			\boxtimes	V1	
Student Information statement and consent form/s	\boxtimes			V1	11/3/16
Tutor Information statement and consent form/s	\boxtimes			V1	11/3/16
Questionnaires/survey instruments (list below)			\boxtimes		
Week 5 "stop, start, continue" online questionnaire			\boxtimes	V1	17/3/16
Week 14 online questionnaire Flipped Classroom Student Engagement Questionnaire			\boxtimes	V2.2	2016
Focus group questions and prompts			\boxtimes	V1	
Translations where languages other than English are used	\boxtimes				
Recruitment materials (list below)	\boxtimes				
Approval from the Radiation Safety Officer	\boxtimes				
CTN/CTX	\boxtimes				
Investigator brochure or Product Information (for drug intervention studies)	\boxtimes				
Research Data Management Plan			\boxtimes	V1	18/2/16
Working with Children's Card	\boxtimes				
SOL Research Integrity Professional Development Program training certificate/s			\boxtimes		

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 <u>Curtin Brand website</u> for information on advertising for recruitment. All forms of print media must contain the HREC approval number.

SECTION 7 – Certification and signatures

Please note forms sent by email using your curtin.edu.au address is a valid electronic signature and you do not need to physically sign the form. If you are the principal investigator send this form, and all relevant documents for submission, attached to an email to your Head of School or Area with a request to approve and forward the form to ethics support officer for your faculty leaving all correspondence in the email trail.

Alternatively you can obtain original signatures and physically submit the application to the Ethics Office, Room 108, Building 100. Please do not rely on internal mail for submission of documents.

Co-Investigators

I declare that:

- I have read the application and all associated documents and the information provided in this application is truthful and complete as possible.
- I undertake to conduct research in accordance with the approved protocol, the most recent National Statement on Ethical Conduct in Human Research, relevant legislation and the policies and procedures of Curtin University.

If it is not possible to obtain sign-off of a CI using an original signature, please attach to this form a copy of an email from the CI confirming all points above. The email **MUST** be sent from their institutional email address with their name, title, email and institution in the signature line. Gmail, Hotmail, Yahoo etc., address **WILL NOT** be accepted. Curtin students **MUST** use their curtin.student.edu.au address.

Name	Signature	Date
Al 1		
Al 2		

Principal Investigator

I declare that:

- The information provided in this application is truthful and as complete as possible.
- I undertake to conduct research in accordance with the approved protocol, the most recent National Statement on Ethical Conduct in Human Research, relevant legislation and the policies and procedures of Curtin University;
- Where I am the Project Supervisor for research described to be conducted by a student of Curtin University, I declare that I have provided guidance to the student in the design, methodology and consideration of ethical issues of the proposed research; that the student has received the relevant research and ethics training for this project; and, that I will monitor the project during data collection.
- I make this application on the basis that the information it contains is confidential and will be used by Curtin University for the purposes of ethical review and monitoring of the research project described herein, and to satisfy reporting requirements to regulatory bodies. The information will not be used for any other purpose without my prior consent.

Name:	PI	Date:	
Signature:			
J			

Head of School/Area

Where the Head of School/Area or nominee has a conflict of interest with the proposed research, e.g. an investigator on the project, a member of the research group, or a personal relationship to any member of the research team, this Declaration is to be completed by the Deputy Head).

- I am satisfied that the research proposal is ready for submission for ethics approval.
- The resources to undertake this project are available.

Name:	[Head of School]	Date:	
Signature:			

End of Form

- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology, 3*(2), 77-101.
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- McWilliam, E. (2009). Teaching for creativity: from sage to guide to meddler. *Asia Pacific Journal of Education*, *29*(3), 281-293.
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