

HUMAN RESEARCH ETHICS

PROJECT APPLICATION FORM

How To Use This Form

1. Consider and refer to relevant guidelines and regulations.

References to specific guidelines are provided, with hyperlinks, throughout this form. The primary guide for human research ethics in Australia is the *National Statement on Ethical Conduct in Human Research (2007) - Updated 2018*. Human research ethics applications at the University of Melbourne are reviewed and approved under the warrant of the *National Statement*. References to the *National Statement* are abbreviated (e.g. *NS* §2.1.)

2. Use plain English.

Use clear, non-technical language in your application. Be concise. Spell out the first instances of acronyms and abbreviations. Avoid jargon. Do not repeat information. Following these directions ensures effective review of your application. It will avoid unnecessary delays which result if applications are not clear and concise.

3. Consider ethical principles.

Your application will be reviewed according to the principles of ethical research outlined in the National Statement, namely:

- Research Merit and Integrity (<u>NS §1.1 §1.3</u>)
- Justice (NS §1.4 §1.5)
- Beneficence (<u>NS §1.6 §1.9</u>)
- Respect (NS §1.10 §1.13)

4. Use the current version of the application form.

Ensure that you are using the current version by downloading this form each time you prepare a new application.

5. Detailed instructions for specific questions are available online.

If you are unsure about how best to answer a particular question, consult the Human Research Ethics **Guidance Document**. That document provides detailed guidance on how to answer specific questions in this form.

6. Where possible, avoid printing this form.

Consult your HEAG to find out if they still require hard copies of your application. If you must print this form, consider printing double-sided and in grayscale (black and white).

7. Save your completed application as a PDF and upload it to Themis.

Refer to your local Human Ethics Advisory Group (<u>HEAG</u>) for detailed instructions on how and when to submit your application.

ANSWER ALL OF THE QUESTIONS IN THIS FORM

Ethics ID number: (assigned by Themis)		
Project Title: (as recorded in Themis)	Identifyii	ng causes of events
Responsible Researcher: (as recorded in Themis)	A/Prof (Charles Kemp
Application Type:	Х	Minimal Risk
(mark with an "X")		Standard Project

1. Project Details

1.1 Project Summary

Summarise your research project in plain language.

[Limit: 300 words]

A) Aims and Objectives

The project is about causal reasoning and aims to characterise how people identify the causes of an event. For example, an airplane crash could be attributed to pilot error, a faulty component, or an unexpected weather pattern, or some combination of the three. Causal judgements are involved in many contexts and often have real-world implications (e,g, legal implications in the case of the plane crash).

Causal judgments have been widely studied and there are existing models of "actual causation" (also known as "singular causation" or "token causation") that aim to capture people's inferences about the causes of a single event. Much of this work, however, does not focus on the role of time. In contrast, we have developed a model that aims to capture how causal judgments are influenced by temporal information, and in particular how people's judgments are influenced by changes of state over time. For example, suppose that an effect needs two different causes to occur --- e.g. an alarm may sound only if two different components both fail. If one of the components has already failed and the second one fails after a while, our model proposes that the failure of the second component will be judged as the primary cause of the effect.

B) Key Question(s)

- 1. Are people's causal judgments influenced by not just the values of all relevant variables at the time the effect occurs, but also the temporal order in which these variables took their values? [Hypothesis: Yes]
- 2. Does our new model account better for people's causal judgments than the two most prominent alternatives (the counterfactual account and the physical process account)? [Hypothesis: Yes]

C) Research Design

Participants will be recruited online via Amazon Mechanical Turk (AMT), Prolific or similar services. After answering a few demographic (optional) and "check" questions designed to ensure they are fluent English speakers who read and understood their task, they will view a set of components (e.g. particle detectors) arranged into networks. Participants will view an animation that shows activation spreading over the network and culminating in the activation of a specified "final node." Participants will then be asked to pick out the node that caused the activation of the final node, or to rank possible causes in order of importance, and we will collect response times in addition to causal judgments. The same procedure will be repeated for multiple different networks that vary in terms of factors including the number of components they contain, the pattern of connections between these components, and the nature of these components. People will be paid at a rate of \$10USD/hr, with an initial pilot being used to derive accurate time estimates.

Specific Guidelines Checklist

Type an "X" in the left-hand column beside all items that apply to your research project. Linked sections of the National Statement contain relevant quidelines and requirements that you need to address when completing your application

	Children and/or young people (< 18 years old) will be recruited as participants.	Refer to <u>NS §4.2</u> .
	People in dependent or unequal relationships will be recruited as participants. (There are pre-existing relationships between participants and researchers, or between participants and others involved in facilitating or implementing the research. E.g. student/teacher, patient/doctor, employee/employer.)	Refer to <u>NS §4.3</u> .
(People in countries other than Australia will be recruited as participants.	Refer to <u>NS §4.8</u> .
	One or more of the following describes the research project: • it will be about Aboriginal and/or Torres Strait Islander individuals or peoples , their health, or their culture(s), language(s) or histories;	Refer to NS §4.7. Refer to Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples
	 it will be about the impact(s) or effect(s) of some phenomenon or phenomena on Aboriginal and/or Torres Strait Islander individuals or peoples; 	and Communities: Guidelines f Researchers and Stakeholders (2018).
	 it will specifically target Aboriginal and/or Torres Strait Islander people to be recruited as participants; 	 Refer to <u>Guidelines for Ethic</u> <u>Research in Australian</u> Indigenous Studies
	 it will be conducted in a geographic location where a significant number of the population are likely to be Aboriginal and/or Torres Strait Islander. 	This application is ineligible for minimal risk review.
	One or both of the following describes the research project:	
	 it will specifically target women who are pregnant to be recruited as participants; it will be focused on women who are pregnant and/or the human foetus (including human foetal tissue or human embryos). 	 Refer to <u>NS §4.1</u>. This application is ineligible for minimal risk review.
	People who may be involved in illegal activities will be recruited as participants, and the research project could potentially expose such activities.	 Refer to <u>NS §4.6</u>. This application is <i>likely</i> ineligible for minimal risk revie
	People with cognitive impairment, intellectual disability, or mental illness will be recruited as participants.	 Refer to <u>NS §4.5</u>. This application is ineligible for minimal risk review.
	People who are highly dependent on medical care will be recruited as participants.	 Refer to <u>NS §4.4</u>. This application is ineligible for minimal risk review.

Comment on the above: The project will make use of Amazon's Mechanical Turk framework to recruit and remunerate participants in the experiment. We will use the infrastructure provided by AMT to ensure that only Americans can participate. The use of this framework is standard practice in many areas of psychology and the experiment will be conducted in full compliance with Amazon's Terms of Use for the Mechanical Turk platform. As far as we are aware, the Mechanical Turk system complies with all appropriate legislation and ethical procedures within the regions it operates.

Additional Modules Checklist

Type an "X" in the left-hand column beside all items that apply to your research project. This checklist will help you determine if you need to complete any other modules in addition to this application form. Linked sections of the National Statement contain relevant guidelines and requirements that you need to address when completing this form and any applicable additional modules.

CICV	ant galacimes and requirements that you need to address w	their completing this form and any applicable additional mediate.
	This research project will involve the creation of a databank (i.e. your stored data will be made available to other parties for secondary use in future research projects).	 Refer to NS §3.1. Complete and attach the <u>Privacy and Databanks Module</u>.
	This research project will involve the collection of information for a databank (i.e. your stored data will be made available to other parties for secondary use in future research projects).	 Refer to NS §3.1. Complete and attach the <u>Privacy and Databanks Module</u>.
	This research project will involve accessing information from an existing databank (i.e. you will be accessing and making use of stored data that was previously collected – not for this specific project – by other parties).	 Refer to NS §3.1. Complete and attach the <u>Privacy and Databanks Module</u>.
	This research project will involve obtaining identifiable (or potentially identifiable) personal information (including health information) about individuals without their consent.	Complete and attach the <u>Privacy and Databanks Module</u> .
	This research project will involve the collection and/or use of human tissue/biological samples or materials (e.g. blood, saliva, cheek swabs, hair, human embryonic or foetal tissue).	
	This research project will involve genomic research.	 Refer to NS §3.3. This application is ineligible for minimal risk review. Complete and attach the Body Tissue and Genetic Research Module.
	This research project will involve medical interventions, therapies or trials.	 Refer to NS §3.1. This application is ineligible for minimal risk review. Complete and attach the <i>Interventions, Therapies and Trials Module.</i>
	This research project will involve administration of ionising radiation.	© Complete and attach the <u>lonising Radiation Module</u> .
Х	None of the above applies to this research project.	

Comment on the above: All data will be non-identifiable and not added to a databank (defined in NS §3.2 as data that is aggregated over time). The data may be made available in completely anonymous and non-identifiable form to other researchers.

2. Background and Method

2.1
Background and Significance

Provide a summary of background information. Explain the significance of the proposed research in the context of this background. **Refer to** <u>NS §5.2.5</u> and <u>NS §3.1</u>

[Limit: 500 words]

A) Background:

Current research on actual causation mainly relies on two different interpretations of causality: the counterfactual account (CF) or the physical process (PP) view. According to the first interpretation (Hume 1774, Lewis 1973, Halpern & Pearl 2005, Icard & al. 2017, Morris & al. 2019), A is said to be a cause of B if and only if A is true and B is true, and A hadn't occurred B wouldn't have occurred. According to the second interpretation (Russell 1912, Walsh & Sloman 2011, Dowe 2004, Wolff 2007), effects have to be physically connected to their causes. In some contexts it has been shown (Hall 2004, Danks 2017) that inutuive causal judgments can be explained by the CF account and not the PP one or the other way around. Yet it appears that none of these accounts can fully explain causal judgments in general. For example suppose that

Suzy and Bob throw a rock at a bottle and that Suzy's rock reaches the bottle just a second before Bob's. According to the CF account, in its simplest formulation, Suzy's throw does not cause the bottle to shatter because if Suzy hadn't thrown her rock, Bob's rock would have still shattered the bottle. However according to the PP account, Suzy's throw is the cause because the rock transmits energy to the bottle which causes it to shatter. In other cases, however it is the PP account that contradicts strong causal intuitions. Suppose that Suzy is now piloting a bomber on a mission to destroy an enemy target. An enemy fighter aircraft is about to shoot her, but Bob who is escorting her destroys the enemy plane which allows Suzy to bomb the target. In this case Bob prevents the enemy from preventing the success of Suzy's mission. The CF account says that Bob's action (of killing the enemy plane) is a cause of the mission success, whereas the PP account denies it.

B) Significance of This Research:

The project aims at solving the dilemma above by interpreting causality in a completely different way, that is by considering causes as changes of states over time. This approach has some precedent in the literature (Glymour 2010, Gerstenberg 2015) but has not been developed carefully and has never been tested experimentally as we intend to do. The approach states that neither CF nor PP accounts of causation can fully capture our causal intuitions because both treat causality as a relationship between static states. In contrast, we focus on events that are changes of state, and identify causes by tracing back the history of changes in a system from the occurrence of the effect up to the last change that initiated the series of changes. This framework aims to synthesize key ideas captured by the CF and PP accounts of causation, but needs to be experimentally tested – which is the goal of the project.

Danks D. Singular Causation. In M. R. Waldmann (Ed.), Oxford library of psychology. The Oxford handbook of causal reasoning, 201–215, Oxford University Press, 2017

Dowe P. Causes are physically connected to their effects: Why preventers and omissions are not causes. In Christopher Hitchcock (ed). Contemporary Debates in Philosophy of Science. Blackwell. 189-196, 2004

Gerstenberg T., Goodman N., Lagnado D., Tenenbaum J. How, whether, why: Causal judgments as counterfactual contrasts. 2015

Glymour C., Danks D., Glymour B., Eberhardt F., Ramsey J., Scheines R., Spirtes P., Teng C.M., Zhang, J. Actual causation: A stone soup essay. *Synthese*, 175(2), 169-192, 2010

Hall N. Two Concepts of Causation. In J. Collins, N. Hall, and L. A. Paul (eds.), Causation and Counterfactuals, Cambridge, MA: The MIT Press, pp. 181–204, 2004

Halpern J.Y. and Pearl J. Causes and explanation: A structural-model approach, Part I: Causes. The British Journal for the Philosophy of Science, 56, 889-911, 2005

Hume D. An enquiry concerning human understanding. Oxford: Clarendon, 1774

Icard T.F., Kominsky J.F, Knobe J. Normality and actual causal strengh. Cognition 164, 80-93, 2017

Lewis D. Causation. Journal of Philosophy, 70, 556-567, 1973

Morris A., Phillips J., Gerstenberg T., Cushman F. Quantitative causal selection patterns in token causation. PloS ONE 14(8), 2019

Russell B. On the Notion of Cause, in J. Slater (ed.), *The Collected Papers of Bertrand Russell v6: Logical and Philosophical Papers 1909–1913*, London: Routledge Press, pp. 193–210,1912

Walsh C.R., Sloman S.A. The meaning of cause and prevent: The role of causal mechanism. Mind & Language, 26(1):21-52, 2011

Wolff P. Representing causation. Journal of Experimental Psychology: General. 136(1):82-111, 2007

2.2 Research Design and Method

Provide details of your research design and your proposed method. **Refer to NS §5.2.5** - **§5.2.6** and **NS §3.1**

Attach a copy of any measures, scales, questionnaires, survey instruments (including online surveys), interview questions/themes, and/or focus group topics/questions to be used.

A) Participants (or Recruitment Targets, such as medical records):

In order to obtain reliable and robust feature ratings, we will recruit around 50 participants per condition using Amazon's Mechanical Turk (AMT), which provides a platform for recruiting workers to carry out online tasks that require human intervention, in exchange for payment. Participants will be registered "Workers" within the AMT platform; most Workers contribute to AMT to make some extra money. All AMT workers are restricted to be 18 years of age or older. Our check items will ensure that they are fluent speakers of English.

Eligibility restrictions include the ability to read and understand the questions, which is ensured by through the use of a short qualification which workers have previously passed checking their English ability. We will also have "check questions" within the experiment which participants cannot continue without getting correct. Participants will be informed before commencing the experiment that they may be excluded if they are not operating a web browser compatible with the software used to implement the experiment. In practice, in the event that a participant carries out the experiment using a non-compliant browser, full payment will still be made.

B) Recruitment:

On AMT Workers are never contacted directly; rather, experiments are posted on the AMT platform as part of the list of tasks available for Workers to perform. Workers select which tasks they wish to contribute to and may return them without completion at any time without penalty.

C) Participant Incentives:

Workers within Amazon's Mechanical Turk platform conduct tasks in exchange for payment, which is based on task rather than time. We set the rate of payment such that the average participant will receive an amount approximately equivalent to US \$10.00 per hour, which is well above the "market rate" established for tasks on Mechanical Turk and above the minimum wage in most US states.

D) Participant Task(s):

Participants will view animations showing activation spreading over networks of nodes up to a final node. They will be asked to click on the node(s) of the graph they will judge as the main cause(s) of the activation of the final node. Participants will be assigned to conditions that vary the nature of the nodes (e.g. whether an active node remains active over time or resets to a default stage), the structure of the network (e.g. whether the nodes are organized into chains or loops), and the timing of activations over the network. The conditions are designed to include cases that allow our new theory to be distinguished from two existing theories (the counterfactual and the physical process accounts).

E) Data/Material Collection Technique(s):

The survey will be coded in Javascript, which ensures precise control over characteristics such as randomisation, dependencies between questions, and presentation format. Data will consist of answers to the questions above as well as (completely optional) demographic questions including age, and gender. The software used to run the experiment will be deployed within Google's "App Engine" framework, although it will be accessed via Mechanical Turk. The Google App Engine framework has an associated database engine where the anonymous data will be stored. Access to this database is secure and will be restricted to the researchers. Once data has been downloaded from Google App Engine for analysis, it will be stored on secure computers in compliance with University data protocols. The data will also be backed up and held on University servers and may be made available in a non-identifiable form to the academic community (e.g., through github).

F) Data Analysis:

Participant responses will be analysed statistically using Python. Statistical analyses may include frequentist or Bayesian statistics, as appropriate.

3. Risks, Benefits and Monitoring

3.1 Potential Risks to Participants

Does your research project pose any potential risks to participants? What are those risks? How will they be negated, minimised or managed? Refer to NS §2.1.

Note that the risks you identify here should also be described in your Plain Language Statement (PLS). Attach a copy of any distress protocol or adverse event protocol (if applicable).

A) Potential Risks

We foresee minimal risk to participants associated with study conduct. The main risk we anticipate is a mild level of boredom, since the task is fairly dull.

B) Risk Management Strategy

To address the risk of boredom participants will be informed that they are not required to complete the study and that they are permitted to stop at any time. Before choosing to participate in the study they will also be shown an estimate of how long it will take and how much money they can expect to earn.

3.2 Potential Risks to Non-Participants

Does your research project pose any potential risks to non-participants? (This could possibly include risks to researchers or independent contractors.) If so, how will these risks be minimised? **Refer to NS §2.1.**

None.

3.3 Risks, Benefits and Justification

In light of the risks and expected benefits of the research project, explain how the expected benefits of the research justify any risks it may pose. **Refer to NS §1.6 - §1.7 and NS §2.1.**

A) Expected Benefits

Taking into account the notion of changes over time as the core representation of causation departs clearly from the current views of causality and may have important implications. For example, two stories with the same causal structure (same facts, same effects) but with different temporal contrasts regarding the occurrence of the events may imply totally different causal judgements. A better understanding of the role of temporal contrasts in causal judgements could therefore mitigate bias and improve concrete decisions based on causal reasoning (e.g. legal decisions in the case of the airplane crash).

B) Justification of Risks by Expected Benefits

The risks are minimal and the expected benefits large – as mentioned already the work can potentially help to improve real-world causal decisions.

3.4 Management and Monitoring

How will researchers manage and monitor conduct of the research project? **Refer to** *NS* §5.5.

A) Management

A/Prof Charles Kemp will keep all data on a password-protected computer associated with the University of Melbourne and will be responsible for storage, making the data available to student researchers for analysis (who will also use password-protected computers). In order to ensure that the research protocol is correctly followed, the responsible researcher will meet with the student on a regular basis throughout the duration of the project. Before being downloaded the data will be hosted on Google App Engine but destroyed once it is downloaded. The data may also be made available (e.g., on github) in anonymised and de-identified form (since AMT prohibits researchers from accessing personal information about participants, this will be trivial).

B) Monitoring

Research is carried out by people clicking on a URL and completing it in their home. No monitoring is necessary.

C) Independent Contractors

No independent contractor will be carrying out any part of the research.

4. Consent

4.1 Obtaining Informed Consent

Type an "X" in the left-hand column beside as many of the following options as apply to your research project. Use the space provided below to explain how you will obtain informed consent from participants. If you seek a waiver of consent, or the use of opt-out consent, use the space provided to justify your request. Refer to NS §2.2, NS §2.3.

	the space provided to justify yo	ur request. Refer to <u>NS 92.2</u>, <u>NS 92.3</u>.
×	Written consent will be sought from (or on behalf of) participants.	Refer to <u>NS §2.2.6.</u>
_	participants.	Attach a copy of your consent form(s).
		Refer to <u>NS §2.2.5 - §2.2.6</u> .
	Verbal consent will be sought from (or on behalf of) participants.	Explain why you have chosen this form of consent, and how an individual's consent to participate will be recorded.
		Attach a copy of your consent script(s).
	Consent will be implied, rather than explicitly obtained.	Refer to <u>NS §2.2.5 - §2.2.6</u> .
	Consent win be implied, father than explicitly obtained.	Explain why you have chosen this form of consent.

	rd parties (e.g. parents/guardians of minors) will vide consent on behalf of participants.	 Refer to <u>NS §2.2.12.</u> Explain who will be providing consent on behalf of participants and why.
will	rd parties (e.g. community elders, school boards) be involved in whole of community participation isions.	Refer to NS §2.2.13. Provide details of which third parties will be involved, why they will be involved, and how this will be accomplished.
This	s application seeks a waiver of consent.	Explain why you are seeking this option. Justify your request by referring to the conditions described in NS §2.3.10 - §2.3.11.
This	s application proposes to use opt-out consent.	Explain why you are seeking this option. Justify your request by referring to the conditions described in <u>NS §2.3.6</u> .

Consent will be achieved online by having participants click 'Next' after response to the consent form, a copy of which is attached to this application.

4.2 Limited Disclosure	Do you propose to use limited disclosure, cond (Answer Yes or No. If Yes, use the space below	realment or deception for this research project? w to explain.) Refer to NS §2.3.
	YES or NO:	NO

	Future Use of Data, Materials, or Tissues	be reused in future research? T following options as apply to	or materials and/or tissues collected for this research project to bype an "X" in the left-hand column beside as many of the your research. Use the space provided to specify which used, if any. Refer to NS §2.2.14 and NS §3.1
	Consent will be specific.		Data/materials/tissues will be used only for this research project (i.e. no future use).
	Consent will be extended	l.	© Data/materials/tissues used in this research project may also be used in future projects that are <i>closely related</i> to this project, <i>or in the same general area</i> of research as this project. Make this clear in PLS
X	Consent will be unspecifi	ied.	© Data/materials/tissues used in this project may also be used in any future research. Make this clear in PLS

Data may be made publicly accessible via a suitably open format and platform (e.g., OSF or github), in accordance with ARC requirements. However, information that may be used to identify individual participants will not be available.

4.4 Conflict of Interest

Does your research present or involve any conflict of interest, whether potential, real, or perceived; or will the researcher(s) have dual roles in relation to the participants? (Answer Yes or No. If Yes, use the space below to explain.) Refer to NS §5.4, University of Melbourne Research Integrity and Misconduct Policy (MPF1318), and Australian Code for the Responsible Conduct of Research §7.2.

YES or NO:	NO

There are no conflicts of interest. All participation is anonymous and voluntary. Researchers have no association with Amazon.

4.5 Information for Participants

How will relevant information about the research project be provided to potential participants? Attach a copy of any advertisement (print or online), Plain Language Statement (PLS), consent form, letter, email, telephone script, and/or debriefing statement to be used. Refer to NS §5.2.25 and NS 3.1

Information as provided in the attached PLS and consent form will be provided to each participant at the link of the study URL. They will be unable to continue to the study until they click a button attesting that they have read and comprehended the information in the PLS and consent form.

Plain Language Statement (PLS): Your PLS must satisfy the requirements set out in the National Statement (NS §2.2.1 §2.2.3, §2.2.6). The Research Ethics and Integrity's website has guidance on composing your plain language statement, as well as an example PLS template. A list of PLS requirements is also provided at the end of this form. Ensure that your PLS is written in plain language. Ensure that the information contained in your PLS is consistent with the information in your application.

Consent Form: Your consent form must satisfy the requirements set out in the National Statement (NS §2.2). The Research Ethics and Integrity's website has guidance on composing your consent form, as well as an example consent form. A list of consent form requirements is also provided at the end of this form. Ensure that your consent form is written in plain language. Ensure that the information contained in your consent form is consistent with the information in your application.

5. Dissemination and Data Management

5.1 Providing Results to Participants

How will the results of the research project be provided to participants in an accessible format? **Refer to** <u>NS §1.5</u> and <u>NS 3.1</u>

Since participation is anonymous, none of the specific results will be made available to specific people. When published, information about the publication will be posted on the websites of the researchers involved, whose names participants will have been made aware of, so that interested participants may seek it out.

5.2 Reporting Project Outcomes

How will outcomes of the research project be made public? Refer to NS §1.3 and NS 3.1

If successful, the project will be published in a high-quality scientific journal such as Psychological Science or Cognition, with the manuscript posted on the authors' websites in compliance with copyright requirements. Results will also be shared with other researchers through informal networks and conference presentations.

5.3 Data Management

How do you propose to manage the data collected in this research project? Specify what types of data will be collected, how they will be stored and in what format. How will access to the data be controlled and by whom? Discuss retention, security, and data sharing plans. What measures will be taken to protect participants' privacy, and their data?

Refer to NS §1.11, NS 3.1, the Australian Code for Responsible Conduct of Research §2, and the University of Melbourne Research Integrity and Misconduct Policy (MPF1318).

A) Privacy and Confidentiality

Data will be anonymous and not identifiable. Researchers do not have access to specific identity information of any researcher and the only demographic questions are generic enough (e.g., age and gender) to not uniquely identify specific people; moreover, anyone may refuse to answer any demographic questions without penalty.

B) Security and Storage of Data

Short-term storage of the data will be on the researchers' password-protected computers. In the long term, the data will be stored on secure servers hosted by the Melbourne School of Psychological Sciences and a non-identifiable version of the data may be made available online.

C) Retention

Records will be retained for a minimum of five years following publication of study findings.

6. Other Issues

6.1	Other Ethical
	Issues

Are there any other issues, not addressed above or in additional modules, which are relevant to the ethical review of your research project? Refer to the relevant sections of the *National Statement* identified in the Specific Guidelines Checklist, if applicable.

N	\sim	n	_

Attachments Checklist

Review your answers above to determine which attachments (if any) are required for your application. **Type an "X" in the left-hand column beside all items that apply to your research project.** Attach a copy of the items you have selected.

X	Plain Language Statement (PLS) for Participants
Х	Consent Form for Participants
	Additional PLS(s) (e.g. for parents, teachers, schools)
	Additional Consent Form(s) (e.g. for parents, teachers, schools; or assent forms for children)
	Recruitment Materials (e.g. advertisement(s), posters, letter(s) or email(s) of invitation)
	Questionnaire(s) and/or Survey Instrument(s)
	Measure(s) and/or Scale(s)
	List of Interview Questions and/or Themes
	List of Focus Group Questions and/or Themes
	Participant Distress Protocol
	Adverse Event Protocol
X	Debriefing Statement
	Approval(s) of research by an HREC external to the University of Melbourne
	Other External Approval(s) (e.g. schools, communities)
	Full Protocol (for Medical Research)

y and Databanks Module Tissue and Genetic Research Module	
De Patricia Madala	
ng Radiation Module	
entions, Therapies and Trials Module	
Documents (e.g. contracts, agreements) – specify which:	
	•

Plain Language Statement (PLS) Requirements:

- 1. Clearly identify the University of Melbourne (i.e. by prominent placement of the University's logo) and the department(s)/school(s)/faculty(-ies) involved. If printed, the PLS should be on University of Melbourne letterhead.
- 2. Clearly identify the title of the project, and the name(s) and contact details of the Principal Researcher and Other Researchers. For student projects, specify the student's level of study.
- 3. Clearly explain the purpose of the research project.
- 4. Clearly explain what participants will be asked to do, and provide an estimated time commitment.
- 5. If participants will be photographed, audio- or video-recorded, clearly state as much.
- 6. Clearly explain any risks arising from participation, as well as any procedures or measures in place to minimise such risks.
- 7. Describe any expected benefits to the wider community. If applicable, also describe any expected benefits to participants.
- 8. List any payments, incentives or reimbursements to be made to participants.
- 9. State that involvement in the project is voluntary and that participants are free to withdraw from participation at any time. Explain any implications of withdrawal, including whether it will be possible for participants to withdraw any data already collected from or about them.
- 10. Describe the likelihood and form of dissemination of the research results, including publication.
- 11. Describe the arrangements in place to protect the confidentiality of participants' data, and advise participants of any legal limitations to such confidentiality. If the sample size for the project is small, advise participants that this may make them identifiable.
- 12. The project HREC number (which is the ethics ID number assigned by Themis) and the date and version number of the PLS must appear on the PLS. If the PLS is printed, put this information in the footer.
- 13. Explain what will happen to participants' data after the research project ends (i.e. how long it will be retained, whether it might be used again for future research and if so who would have access.)
- 14. Include the following statement: "This research project has been approved by the Human Research Ethics Committee of The University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: humanethics-complaints@unimelb.edu.au All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project."
- 15. If the research is externally funded, state the amount(s) and source(s) of funding for the research.
- 16. If there are any potential conflicts of interest for any of the researchers, sponsors (if applicable) or institutions, disclose these potential conflicts of interest.
- 17. If any participants will be in a dependent relationship with any of the researchers, state that decisions about participation will not affect the dependent relationship. (E.g. students' grades will not be affected if they decline to participate or withdraw from the project at any stage).

Consent Form Requirements:

- 1. Clearly identify the University of Melbourne (i.e. by prominent placement of the University's logo) and the department(s)/school(s)/faculty(-ies) involved. If printed, the consent form should be on University of Melbourne letterhead.
- 2. Clearly identify the title of the project, the name(s) and contact details of the Principal Researcher and Other Researchers. For student projects, specify the student's level of study.
- 3. If participants will be photographed, audio- or video-recorded, clearly state as much.
- 4. State that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied. Also state that the purpose of the project is research.
- 5. Describe the arrangements in place to protect the confidentiality of participants' data, and advise participants of any legal limitations to such confidentiality. If the sample size for the project is small, advise participants that this may make them identifiable.

Declaration by the Responsible Researcher

The information contained in this application is, to the best of my knowledge and belief, accurate.

I have read the University's current human ethics guidelines. I accept responsibility for the conduct of the procedures set out in the attached application in accordance with: those guidelines, with the <u>University's Research Integrity and Misconduct Policy (MPF1318)</u>, and with any other condition laid down by the University of Melbourne's Central Human Research Ethics Committee (CHREC), its Human Ethics Sub-Committees (HESCs), or by the Human Ethics Advisory Group (HEAG) which will review this application. I have attempted to identify all risks related to the research that may arise in conducting this research. I acknowledge our obligations as researchers and the rights of the participants stipulated in the <u>National Statement on Ethical Conduct in Human Research (2007) - Updated 2018</u>. I certify that the research team has the appropriate qualifications, experience and facilities to conduct the research described in the attached application, and to deal with any emergencies and contingencies related to research that may arise throughout the life of the project.

If approval is granted, the project will be undertaken in strict accordance with the approved protocol and relevant laws, regulations and guidelines.

I, the Responsible Researcher, agree to:

- * start this research project <u>only</u> after obtaining final approval from the HESC (if this is a standard project), or the HEAG (if this is a minimal risk project);
- * carry out this research only where adequate funding is available to enable the research to be carried out according to good research practice and in an ethical manner;
- provide additional information as requested by the CHREC, HESC, or HEAG;
- * provide progress reports to the CHREC, HESC, or HEAG as requested, including annual and final reports;
- * maintain the confidentiality of all data collected from, or about, research participants and maintain security procedures for the protection of their privacy;
- * submit an amendment if any modification to the research design or protocol is proposed (including any change of researchers) and to proceed with the research only after the amendment has been approved by the HESC (if this is a standard project) or by the HEAG (if this is a minimal risk project);
- * notify the HESC (if this is a standard project) or the HEAG (if this is a minimal risk project) in writing immediately if any adverse event occurs during the course of the research;
- * notify the HESC (if this is a standard project) or the HEAG (if this is a minimal risk project) in writing immediately if any complaints are received about the research;
- * comply with an audit of the research undertaken, if requested by the CHREC, HESC, or HEAG;
- * use only the data/tissue samples collected for this research, and for which HESC/HEAG approval has been given.

I certify that all members of the research team have read this application and the <u>National Statement on Ethical Conduct in</u> <u>Human Research (2007) - Updated 2018</u> and that they have agreed to comply with the provisions of the latter.

Responsible Researcher Name	Signature	Date
Charles Kemp	CSKemp	10/4/20

Declaration by Human Ethics Advisory Group (HEAG)

For HEAG use only.

Enter the date the application was received, then type an "X" in the left-hand column beside each item as applicable.

Date Application Received:

Technical review has been completed by the HEAG.	The merit of the proposed research project set out in this application has been reviewed on technical grounds.
	Refer to <u>NS §1.1</u> .
Ethical review has been completed by the HEAG.	The HEAG has reviewed the proposed research project set out in this application for compliance with the principles of Human Research Ethics.
The Minimal Risk review process is appropriate for the proposed research project set out in this application.	Complete Declaration A (below)
The Standard Project review process is appropriate for the proposed research project set out in this application	Complete Declaration B (below)

Declaration A (Minimal Risk):

The HEAG has reviewed this project. The HEAG considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed. The HEAG grants approval for this research project to commence. The HEAG considers that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research described in the attached application in a manner that complies with the University's policy on the management of research data and records, and to deal with any emergencies and contingencies that may arise. [Note: If the HEAG Chair is also a researcher in this project, the declaration should be signed by another authorised member of the HEAG.]

Name of HEAG Chair/Authorised Member	Signature	Date

Declaration B (Standard Project):

The HEAG has reviewed this project and considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed. The HEAG regards this project as ready to submit to the HESC. The HEAG considers that the researcher(s) has/have the necessary qualifications, experience and facilities to conduct the research described in the attached application in a manner that complies with the University's policy on the management of research data and records, and to deal with any emergencies and contingencies that may arise. [Note: If the HEAG Chair is also a researcher in this project, the declaration should be signed by another authorised member of the HEAG.]

Name of HEAG Chair/Authorised Member	Signature	Date