Initial Approval Submission - New Project ☐ Complete

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***SAVE before ticking 'Complete' or closing the form. --- If Complete is ticked, un-tick it to edit form.

Human Research Ethics Committee

Initial Approval Submission - New Project

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

When to use this form

This form is an **Initial** submission to the University of Newcastle (UON) Human Research Ethics Committee (HREC) for approval for a **new research project** where the HREC is the lead committee.

An Initial submission is the first application to the HREC for ethics approval for this research project or activity.

Prior to completing and submitting this application, it is recommended that you consult with a Research Ethics Advisor (REA) as it may accelerate the review process. For a **list of REA's** please go to this link.

*** I confirm I am applying for Initial approval for a new research project where the UON HREC is the lead committee.** ☑

Eligibility for Expedited Review

The HREC applies a hierarchical level of review to submissions for ethics approval. This reflects the ethical issues and possible risks to research participants presented by the research protocol.
Negligible Risk Research – describes research in which there is no foreseeable risk of harm or discomfort, and any foreseeable risk is no more than inconvenience. E.g. minor survey or interview on a benign topic, giving up time.

Low Risk Research – describes research in which the only foreseeable risk is one of discomfort. E.g. minor side effects, discomfort associated with blood tests, emotional discomfort induced by an interview or survey, management of relationships involving a power imbalance, embarrassment, management of incidental findings or observations, risks to confidentiality and privacy.

Applications which fall into the above categories of risk are eligible for expedited review.

More than Low Risk Research – describes research in which there is potential for harm. E.g. physical, psychological, social, economic or legal harms. The risk can be associated with the activities of participation (e.g. novel interventions or trials, exposure to ionising radiation) or the potential vulnerability of the research population (e.g. Aboriginal & Torres Strait Islander peoples, people with a cognitive impairment, intellectual disability or mental illness, women who are pregnant) as defined by the National Statement on Ethical Conduct in Human Research. This requires the completion of the Human Research Ethics Application (HREA) in addition to this submission, and full HREC review.

Details about the levels of review and response times are available from the Human Research Ethics website.

NOTE: Human research is to be informed by, and comply with the *National Statement on Ethical Conduct in Human Research, 2007*.

Please proceed to answer all questions in the order they are presented. This is an interactive eform. It will determine the level of review required for your proposed research. If your research requires Level 3 review, you will be directed to complete the HREA and this eform will become the *HREA Supplement*.

* *Tick to continue* ☑

HREA

* Have you aleady determined that you will have to complete the *Human Research Ethics Application* (HREA), i.e. your research has the potential for significant risk? ☐ Yes ☑ No

Help

* Display Help for questions? *(recommended - appears as blue text)* ☐ Yes ☑ No

Protocol Identification

* Project Title:

* Project summary:

Max 6 lines

Duration of Project

Provide the anticipated start and end dates for the whole of the project, including participant follow-up if applicable and data analysis.

* Anticipated start date: * Anticipated end date:

* Are there any time-critical aspects relating to the research of which the HREC should be aware? Yes ☐ No ☑

Applicant(s)

- Identify all members of the research team and select their 'Role' on the project from the available options.
  If the person is not in the picklist, you will be asked to identify them at a later question.
- **End Date** - Leave blank on Initial submission. Only enter date for Variation submission if person is leaving project.
- 'CI/Supervisor' is the Chief Investigator, or in the case of student research, the Project Supervisor. **This application can only be submitted by the CI/Supervisor.**
- At 'Role' only select 'Student Researcher' if the person is conducting the research as a component of their studies. Otherwise, for students employed on the project select 'Co-Investigator'.
- If a 'Student Researcher' is involved in the project their supervisor must also be identified as an investigator on the project.

Email addresses - important note:
All communications from the HREC are sent via email.

Personnel with an active University of Newcastle computer account , ie you are staff, a student, conjoint staff or an affiliate. By default that account gives you a UON email address. *All email communications from the HREC will be sent to that address*.

Research personnel who do not have a UON computer account, but are in the list of personnel. Any changes to their email addresses need to be notified to Human Research Ethics Administration by emailing Human-Ethics@newcastle.edu

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Research Personnel Add

Delete Research Personnel

Name:

CI / Supervisor	Start Date	End Date	Role
☑	11-Oct-2019		CI

Certification: Office use only

Certification	Begin	End
-	-	-

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Research Personnel Not Listed

* Were any members of the research team not listed in the personnel picklist? ☐ Yes ☑ No

Student Researchers

* Was one or more people given the role of Student Researcher? ☐ Yes ☑ No

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Project Funding/Support

Yes ☐ No ☑ * Is the research the subject of a contract / agreement / grant awarded from or under consideration by an internal or external grants body, sponsor, etc?

Approval From Other HRECs

Yes ☐ No ☑ * Has the research been approved, or is under consideration, by another Human Research Ethics Committee (HREC)?

* *Tick to continue* ☑

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Type of Research

Does your project involve:

Yes ☐ No ☑ * Research to be conducted outside Australia involving participants NS4.8

Yes ☐ No ☑ * Research on workplace practices or possibly impacting on workplace relationships

Yes ☐ No ☑ * Deception or limited disclosure to participants NS2.3.1

Yes ☑ No ☐ * Access to existing data sets, databanks, or human tissue NS3.2

Yes ☐ No ☑ * Collection or extraction of human tissue (including cell lines), blood or other body fluids NS3.4

Yes ☐ No ☑ * Access to personally identifiable information / records / human tissue samples (including cell lines other than those acquired commercially) without specific consent from the individuals to whom the information/records relate NS2.3; NS2.3.6; NS3.4

Yes ☐ No ☑ * Human genetic testing / research NS3.5

Yes ☐ No ☑ * A cellular therapy

Yes ☐ No ☑ * Exposing participants to ionising radiation NS2.1

Yes ☐ No ☑ * Clinical trial under the CTN or CTX scheme

Yes ☐ No ☑ * Use of gametes or use or creation of embryos

Yes ☐ No ☑ * Use of drugs; alternative / complementary therapies, care, surgical, or other therapeutic or diagnostic procedures and devices NS3.3

Yes ☐ No ☑ * An innovation or intervention which is not standard practice in the study population NS3.3

Yes ☐ No ☑ * Other type of research not covered above
Note: You must tick **Yes** if you have answered 'No' to all of the above

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Research Population

The category and source of participants being sought for this research are:

Select **all that apply** even if there will not be direct contact with the participants.
You must **select at least one**.

- ☐ Adults 18 years of age or old
- ☐ Children, or young people under 18 years who are not University students NS4.2

- ☐ A focus on Aboriginal and Torres Strait Islander (ATSI) peoples, groups, communities or issues NS4.7 **NB: If relevant this box must be ticked and the application will not be eligible for expedited review.**
- ☐ A focus on women who are pregnant, and/or research involving the human foetus NS4.1
- ☐ A focus on people with a cognitive impairment, an intellectual disability, or a mental illness NS4.5
- ☐ Adult participants who will not be competent to give consent are expected to be recruited NS2.2.12
- ☐ People highly dependent on medical care who may be unable to give consent, eg unconscious or too ill NS4.4

- ☐ The general public

- ☐ Students or staff of the University of Newcastle
- ☐ Students or staff of other universities / colleges
- ☐ School children, ie recruited through schools

- ☐ Volunteer registers or databases
- ☐ Members of particular community groups/ organisations
- ☐ Employees of particular organisations
- ☐ Clients / patients of health service providers
- ☐ Hospital in-patients
- ☐ Clients of organisations / community services
- ☐ Prisoners or those held in detention

- [ ] People who have a sight or hearing impairment
- [ ] People with a specific health condition
- [ ] People in a dependent or unequal relationship with the researchers
- [ ] Participants not proficient in the English language

- [ ] Records / information about people without contact with those people
- [x] Human tissue collections without contact with the donors
- [ ] People who could be exposed to civil, criminal or other proceedings as a result of the research

- [ ] Other

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Research Methods/Techniques

The research methods / techniques to be used in the research are:

Select all that apply. You must **select at least one**.

- [ ] Computer based tests
- [ ] Data linkage
- [ ] Focus groups
- [ ] Interviews face-to-face
- [ ] Interviews telephone
- [ ] Internet / web based research
- [ ] Observation of people
- [ ] Covert observation NS2.3.1
- [ ] Photographs of people

- [ ] Physical activities / exercises / tests
- [ ] Psychological tests

- [ ] Questionnaire / survey / diary anonymous
- [ ] Questionnaire / survey / diary identifying
- [ ] Record / document analysis
- [ ] Taping audio / video

- [ ] Access to and/or use of information from a Commonwealth Agency
- [ ] Access to and/or use of information from a private sector organisation

- [ ] Case study
- [ ] Case-control study
- [ ] Epidemiological or other quantitative research
- [ ] Qualitative research
- [ ] Randomised controlled trial
- [ ] Intervention study

- [ ] Administration of drug / medicine (incl complementary / alternative)
- [ ] Use of a placebo
- [ ] Use of a medical device
- [ ] Human stem cell therapy

- [x] Other

* Please specify:

Max 300 words

* Of the tests or procedures to be used, are any on the HREC Register of Approved Tests and Procedures?

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Consent Process

What method(s) of consent will be used to enable the research to be conducted? NS2.2

Select all that apply. You must **select at least one**.

- ☐ Written informed consent
- ☐ Recorded informed consent
- ☐ Parent / Guardian / Carer consent
- ☐ Child's assent with parent / guardian consent
- ☐ Young person 16-17 years consent
- ☐ Child
- ☐ Organisational consent, *ie from a CEO, Director, Manager, Principal, etc.*
- ☐ Implied consent
- ☐ Retrospective consent
- ☐ Waiver of informed consent sought
- ☐ Waiver of parent / guardian consent sought
- ☐ Existing consent
- ☑ Other

* Please provide details of the other consent process.

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Research Sites

* List the research sites, ie the communities / schools / hospitals / organisations etc from which participants will be sourced.

If more than 10, give number and type, eg "12 NSW government primary schools in the Hunter region"

* Is your research a single site or multi-centre project *(click on icon to select)*?

Participant Numbers

* What is the total number of participants to be recruited at all sites involved in the research? 0

* What is the total number of participants covered by this application? 0

* What is the rationale for that number?

* *Tick to continue* ☑

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Follow-Up Questions

Based on your answers to the above questions, additional information is required on the following features of your research.

Access to existing data sets, databanks, or human tissue banks

Yes ☐ No ☑ * Is the data / tissue held in identifiable or potentially re-identifiable form?

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Eligibility for Expedited Review

Yes ☐ No ☑ * Will participants be identifiable, either directly or indirectly, in the research?

Yes ☐ No ☑ * Are the potential participants in an unequal relationship? NS4.3

Yes ☐ No ☑ * Does the research involve physically invasive procedures NS2.1

Yes ☐ No ☑ * Is there a risk of physical injury to participants NS2.1

Yes ☐ No ☑ * Might the research involve pain or discomfort for participants? NS2.1

Yes ☐ No ☑ * Might the research cause participants psychological or emotional stress? NS2.1

Yes ☐ No ☑ * Does the research involve the collection of sensitive personal information?

Yes ☐ No ☑ * Could the research expose participants to economic loss or damage to their reputation? NS2.1

Yes ☐ No ☑ * Could the research have a negative impact on personal relationships? NS2.1

Yes ☐ No ☑ * Will potential participants be offered inducements that could be considered coercive? NS2.2.10; NS3.3.5

Project eligible for expedited review

*

Your project appears to qualify for Negligible Risk Research Expedited Review. Tick to continue. ☑

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Project Details

In the following sections, provide a brief 'plain English' description of the project. NS1

* Background to project:

Max 250 words

* Aims / hypotheses / questions:

Max 150 words

* Research design:

Max 250 words

* Potential value and significance of the research:

Max 250 words

* Experience and skills of researchers. NS1.

Max 300 words

Participants

* How, and by whom, will potential participants be selected, and
(a) initially contacted, and
(b) recruited? NS1.4; NS3.1

Provide information on the source(s) of the cell lines.

If commercial, provide details and a link to the commercial site.

If cell lines are being obtained from other researchers, provide some information on the provenance of the cell lines.

Max 300 words

* Detail the procedure to be used to ensure voluntary and informed consent NS2.2

Max 300 words

* List the inclusion and exclusion criteria NS1.4

* What is required of participants?

Max 300 words

* What, if any, benefits might there be from the research for participants or others? NS1.6

Describe in terms of both potential benefits to the broader community.

Max 300 words

* Will participants receive any reimbursements / payments / rewards for participating in the research? NS2.2.10; NS3.3.5 ☐ Yes ☐ No

Analysis and Reporting

* How will the information you receive be analysed / interpreted? What specific approaches or techniques (statistical or qualitative) will be employed?

Max 300 words

* Detail how the results of the research will be reported / disseminated, including appropriate provision of results to participants. NS1.1; NS1.3; NS1.4; NS2.2.6; NS3.1.4; NS3.1.11

Max 300 words

Storage, Access and Disposal of Data

* Detail the mechanisms that will be in place to ensure appropriate storage, access and disposal of data.

Max 300 words

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Safety Implications

Does the proposed research involve work on, use of, or exposure to any of the following?

Yes ☐ No ☐ * Cash reimbursements / payments to research participants

Yes ☐ No ☐ * Fieldwork / off campus activity eg interviews

Yes ☐ No ☐ * Recombinant DNA

Yes ☐ No ☐ * Genetically modified organisms

Yes ☐ No ☐ * Biologically hazardous micro-organisms

Yes ☐ No ☐ * Chemically hazardous materials

Yes ☐ No ☐ * Human body fluids or tissue

Yes ☐ No ☐ * Radioisotopes / unsealed sources

Yes ☐ No ☐ * Ionising radiation

Yes ☐ No ☐ * Non-ionising radiation

Yes ☐ No ☐ * Any other potential safety hazard for either participants or researchers?

Confirmation

* The information I have provided in this submission is accurate and complete. ☐
(This will close all Help text.)

Comments

Please use this section if you would like to provide additional information regarding your research that has not been covered elsewhere in the submission, or if you wish to make comments about this submission form.

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Steps to complete this submission

Before you can complete the following Declaration and make this submission to the Human Research Ethics Committee, you need to upload supporting documentation (eg Participant Information Statement, Consent Form, etc), evidence of Peer Review and Head of School approval. To do this:

1. Go to the Menu located at the top left of this form and **Save**. At this stage **do not** tick the "Completed" box which is on the top right.
2. To make a copy of your saved eform to send for Peer Review and Head of School sign off, click **Print** in the top left menu and then select either *Print* or *Save* from the PDF options.
3. **Close** this submission by clicking on the **X** button, top right.
4. On the **Components for Initial** screen, **Upload** each supporting document by clicking on the Add Institution Forms/Supporting Documents link.
5. **Download** the *Peer Review Declaration* and the *Head of School Declaration* documents from the Human Research Ethics website.
6. Submit the *Peer Review Declaration* document to your Faculty's Peer Review process with a full copy of your ethics submission.
7. When the Peer Review declaration has been completed, that document and the submission is then to be **submitted to your Head of School** together with the *Head of School Declaration* for completion.
8. **Upload** the completed *Head of School Declaration* and the *Peer Review Declaration* to this submission. It is the applicant's responsibility to ensure the Declarations are completed and uploaded with their submission.
9. Open your Initial submission and the eform. Complete your Declaration at the end of the form.
10. **Save** and then tick the **Completed** box on the form.
11. Close the form. On the **Components for Initial** screen, click **Submit**

Declaration

In making this submission, I declare that:

- The research protocol conforms to the *National Statement on Ethical Conduct in Human Research, 2007*, which I have read.
- I undertake to conduct the research in accordance with the approved protocol, the *National Statement*, relevant legislation and the policies and procedures of the University of Newcastle.
- Where I am the project supervisor for the research described herein which will be conducted by a student of the University of Newcastle, I declare that I have provided guidance to the student in the design, methodology and consideration of ethical issues of the proposed research.
- I make this application on the basis that the information it contains is confidential and will be used by the University of Newcastle 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.

Yes ☐ No ☐ * Each member of the research team is being identified in this submission with his/her knowledge and consent; they have access to the submission; and I have made them aware of the requirement for the research to be conducted according to the approved protocol.

I have uploaded required documents as follows:

_____ * Peer Review Declaration

_____ * Head of School Declaration

_____ * Participant Information Statement(s)

_____ * Verified translations of Participant Information Statement(s)

_____ * Participant Consent Form(s)

_____ * All recruitment material, eg advertisements, posters

☐ * Surveys / questionnaires

☐ * Focus group / Interview schedule(s)

☐ * Funding application(s) / Contract / Agreement not administred by University of Newcastle

☐ * Approval(s) from other HRECs

* I have completed all requirements for this submission. ☐

*** Chief Investigator / Project Supervisor:**

* Date: 05-Dec-2019

Please don't forget to SAVE before ticking 'Complete' or closing the eform