**Office use only**

Reference number:

Quiz results received for all applicants? Y/N

|  |  |
| --- | --- |
| **DEAKIN UNIVERSITY HUMAN ETHICS ADVISORY GROUP****LOW-RISK APPLICATION FORM** |  |

The [*National Statement on* *Ethical Conduct in Human Research*](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) (2007) - updated 2018 defines low risk research as:

‘Research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants

is more serious than discomfort is not low risk’.

**Project Title:**

**Proposed Start Date:**       **Proposed end date:**

**Principal Investigator/s:**

**Student Investigator/s (if applicable):**       **Student id:**

**Degree/s for which student/s enrolled:**

**School:**       **Faculty:**

**Contact Telephone No:**

**Email:**

**Contact details of all researchers involved in the project:**

**Name Role Email Phone**

***Please note****: There has been an update by Microsoft which blocks links to single sign-on web pages.*

*To access the Deakin Human Ethics Guidelines referred to in this form, cut and paste the following address to your browser:*

<http://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/dheg>

*Links to external sites in this form will still work.*

 **COVID-19**

Please indicate whether:

1. Your project is not designed to align with current COVID-19 restrictions but will be delayed until all restrictions are lifted and will be modified with approval prior to commencement in the event that unforeseen flow-on effects from the virus raise new ethical issues [ ]

OR

1. Your project is designed to align with current COVID-19 restrictions and will be conducted once approval is granted [ ]

**PART A: Excluded Categories** (see *National Statement* [Chapter 5.1.6](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#guidelines___chapter_5_1))

**1 Does your project involve any of the following?**

Yes [ ]  No [ ]  Aboriginal or Torres Strait Islander Peoples or issues

Yes [ ]  No [ ]  Research involving pregnant women or the human fetus

Yes [ ]  No [ ]  People highly dependent on medical care who may be unable to give consent

Yes [ ]  No [ ]  People with a cognitive impairment, an intellectual disability, or mental illness

Yes [ ]  No [ ]  People who may be involved in illegal activities where the research is intended to study or expose illegal activity or that is likely to discover it

Yes [ ]  No [ ]  Clinical trials - defined as “…*any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes”* (World Health Organisation)

Yes [ ]  No [ ]  Human genomic research

Yes [ ]  No [ ]  Human biospecimens including human cells (Please note: where researchers want to re-use human biospecimens that were originally collected as per a Deakin approved ethics application, their future use *may* be eligible for low risk review if the researchers intend to seek specific consent from participants for the new project and if all other aspects of the project are low risk)

Yes [ ]  No [ ]  Projects involving ionising radiation

Yes [ ]  No [ ]  Travel to regions classified as Level 2, 3 or 4 (see [DFAT](http://smartraveller.gov.au/resources/Pages/travel-advice-explained.aspx) and Section 35 of the Deakin Guidelines)

Yes [ ]  No [ ]  Projects involving active concealment or planned deception of participants

Yes [ ]  No [ ]  Risk of harm to participants (more serious than discomfort, *National Statement* [Chapter 2.1.6](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#guidelines___chapter_2_1))

Yes [ ]  No [ ]  Opt-out consent in relation to the collection of \***health or sensitive data** from participants (*National Statement*, [Chapter 2.3](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#introduction___chapter_2_3)). Please complete a [Human Research Ethics Application](https://hrea.gov.au/) (HREA) that includes a request to waive the requirement for consent (required under Privacy Legislation) and submit to DUHREC, attaching the [Privacy Supplement](https://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/human-ethics-forms-and-guidelines/application-forms).

Yes [ ]  No [ ]  A waiver of the requirement for consent when accessing collections of potentially **identifiable \*health or sensitive data+**. Please complete a [Human Research Ethics Application](https://hrea.gov.au/) (HREA) and submit to DUHREC attaching the [Privacy Supplement](https://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/human-ethics-forms-and-guidelines/application-forms). Please note if you are accessing **pre-existing collections of non-identifiable data** you may be eligible for an exemption (see Q.3, page 3 for more information).

**If you selected yes to ANY of these elements, your project is not eligible for low-risk review.** You should complete a higher than low risk application form (the [Human Research Ethics Application](https://hrea.gov.au/) (HREA) for review by DUHREC (see [Section 6.5](https://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/dheg/g6) of the Deakin Guidelines).

**+ Please note:** if you are seeking access to existing collections of **potentially identifiable data**, that are **neither health nor sensitive data**, your project may still be eligible for low risk review even if you are seeking to waive the requirement for consent (i.e. you are not planning to obtain consent from participants to access their data) so long as every other aspect of your project is low risk. If this is the case, please complete Q.1 in Section 2 of the Checklist, and Questions 3 and 11 in Part C of this form. Please also note: this only applies to existing collections of data. If you are prospectively collecting data directly from participants, you will need to apply for ethics approval and seek participant consent prior to collecting the data. If you are using **opt-out consent in relation to the collection of non-health or non-sensitive data**, and every other aspect of your study is low risk, please address the National Statement 2.3.6 a-i (see Part C: Q.10: Consent).

**\* Please see Part F: Glossary, page 15 of this form for definitions of health and sensitive data.**

**2 Does your project involve ethical review by another Australian organisation?**

Yes [ ]  No [ ]  If yes, your project should not be submitted for review by a HEAG. You should consult [Section 6](https://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/dheg/g6) of the Deakin Guidelines regarding the processes which apply to applications previously approved by another organisation.

**3 Does your project involve ONLY use of existing collections of non-identifiable data?**

Data are non-identifiable when they do not identify the people to whom the information relates – identifiers should never have been collected, or should have been permanently removed from the data set before you received it.

Yes [ ]  No [ ]  If yes, you should complete the application form for Exemption from Ethical Review (see Section 6 of the Deakin Guidelines). Please note: **research using human biospecimens is not eligible for an exemption.**

**PART B: Checklist**

This checklist will help you decide whether your research may be submitted for review by your Faculty HEAG. Research is eligible for low-risk review if the foreseeable risk level is no more than discomfort. If you answer ‘YES’ to any items on the checklist **your project is not eligible for low risk review** **unless** you can explain how this potential risk will be managed or minimised to ensure that the project remains low risk. This should be explained in the special case assessment section (Section 6) below.

**It is your responsibility to assess the level of risk associated with your project. If your project is not considered low risk by the HEAG, you will be required to complete a high-risk application for submission to DUHREC.**

***Please ensure you include all signatures before submitting the application***

***as approval cannot be granted until they are received.***

# 1 Are any of the following topics to be covered in part or in whole?

|  |  |  |
| --- | --- | --- |
| Parenting | [ ]  YES | [ ]  NO |
| Sensitive personal issues | [ ]  YES | [ ]  NO |
| Sensitive cultural issues | [ ]  YES | [ ]  NO |
| Grief, death or serious/traumatic loss | [ ]  YES | [ ]  NO |
| Gambling | [ ]  YES | [ ]  NO |
| Eating disorders | [ ]  YES | [ ]  NO |
| Illicit drug taking | [ ]  YES | [ ]  NO |
| Substance abuse | [ ]  YES | [ ]  NO |
| Self-report of criminal behaviour | [ ]  YES | [ ]  NO |
| Any psychological disorder, depression, mood states and/or anxiety | [ ]  YES | [ ]  NO |
| Suicide | [ ]  YES | [ ]  NO |
| Sexuality, sexual behaviour or gender identity | [ ]  YES | [ ]  NO |
| Race or ethnic identity | [ ]  YES | [ ]  NO |
| Any disease or health problem | [ ]  YES | [ ]  NO |
| Fertility | [ ]  YES | [ ]  NO |
| Termination of pregnancy | [ ]  YES | [ ]  NO |

# 2 Are any of the following procedures to be employed?

|  |  |  |
| --- | --- | --- |
| Waiver of consent for access to collections of identifiable data that are neither health nor sensitive data (please see Part F: Glossary for definitions of health and sensitive data). | [ ]  YES | [ ]  NO |
| Use of personal data obtained from Commonwealth or State Government Department/Agency | [ ]  YES | [ ]  NO |
| Concealing the purposes of the research | [ ]  YES | [ ]  NO |
| Covert observation | [ ]  YES | [ ]  NO |
| Audio or visual recording without consent | [ ]  YES | [ ]  NO |
| Recruitment via a third party or agency | [ ]  YES | [ ]  NO |
| Withholding from one group specific treatments or methods of learning, from which they may ‘benefit’(e.g. in medicine or teaching) | [ ]  YES | [ ]  NO |
| Psychological interventions or treatments | [ ]  YES | [ ]  NO |
| Administration of physical stimulation | [ ]  YES | [ ]  NO |
| Invasive physical procedures | [ ]  YES | [ ]  NO |
| Infliction of pain | [ ]  YES | [ ]  NO |
| Administration of drugs or placebos | [ ]  YES | [ ]  NO |
| Administration of other substances  | [ ]  YES | [ ]  NO |
| Use of medical records where participants can be identified or linked | [ ]  YES | [ ]  NO |

#### 3 PARTICIPANT VULNERABILITY ASSESSMENT

 **Does the research specifically target participants from any of the following groups?**

|  |  |  |
| --- | --- | --- |
| Children or young people under 18 years | [ ]  YES | [ ]  NO |
| People with a physical disability or vulnerability | [ ]  YES | [ ]  NO |
| People whose ability to give consent is impaired  | [ ]  YES | [ ]  NO |
| Residents of a custodial institution | [ ]  YES | [ ]  NO |
| People unable to give free informed consent because of difficulties in understanding the Plain Language Statement or Information Sheet (e.g. language difficulties) | [ ]  YES | [ ]  NO |
| Members of a socially identifiable group with special cultural or religious needs or political vulnerabilities  | [ ]  YES | [ ]  NO |
| People in dependent or unequal relationship with the researchers (e.g. lecturer/student, doctor/patient, teacher/pupil, professional/client) | [ ]  YES | [ ]  NO |
| People with existing relationships with the researcher (e.g. relative, friend, co-worker)  | [ ]  YES | [ ]  NO |
| People in a workplace setting with the potential for coercion or problems of confidentiality (e.g. employer/employee) | [ ]  YES | [ ]  NO |
| Participants able to be identified in any final report when specific consent for this has not been given | [ ]  YES | [ ]  NO |
| Persons not usually considered vulnerable but would be thought so in the context of the project  | [ ]  YES | [ ]  NO |

**4. RESEARCH IN OVERSEAS SETTINGS ASSESSMENT**

 **Does the research involve any of the following?**

|  |  |  |
| --- | --- | --- |
| Research being undertaken in a politically unstable area | [ ]  YES | [ ]  NO |
| Research involving sensitive cultural issues | [ ]  YES | [ ]  NO |
| Research in countries where criticism of government and institutions might put participants and/or researchers at risk | [ ]  YES | [ ]  NO |
| \*Please indicate which DFAT level of advice applies to the region you intend visiting (see [DFAT](http://smartraveller.gov.au/resources/Pages/travel-advice-explained.aspx) and Section 35 of the Deakin Guidelines) | [ ]  1 | [ ]  2 | [ ]  3 | [ ]  4 |
| *\*Note: Travel to regions classified as Level 2 (or above) is considered higher than low risk and not eligible for review by a HEAG.* |

## 5. OTHER RISKS

|  |  |  |
| --- | --- | --- |
| Are there any risks to the researcher, (e.g. research undertaken in unsafe environments or trouble spots)? | [ ]  YES | [ ]  NO |
| Are there any other risks not covered in this assessment that you consider may be relevant? | [ ]  YES | [ ]  NO |

**6. SPECIAL CASE ASSESSMENT**

If you have answered ‘YES’ to an item in the checklist but you still believe that because of the particular nature of the project and the participants your project may still be eligible for low risk review. Please provide details below, or attach an additional sheet.

**SPECIAL CASE DETAILS:**

**PART C: Project**

## Aims of the project/the research question(s)/hypothesis

## Research design and methods

Give a concise and simple description of the proposed research design and the methods to be used. Please include all data collection procedures and all groups of participants.

Describe how the design and methods of the project will enable adequate exploration of the research questions and achieve the aims of the research.

Describe how the design of the project will maintain respect for participants.

Has the project been reviewed by a formally constituted academic, scientific or professional review process and if so, what was the outcome of that review?

## Use of existing stored data

Please list any existing stored data that you plan to use as part of the project e.g. health or employment records used for recruitment, or comparison. Please include in your answer:

* The type and number of records being accessed;
* Whether the records identify individual people; and
* How you will obtain permission to use them (consent from individuals or permission from custodians of non-identifiable data). Or, if not seeking consent, please indicate here that you are seeking a waiver of the requirement for consent and answer Q.11 below (please note waivers of consent can only be sought via low risk review **where the data are neither health nor sensitive data**).

 (See the *National Statement* [Chapter 3.1](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#guidelines___chapter_3_1) and [Chapter 3.2](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#introduction___chapter_3_2); and [Section 25](https://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/dheg/g25) of the Deakin Guidelines for more information.)

Please describe any stored biospecimens that you intend to use as part of the project. **Please note:** projects involving biospecimens may only be considered low risk if they were collected as part of a project that was approved by a Deakin ethics review body, you intend to seek the consent of the participants for the re-use of their biospecimens as described in this application and the project is low risk in all other respects.

(see the *National Statement* [paragraphs 3.2.11-3.2.14](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_3_2__human_biospecimens_in_laboratory_based_research) for more information)

## Risks and benefits

**Give a summary of the expected benefits of this project**

This may include benefits to the broader community, the participants, people with whom the participants identify or the researcher (see the *National Statement* on [benefits](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#section_2__themes_in_research_ethics__risk_and_benefit__consent) for more information). Among other things, benefits may include a contribution to knowledge or understanding, improved social or individual wellbeing, or the skill and expertise of researchers.

**Provide a justification for the potential benefits**

Potential benefits should be based on either relevant literature or a review of prior research unless, due to the novelty of the question, there is scarce literature or prior research.

**Give a summary of the expected risks of this project and how they will be managed**

This should include any risks to participants, researchers, to the environment or to Deakin or other organisations (see the *National Statement* on [assessment of risk](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#section_2__themes_in_research_ethics__risk_and_benefit__consent) for more information).

## Monitoring

As the researcher, how will you monitor the progress of the research?

You should include details of planned communication between members of the research team (e.g. face to face meetings, email, telephone or Skype) (see the *National Statement* [Chapter 5.5.3](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#introduction___chapter_5_5http://www.nhmrc.gov.au/book/chapter-5-5-monitoring-approved-research) for more information).

## Resources

Please explain the amount and source of funding (sponsorship, tender, grant etc.). If there are specific resources required for the project how will they be provided?

## Conflict of interest

Do any of the researchers or others involved in this project have any conflict of interest in relation to it? If so, please explain how this will be managed (see the *National Statement* on [Conflict of Interest](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_5_4__conflicts_of_interest) for more information).

**PARTICIPANTS**

## Describe your participant group/s

Please include the following information for each participant group how many participants you plan to recruit:

* a justification for the number of participants chosen for each participant group
* the inclusion and exclusion criteria.

(See the *National Statement* [Section 4](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#section_4__ethical_considerations_specific_to_participants) for more information.)

## Explain your recruitment process

Please include the following information for each participant group:

* How will you locate the participants that you plan to recruit? If through existing records or contact lists, please explain how this will be done in a way that does not infringe privacy requirements.
* How will initial contact be made?
* If you plan to use a document or spoken statement e.g. flyer, letter, advertisement, phone call, please attach a copy of the document or script to this application.
* All advertisements (both written and spoken) must include the following statement: “This study has received Deakin University ethics approval (reference number: insert reference number here).”
* Will the participants be screened?
* If there is a screening tool, please attach a copy.

(See [Section 8](https://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/dheg/g8) of the Deakin Guidelines for more information.)

**CONSENT**

## Describe the consent process

There are a variety of ways in which consent can be established, most commonly by giving participants a Plain Language Statement and Consent Form (PLSCF) or by return of a survey. You may wish to consult [Section 9](https://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/dheg/g9) of the Deakin Guidelines for more information. Please include details such as:

* how and when you will provide consent materials to your potential participants
* how, when and to whom participants will indicate their consent
* If you are seeking **opt-out consent in relation to non-health or non-sensitive data**, please address the National Statement [Chapter 2.3](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__296), 2.3.6 a-i.

(See the *National Statement* [Chapter 2.2](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_2__general_requirements_for_consent), [Chapter 2.3](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_3__qualifying_or_waiving_conditions_for_consent) and Element 3 of [Chapter 3.1](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_3_1__the_elements_of_research) for more information.)

1. **Waiver of Consent**

Are you seeking a waiver of consent (in relation to accessing **collections of potentially identifiable data** that are **neither health nor sensitive\*** data)? (See the *National Statement*, [Chapter 2.3](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_3__qualifying_or_waiving_conditions_for_consent) for more information.) [ ]  YES [ ]  NO

If yes, please describe how this complies with the [NS 2.3.10 a-i](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__296) requirements below:

1. involvement in the research carries no more than low risk to participants:

1. the benefits from the research justify any risks of harm associated with not seeking consent:

1. it is impracticable to obtain consent (for example due to the quantity, age or accessibility of records):

1. there is no known or likely reason for thinking participants would not have consented if they had been asked:

1. there is sufficient protection of their privacy:

1. there is an adequate plan to protect the confidentiality of data:

1. in case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them:

1. the possibility of commercial exploitation of derivatives of the data or tissue\*(please note waivers of consent in regards to accessing \*human tissue or biospecimens are not eligible for low risk review) will not deprive the participants of any financial benefits to which they would be entitled:

1. the waiver is not prohibited by State, federal or international law:

**\* Please see Part F: Glossary, page 15 of this form for definitions of health and sensitive data.**

## Will there be reimbursement of expenses or incentives to participate?

Where expenses will be reimbursed please state:

* the nature of the expenses incurred by participants
* the maximum value of any intended reimbursement.

Where incentives to participate are offered, please explain:

* why you consider that the proposed incentive will not encourage participants to take risks they would not otherwise take. In doing so, please consider both the risks associated with participation and the value of the incentive, relative to your participant group.

(See the *National Statement* [Chapter 2.2.10-2.2.11](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_2_2__general_requirements_for_consent); and [Section 8](https://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/dheg/g8) of the Deakin Guidelines for more information.)

## Pre-existing or unequal relationships

Do any of the proposed participants have existing relationships with the researchers, each other or with any other organisation involved in the research? Please explain the relationships, and how you will make sure that participants do not feel pressured to take part.

(See the *National Statement* [Chapter 4.3](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_4_3__people_in_dependent_or_unequal_relationships); and the [Section 22](https://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/dheg/g22) of the Deakin Guidelines for more information.)

## Does your project include children or young people under 18 years?

If your project involves people under the age of 18, please answer the following questions.

* What age group is involved?
* Will parental/guardian consent be obtained? If the young people will consent on their own behalf, how their capacity to do this will be judged?
* Is it necessary to involve people under 18? Could your projects be undertaken with adult participants?
* Is the methodology appropriate for children/young people?
* Is there any reason to consider that participation in the research is not in the best interests of the children/young people?

(For further information, consult the *National Statement* [Chapter 4.2](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_4_2__children_and_young_people); and [Section 19](https://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/dheg/g19) of the Deakin Guidelines.)

## Language and communication issues

Will your project involve people who cannot communicate easily in English? (e.g. people who are not confident English speakers, or who have a disability, such as a hearing impairment that requires special arrangements for participation). If so, please explain how translation/interpretation issues will be managed.

(For further information consult [Section 24](https://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/dheg/g24) of the Deakin Guidelines.)

## People in other countries

If you are planning to undertake research in other countries, please answer the following questions. What are the legal and ethical requirements for conducting research in the designated country?

* What arrangements will be in place for a local, readily accessible contact to receive responses, questions and complaints about the research? (*National Statement* [Chapter 4.8.16](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_4_8__people_in_other_countries))
* How will the research be monitored on site?
* Are there cultural sensitivities relating to the research? How will these be managed?

If the research is to be conducted in a language other than English, please ensure that you have covered all relevant language issues under question 14.

(For further information consult the *National Statement*, [Chapter 4.8](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_4_8__people_in_other_countries); and Section 35 of the Deakin Guidelines.)

1. **Return of research results or findings to participants**

If the results/findings of the research will be returned to participants, please explain:

* If the individual research results for each participant will be returned to that participant
* If the overall research findings will be returned to participants
* How these results/findings will be provided to participants/how the process will be managed and
* Any risks associated with returning the results/findings

Where the results/findings could have significant health, social, economic, legal, psychological or other implications for participants or their relatives, please provide an ethically defensible plan to disclose or withhold results or findings of the research. The plan should include:

* What results will be returned (if any)
* Whether the participants will be advised in advance of the option to receive the findings or results
* Whether the findings or results may be given to anyone else and if so, whether participants will be informed of this in advance
* If applicable, the process for determining whether participants’ relatives wish to receive the findings or results
* How the findings or results will be returned in a manner that is appropriate and accessible
* The relevant expertise of the person who may be communicating the results and
* Any measures to protect the level of privacy desired by participants.

For further information, consult the National Statement paragraphs [3.1.63 - 3.1.65](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_3_1__the_elements_of_research).

Where the research involves the use of biospecimens (see exception to excluded categories of research in Section A), please also include the additional details for the ethically defensible plan described in the National Statement [3.2.15](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_3_2__human_biospecimens_in_laboratory_based_research) points a-i:

**CONFIDENTIALITY / PRIVACY**

## Will you be collecting data/information in identified form?

Data are generally divided into:

* **identifiable** (also called personal): the person to whom the data relates can be established from the data – either because they are named, or information that identifies them is included (e.g. position in an organisation at the time)
* **re-identifiable** (also called coded): the identifiers have been removed from the information and replaced with a code.
* **non-identifiable**: the data were collected anonymously, or all identifiers have been permanently removed.

Please explain the form in which the data will be collected. If you plan to collect it in identified form and later remove the identifiers, please explain how and when.

(See Section 10 of the Deakin Guidelines for more information.)

1. **How will the research comply with relevant regulations or guidelines authorised by law?**

For example, the mandatory reporting requirements for disclosure of child abuse. For more information see National Statement [3.1.66 - 3.1.68](https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#chapter_3_1__the_elements_of_research).

1. **Storage of data/information**

Data storage should meet the requirements of the Research Conduct Policy and the Research Data and Primary Materials Management Procedure which can be found in the [Deakin Legislation and Policy Library](http://www.deakin.edu.au/about-deakin/leadership-and-governance/legislation-and-policy-library). In most cases data should be stored securely at Deakin, for a period of at least five years after the final publication of the research outcomes. If the data will be stored in another location, please explain this, and how data security will be maintained. You should include:

* whether the data will be identified/re-identifiable/non-identifiable
* how security will be maintained (locked storage, secure server, etc.)
* how long the data will be stored and
* if and when the data will be disposed of and how security will be maintained.

(See Section 10.8 of the Deakin Guidelines for more information.)

1. **Collaborative research**

If the research involves multiple researchers collaborating on collection, storage and/or analysis of data, please outline your arrangements for:

* Custodianship of the data
* Storage, retention and destruction of the data or materials
* Rights of access to the data or information
* Rights to analyse or use and re-use the data or information and
* Rights to produce research outputs based upon the data

1. **Intellectual property, copyright and ownership**

Please detail any intellectual property (individual, community, organisational, commercial), ownership or copyright arrangements related to the data or outputs of the research:

## Publication of results

(See [Section 4](http://www.nhmrc.gov.au/guidelines/publications/r39) of the [Australian Code for the Responsible Conduct of Research](https://nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018) for more information.)

Whose responsibility will it be to notify participants of the outcome of the research?

How will you notify participants of the outcome of the research?

How will your research be reported/published?

How will you manage participant confidentiality?

**PART D: Declarations**

**1** I/We, the undersigned declare that the information supplied in this application is true and accurate to the best of my/our knowledge.

I / We the undersigned have read the *National Statement on Ethical Conduct in Human Research* and accept responsibility for the conduct of the project detailed in this application in accordance with the principles contained in the Statement and any other conditions laid down by Deakin University or the Human Ethics Advisory Group.

I/We the undersigned, declare that where the research project may involve contact with a child or young person under the age of 18, I/we have a current Working with Children Check.

Where the project involves a student researcher, as the supervisor I accept responsibility for ensuring that ethics approval is obtained prior to commencing the research and for overseeing the ethical conduct of the project as detailed in the ethics application.

##  Signatures:

Principal Investigator/s       Date:

       Date:

 Associate Investigator/s       Date:

       Date:

       Date:

       Date:

 Student Investigator/s       Date:

       Date:

       Date:

       Date:

**2 ACKNOWLEDGEMENT OF HEAD OF SCHOOL\*/DIRECTOR OF RESEARCH OR THEIR NOMINEE**

I the undersigned acknowledge that the Faculty has considered and approved the academic worth of the project described in this application.

Name:

Title:

Signature:       Date:

\*If the Head of School (or similar) is also a member of the research or supervisory team, a more senior member of University staff e.g. Dean or Associate Dean (Research) must sign the project as authorising officer.

**Part E: Attachments**

Have you attached the following?

**Yes [ ] No [ ]  N/A [ ]** A copy of the email or certificate confirming successful completion of the online human ethics quiz (first time applicants) or project id of an ethics application/s on which you are listed. For more information on the quiz, copy and paste the following link into your browser: <http://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/human-research-ethics-training>

**Yes [ ] No [ ]  N/A [ ]** A copy of any advertisements/flyers or other recruitment materials. All advertisements (both written and spoken) must include the following statement: “This study has received Deakin University ethics approval (reference number: insert reference number here).”

**Yes [ ] No [ ]  N/A [ ]** A copy of the Plain Language Statement and Consent Form (PLSCF) or other consent materials to be used in the project

**Yes [ ] No [ ]  N/A [ ]** A copy of any survey, list of questions/topics for interviews, or other materials to be used in this project. Please note Deakin University’s preferred online survey platform is Qualtrics. More information on Qualtrics can be found [here](https://researchsurveys.deakin.edu.au/ControlPanel/) or for technical assistance contact eresearch@deakin.edu.au

**Yes [ ] No [ ]  N/A [ ]** Any other documents to be supplied to the participants or used in the conduct of the project

**Yes [ ] No [ ]  N/A [ ]** A letter of support from the organisation/s involved or an organisational PLSC if you are proposing to recruit participants through an external organisation/s

**Yes [ ] No [ ]  N/A [ ]** A completed Organisational Consent Form Coversheet (available on the [Application Forms page](https://www.deakin.edu.au/students/research/research-support-and-scholarships/integrity-secure/human-ethics/human-ethics-forms-and-guidelines/application-forms)) if you are recruiting Deakin staff and students

**Please submit all documents via email to your faculty’s HEAG:**

 Faculty of Arts and Education artsed-ethics@deakin.edu.au

 Faculty of Business and Law blethics@deakin.edu.au

 Faculty of Health health-ethics@deakin.edu.au

 Faculty of Science, Engineering and sciethic@deakin.edu.au

 Built Environment

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| Please note: if the hyperlinks in this form result in an error message, return to the form and:1. *right click on the hyperlink*
2. *click on Edit Hyperlink*
3. *copy the URL to your browser.*
 |

Deakin University is collecting your personal information on this form for the primary purpose of processing your human research ethics application. It will also use this information for monitoring your compliance with the approved protocol. For these purposes Deakin may also provide this information to potential research participants, past or current research participants, or other interested parties in your research. You are not required to provide the information requested, however if the information is not provided, Deakin may not be able to process your ethics application. Deakin manages personal information it holds, including requests by individuals for access to their personal information, in accordance with the Privacy and Data Protection Act 2014 (Vic). Deakin’s Privacy Policy may be viewed on Deakin’s [Policy Library](https://policy.deakin.edu.au/?_ga=1.41072994.1915361819.1415758364). Information on privacy at Deakin is available at <http://www.deakin.edu.au/footer/privacy>.  Questions about privacy may be directed to the Privacy Officer on (03) 5227 8524 or by email to privacy@deakin.edu.au.

**Part F: Glossary**

**Health Data:**

(a) information or an opinion about:

i. the physical, mental or psychological health or a disability (at any time) of an individual; or

ii. an individual’s expressed wishes about the future provision of health, disability or aged care services to him or her; or

iii. a health, disability or aged care service provided, or to be provided, to an individual; that is also personal information; or

(b) other personal information collected to provide, or in providing, a health, disability or aged care service; or

(c) other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances; or

(d) personal information that is genetic information about an individual in a form which is or could be predictive of the health (at any time) of the individual or any of his or her descendants.

**Sensitive Data:**

means information or an opinion about an individual’s:

* racial or ethnic origin; or
* political opinions; or
* membership of a political association; or
* religious beliefs or affiliations; or
* philosophical beliefs; or
* membership of a professional or trade association; or
* membership of a trade union; or
* sexual preferences or practices; or
* criminal record; or
* health information about an individual, or
* genetic information about an individual that is not otherwise health information; or
* biometric information that is to be used for the purpose of automated biometric verification or biometric identification; or biometric templates.