Application number: Research start date:

Date received: Research end date:

Unitec Human Ethics Application – Form A

FOR APPROVAL OF PROPOSED RESEARCH INVOLVING HUMAN PARTICIPANTS

For all research that involves or may involve potential for contentious or sensitive issues.

(All applications are to be typed and presented using language that is free from jargon and comprehensible to lay people)

Section A: General Information

**Project title:**

**Projected start date: Projected end date:**

**Academic Staff Application (excludes staff applying for ethics as students)**

Full name of staff applicant/s:

Title/Department:

Campus (*mark one only*): [ ] Albany [ ] Mt Albert [ ] Waitakere

Telephone:

Email Address:

**Student Applications**

Full Name:

Telephone:

Email Address:

Postal Address:

Employer (if applicable):

Full Name of Principal Supervisor(s):

School/Department/Institute:

Campus (mark one only): [ ] Albany [ ] Mt Albert [ ] Waitakere

Telephone:

Email Address:

Other Applicants – Co-researchers/co-supervisors/organisations

Full Name:

Name of organisation (*if applicable*):

Role in project (co-researcher, supervisor, sponsor, etc):

Telephone:

Email Address:

Postal Address:

School/Department/Institute:

Summary of Project

Please outline in no more than 200 words in plain, non-technical language why you have chosen this project, what you intend to do and the methods you will use.

List the Attachments to your Application

Consent forms – participant and organisation [ ]

Information sheets [ ]

Interview questions [ ]

Focus group schedules [ ]

Questionnaire/s [ ]

Other (please specify):

Applications that are incomplete, lacking the appropriate signatures or submitted after
the specified application deadline date will not be processed. This will mean delays for the project.

Applications must be submitted in the following formats:

One signed hard copy to be sent or hand delivered to the Ethics Secretary at:

Research Office and Postgraduate Centre
Penman House
Building 55, Level 1
Unitec Mt Albert Campus
Gate 4, 139 Carrington Rd
Mt Albert, Auckland

One electronic copy complete with supporting documents to be emailed to the Ethics Secretary at: ethics@unitec.ac.nz

Note: If no hard copy, complete signed e-copies of applications will be accepted.
E-copies to be sent to: ethics@unitec.ac.nz

Note: Email trails are unable to be accepted in lieu of signature/s.

Section B: Project Information

Does this project have any links to previously submitted ethics application(s)?
[ ]  Yes / [ ]  No

If yes, list the UREC or HDEC application number/s (if assigned) and relationship/s.

Is approval from other Ethics Committees being sought for the project? [ ]  Yes / [ ]  No

If yes, list the other Ethics Committees.

Section B.1: Project Details

Provide a brief rationale for the research, including the value and benefit of the project.

State concisely the aims, question and/or hypothesis of the project.

What methodology best describes your research approach?

*(e.g Randomised controlled trial, experiment, survey, action research, phenomenology, ethnography, grounded theory, case study or other: please specify)*

What methods are you using to address the aims, questions and/or hypothesis identified in question 8?

(Mark the appropriate boxes)

Questionnaire [ ]

Focus Group [ ]

Interview [ ]

Experimental, Observational or Interventional Study [ ]

Other (please specify):

Will electronic media (e.g. email or the internet) be used for the collection of data from
participants? [ ]  Yes / [ ]  No

Where will the project be conducted? Include information about the physical location(s)/setting(s).

If the project is based overseas:

i) Specify which countries are involved:

ii) Outline how overseas country requirements (if any) have been complied with:

iii) If the research is to be conducted overseas, describe the arrangements you will make for local participants to express concerns regarding the research.

Describe the experience of the researcher and/or supervisor to undertake this type of project?

Section B.2: Participants

Describe the intended participants.

How many participants will be involved?

What is the reason for selecting this number?

*(Where relevant, attach a copy of the Statistical Justification to the application form)*

Describe how potential participants will be identified and recruited?

Does the project involve recruitment through advertising? [ ]  Yes / [ ]  No

*(If yes, please attach an example of the advertisement)*

Who will make the initial approach to potential participants?

Describe criteria (if used) to select participants from the pool of potential participants.

How much time will participants have to give to the project?

Describe any professional or other relationship between the researcher and the participants? (e.g. employer, employee, work colleague, lecturer/student, practitioner/patient, researcher/family member).

Indicate how any resulting conflict of role will be addressed.

 Will any payments, koha or other compensation be given to participants? [ ]  Yes / [ ]  No

If yes, describe what, how and why.

(Note that compensation (if provided) should be given to all participants and not constitute an inducement. Details of any compensation provided must be included in the Information Sheet.)

Section B.3: Data Collection

Does the project include the use of participant questionnaire/s? [ ]  Yes / [ ]  No

(If yes, attach a copy of the Questionnaire/s to this form and include this in your list of attachments (Q)

If yes:

i) Indicate if the participants will be anonymous (i.e. their identity be unknown to the researcher and no information collected on the participant’s identity?

ii) Describe how the questionnaire will be distributed and collected.

Does the project involve observation of participants? [ ]  Yes / [ ]  No

If yes, please describe.

Does the project include the use of focus group/s? [ ]  Yes / [ ]  No

If yes, describe the location of the focus group and time length, including whether it will be in work time.

If yes, ensure the researcher asks permission for this from the employer.

Does the project include the use of participant interview/s? [ ]  Yes / [ ]  No

If yes, attach a copy of the Interview Questions/Schedule to this application form.

If yes, describe the location of the interview and estimated time length, including whether it will be in work time.

If yes, ensure the researcher asks permission for this from the employer.

Does the project involve sound recording or image recording e.g photo/video?
[ ]  Yes / [ ]  No

If yes, please describe.

(If agreement for recording is optional for participation, ensure there is explicit consent on the Consent Form)

If recording is used, will the record be transcribed? [ ]  Yes / [ ]  No

If yes, state who will do the transcribing.

If not the researcher, a Transcriber’s Confidentiality Agreement is required – attach a copy to this application form. Normally, transcripts of interviews should be provided to participants for review, however, if the researcher considers that the right of the participant to review is inappropriate, a justification should be provided below.

Does the project involve other methods of data collection not covered in Qs 25-31?
[ ]  Yes / [ ]  No

If yes, describe the method used.

Does the project require permission to access databases? [ ]  Yes / [ ]  No

If yes, attach a copy of the draft request letter/s to this form. Include this in your list of attachments (Q).

Who will carry out the data collection?

If this is to be carried out by anyone other than the named investigators on this application, please provide their details and ensure a confidentiality agreement is in place.

Will any information be obtained from any source other than the participant?
[ ]  Yes / [ ]  No

If yes, describe how and from whom.

Will any information that identifies participants be given to any person outside the research team? [ ]  Yes / [ ]  No

If yes, indicate why and how – ensure this is explained on the information sheets.

1. Will the participants be anonymous (i.e. their identities are unknown to the researcher and no information collected on the participant’s identity?) [ ]  Yes / [ ]  No

If no, explain how confidentiality of the participants’ identities will be maintained in the treatment and use of the data.

Will an institution (e.g. school) to which participants belong be named or be able to be identified? [ ]  Yes / [ ]  No

If yes, explain how you will make the institution aware of this and how organisational consent will be obtained from the institution - attach organisational consent forms to this application if required.

Outline how and where:

i) The data will be stored;

(Pay particular attention to identifiable data, e.g. recordings, videos and images)

ii) Consent Forms will be stored*;*

(Note that Consent Forms should be stored separately from data. UREC expects Consent Forms to be stored on site at Unitec)

iii) Who will have access to the data/Consent Forms?

iv) How will the data/Consent Forms be protected from unauthorised access?

How long will the data from the project be kept, who will be responsible for its safe keeping and eventual disposal? (Note that health information relating to an identifiable individual must be retained for at least 10 years, or in the case of a child, 10 years from the age of 16).

What are the criteria for participants who wish to opt out of research/right to withdraw from research?

Do you anticipate that the results of your research may be subject to an embargo? If yes, outline the possible reasons your research may be embargoed. (It is expected that research is made available for public access through publication or other means, unless there is compelling reason for restricting access to it).

Section C: Benefits/Risk of Harm

What are the possible benefits (if any) of the project to individual participants, groups, communities and institutions?

What discomfort (physical, psychological, social), incapacity or other risk of harm are individual participants likely to experience or at any risk of as a result of participation?

Describe the strategies you will use to deal with any of the situations identified in Q42.

Is there any risk of harm of the project to the researcher?

Describe the strategies you will use to deal with any of the situations identified in Q44.

What discomfort (physical, psychological, social) incapacity or other risk of harm are groups/communities and institutions likely to experience as a result of this research?

Describe the strategies you will use to deal with any of the situations identified in Q46.

Is ethnicity data being collected as part of the project? [ ]  Yes / [ ]  No

If yes, please describe how the data will be used.

(Note that harm can be done through an analysis based on insufficient sample or sub-set numbers).

If participants are children/students in a pre-school/school/tertiary setting, describe the arrangements you will make for children/students who are present but not taking part in the research.

(Note that no child/student should be disadvantaged through the research)

Is deception involved at any stage of the project? [ ]  Yes / [ ]  No

If yes, justify its use and describe the debriefing procedures.

Section D: Informed and Voluntary Consent

By whom and how, will information about the research be given to potential participants?

(Attach copies of information sheet/s to the application form.)

Will consent to participate be given in writing? [ ]  Yes / [ ]  No

(Attach copies of Consent Form/s to the application form)

If no, justify the use of oral consent.

Will participants include persons under the age of 16? [ ]  Yes / [ ]  No

If yes, indicate:

i) The age group and competency for giving consent.

ii) If the researcher will be obtaining the consent of parent(s)/caregiver(s). [ ]  Yes / [ ]  No

(Note that parental/caregiver consent for school-based research may be required by the school even when children are competent. Ensure Information Sheets and Consent Forms are in a style and language appropriate for the age group.)

Will participants include persons whose capacity to give informed consent may be compromised (this includes children)? [ ]  Yes / [ ]  No

If yes, describe the consent process you will use.

Will the participants be proficient in the language the research is being conducted in? (e.g. English. It is important the participants are able to understand the consent forms)

[ ]  Yes / [ ]  No

If no, all documentation for participants (Information Sheets/Consent Forms/Questionnaire etc) must be translated into the participants’ first-language.

(Attach copies of the translated Information Sheet/Consent Form etc to the application form, as well as verification that the translations are correct and have been professionally checked.)

Section E: Conflict of Interest

Please provide details of any potential conflicts of interest throughout the course of research.

(Attach relevant documentation to the application form.)

Is the project to be funded or supported in any way, e.g. supply of products for testing?
 [ ]  Yes / [ ]  No

If yes:

i) State the source of funding or support:

Unitec Academic or Faculty Unit

Unitec Strategic Research Fund

External Organisation (provide name and detail of funding/support)

ii) Does the source of the funding present any conflict of interest with regard to the research topic? [ ]  Yes / [ ]  No

 If yes, identify any potential conflict of interest due to the source of funding and explain how this will be managed.

Does the researcher/s have a financial interest in the outcome of the project?
[ ]  Yes / [ ]  No

If yes, explain how the conflict of interest situation will be dealt with.

Section F: Māori Social and Cultural Responsiveness

Important note: Applicants should read [Guidelines for Researchers Regarding Māori Social and Cultural Responsiveness](https://moodle.unitec.ac.nz/pluginfile.php/124949/mod_folder/content/0/Ethics_Policies_and_Guidelines/Guidelines%20for%20Researchers%20Regarding%20Maori%20Social%20and%20Cultural%20Responsiveness.pdf?forcedownload=1) to answer the questions in this section adequately.

1. Is it apparent that Māori will be directly involved in or impacted by the project?

[ ]  Yes / [ ]  No

If no, answer the following three points below. If yes, answer Q60–61.

i) What Māori involvement there may be, and

ii) How this will be managed, and

iii) What impact on Māori this project may have

(To be answered when “yes” is indicated in Question 59). Identify the person/s and/or group/s with whom consultation/advice has taken place or is planned and describe the consultation process. Include information on the processes in place for the ongoing provision of cultural advice and support, and the ongoing involvement of the group/s consulted.

*(Attach any evidence of consultation/planned consultation to the application form, e.g. a letter from an iwi authority.)*

(To be answered when “yes” is indicated in Question 59). Describe how information resulting from the project will be shared with the group/s consulted?

Section G: Cultural Issues

1. What ethnic or social group/s (other than Māori) does the project involve?

Are there any aspects of the project that might raise specific cultural issues?
[ ]  Yes / [ ]  No

If yes, explain and complete questions 63–66. Otherwise, proceed to Section H.

Does the researcher speak the language of the target population? [ ]  Yes / [ ]  No

If no, specify how communication with participants will be managed.

Identify the group/s with whom consultation has taken place or is planned.

(Where consultation has already taken place, attach a copy of the supporting documentation to this form.)

Describe any ongoing involvement of the group/s consulted in the project.

Describe how information resulting from the project will be shared with the group/s consulted.

Section H: Sharing Research Findings

Describe how information resulting from the project will be shared with participants and disseminated in other forums, e.g. peer review, publications, conferences.

(Note that receipt of a summary is one of the participant rights.)

Section I: Invasive Procedures/Physiological Tests

1. Does the project involve the collection of tissues, blood, other body fluids or physiological tests? [ ]  Yes / [ ]  No

If yes, complete Section I, otherwise proceed to Section J.

If yes, are the procedures to be used governed by Standard Operating Procedure(s)? If so, please name the SOP(s). If not, identify the procedure(s) and describe how you will minimise the risks associated with the procedure(s)?

Describe the material to be taken and the method used to obtain it. Include information about the training of those taking the samples and the safety of all persons involved. If blood is taken, specify the volume and number of collections.

Will the material be stored? [ ]  Yes / [ ]  No

If yes, describe how, where and for how long.

1. Describe how the material will be disposed of (either after the research is completed or at the end of the storage period).

(Note that the wishes of relevant cultural groups must be taken into account.)

Will material collected for another purpose (e.g. diagnostic use) be used? [ ]  Yes / [ ]  No

If yes, did the donors give permission for use of their samples in this project? (Attach evidence of this to the application form.

If no, describe how consent will be obtained. Where the samples have been anonymised and consent cannot be obtained, provide justification for the use of these samples.

Will any samples be imported into New Zealand? [ ]  Yes / [ ]  No

If yes, provide evidence of permission of the donors for their material to be used in this research.

Will any samples go out of New Zealand? [ ]  Yes / [ ]  No

If yes, state where. (Note this information must be included in the Information Sheet)

Describe any physiological tests/procedures that will be used.

Will participants be given a health-screening test prior to participation? [ ]  Yes / [ ]  No

(If yes, attach a copy of the health checklist)

Section J: DECLARATION (Complete appropriate box)

ACADEMIC STAFF RESEARCH

Academic Staff Applicant

I have read Unitec’s Research Ethics Policy and Research Ethics Guidelines. I understand my obligations and the rights of the participants. I agree to undertake the research as set out in Unitec’s Research Ethics Policy and Research Ethics Guidelines. My Head of Department knows that I am undertaking this research. The information contained in this application is to the very best of my knowledge accurate and not misleading. It has been peer reviewed before submission.

Staff Applicant’s SignatureDate:

Print Name

STUDENT RESEARCH

Student Applicant

I have read Unitec’s Research Ethics Policy and Research Ethics Guidelines and discussed the ethical analysis with my Supervisor. I understand my obligations and the rights of the participants. I agree to undertake the research as set out in Unitec’s Research Ethics Policy and Research Ethics Guidelines.

The information contained in this application is to the very best of my knowledge accurate and not misleading.

Student Applicant’s SignatureDate:

Print Name

SUPERVISOR

I have assisted the student in the ethical analysis of this project. As supervisor of this research I will ensure that the research is carried out according to Unitec’s Research Ethics Policy and Research Ethics Guidelines.

Supervisor’s SignatureDate:

Print Name

HEAD OF DEPARTMENT

I declare that to the best of my knowledge, this application complies with Unitec’s Research Ethics Policy and Research Ethics Guidelines and that I have approved its content and agreed that it can be submitted.

Head of Department SignatureDate:

Print Name