HUMAN RESEARCH ETHICS:
A Handbook for USP Researchers

This Handbook explains the values and principles that guide processes and practices of research involving human participants at the University of the South Pacific.

The ethical values and principles described here apply to all University activities, to all its staff and student researchers including those visiting for short periods, and to any research agreements or partnerships that the University establishes.

The University's human ethics will be compliant with the laws of individual University member states, particularly in relation to privacy, confidentiality, ownership, intellectual property requirements, research permit requirements and human rights.

First Edition

Published by the Research Office

The University of the South Pacific

Printing courtesy of AusAID

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1. Introduction

Research is work undertaken systematically in order to increase knowledge (including knowledge about people, cultures and societies) and to use this knowledge to gain new insights into particular issues. Research may be inter-disciplinary and may involve different approaches and methods.

At the University of the South Pacific, most research is focused on the Pacific region (islands and ocean). It aims to be relevant to the needs of the region, and as such may involve the active participation of Pacific peoples.

Ethics are the moral principles or values held by an organisation, group, or individual that govern their behaviour. For research at the University of the South Pacific, these principles are overt, written down, and underpin relevant policies, processes, and practices of the organisation and the researchers who work within it. This Handbook specifically governs ethics in research involving people; a separate Handbook exists for animal research ethics.

Human ethical policies are needed not only to guide research processes and practices but also to protect researchers and the institutions where they work. They are also necessary to protect the rights and well-being of both research participants and of the communities and countries in which research is conducted.

2. Ethical Principles

Ethical principles relating to research involving people are intended to protect, maintain and sustain individuals and communities, and to recognise the legitimacy of their knowledge and world views. The ethical principles listed below incorporate universal principles, which guide ethical research involving people everywhere, and those that are considered to be specific to the Pacific region, which should additionally guide research by persons at the University of the South Pacific.

2.1. Respect for human dignity, human rights and fundamental freedoms

All research conducted by persons affiliated with the University of the South Pacific will give due respect to human dignity, human rights and fundamental freedoms.

2.2. Maximising benefit and avoiding harm to humans

All research conducted by persons affiliated with the University of the South Pacific will make every effort to maximise its benefits to individuals and communities and avoid any harm to them as a result of the research, either during the research process or after it has been completed.

2.3. Sensitivity to Pacific context

All research conducted by persons affiliated with the University of the South Pacific will be sensitive to the contexts of Pacific Islands research, particularly in respect of the following four values:

2.3.a. Respect

Respect is fundamental to all ethical relationships in the Pacific. Respect acknowledges the primacy of the group but at the same time it recognises the individual as a valued member of the group. Respect in its practice is always context-specific and varies in its interpretation and usage even within the same cultural context. Respect is demonstrated through humility and is reciprocal.

2.3.b. Cultural competency

Researchers must understand the rudiments of the cultures in which they are working. Cultural competency involves this understanding but also acknowledges that researchers and research participants often bring to the research exercise their own cultural beliefs, values and practices. Researchers must be aware of how these influence their engagements with the people they are studying.

2.3.c. Meaningful engagement

Meaningful engagement between the researchers and research participants requires developing, maintaining, and sustaining relationships which involve mutual trust. This is not something that can be hurried. All protocols that normally apply to visitors from within the same culture must be followed when engaging individuals and communities for a research project, even though the researcher(s) may not be part of that culture.

2.3.d. Utility

An important aim of research at the University is to assist Pacific communities and states meet their needs and achieve their aspirations while, at the same time, achieving international recognition in areas that reflect the University's geographical and cultural contexts. Research involving human informants or subjects will be expected to lead to practical outcomes of benefit to Pacific communities. Every attempt must therefore be made to engage these communities in ways that ensure the utility of the research. One desired way of achieving this is reporting research outcomes in the languages of the participating communities to ensure its understanding and dissemination.

2.4. Consent

All research conducted by persons affiliated with the University of the South Pacific will be carried out only with the prior, free, and informed consent of all persons concerned, whether individuals or communities, based on adequate information. The consent may be withdrawn by a particular individual or community at any time for any reason without disadvantage or prejudice.

The request for consent will be appropriate to the circumstances although it is recognised that cultural and educational barriers may inhibit some projects from being fully comprehended by human subjects. In such cases, the University's Research Ethics Committee will advise on the necessary minimum level of informed consent.

2.5. Respect for human vulnerability and personal integrity

In the process of applying and advancing scientific knowledge, all research conducted by persons affiliated with the University of the South Pacific will identify and acknowledge those individuals and groups that are especially vulnerable and ensure that they are protected and their personal integrity is respected.

2.6. Privacy and confidentiality

All research conducted by persons affiliated with the University of the South Pacific will respect, as agreed in advance, the privacy of participants in research activities and the confidentiality of any information that they supply. Information obtained during research should not normally be used in ways or disclosed for purposes other than those for which it was collected.

2.7. Equality, justice and equity

All research conducted by persons affiliated with the University of the South Pacific will acknowledge the dignity and the rights of all participants in research activity and ensure that they are treated justly and equitably.

2.8. Non-discrimination and non-stigmatisation

All research conducted by persons affiliated with the University of the South Pacific will ensure that no individual or group is discriminated against or stigmatised on any grounds in violation of human dignity, human rights and fundamental freedoms.

2.9. Respect for cultural diversity and pluralism

All research conducted by persons affiliated with the University of the South Pacific will respect cultural diversity and pluralism, especially in recognition of the cultural diversity of the Pacific. Such considerations will not be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon any of the other ethical principles expressed here.

2.10. Social responsibility and sustainable futures

All research conducted by persons affiliated with the University of the South Pacific will endeavour to promote the well-being and sustainability of Pacific cultures and environments.

2.11. Sharing of benefits

All research conducted by persons affiliated with the University of the South Pacific will ensure that any resulting benefits and applications will be shared with Pacific peoples and states for their benefits, as well as the international community.

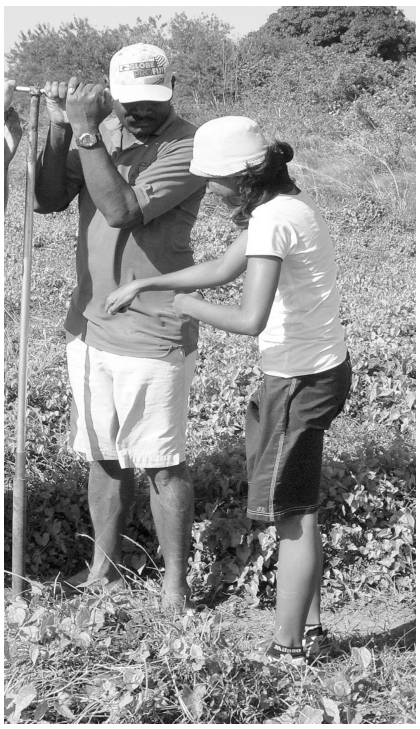
2.12. Protection of the environment, biosphere and biodiversity

All research conducted by persons affiliated with the University of the South Pacific will pay due regard to the connections and relationships among human beings, the environment and other forms of life. In the Pacific context, these relationships include traditional knowledge and skills, appropriate access to and utilisation of resources.

There are complex and difficult ethical issues relating to many research activities in these areas. The University will engage with appropriate bodies among its member states and externally to ensure that ethical issues relating to research in medical science, science and technology that impact on Pacific peoples, communities, their environments and resources, are adequately and effectively addressed.

2.13. Ethical decision-making and transparency

In all its teaching and research activities, the University will promote professionalism, honesty, integrity, respect and transparency. Conflicts of interests will be declared. Knowledge will be appropriately shared.



3. The University Research Ethics Committee (UREC)

The University Research Ethics Committee at the University of the South Pacific is chaired by the Pro Vice-Chancellor (Research and Innovation) or nominee, and comprises one representative from each Faculty with experience of the ethical conduct of research in the Pacific. The University Research Ethics Committee will generally consider applications only at the times of its scheduled meetings. These will usually be two weeks in advance of the meetings of the University Research Committee so that submissions approved by the Ethics Committee can be considered by the Research Committee.

The Terms of Reference for the University Research Ethics Committee at the University of the South Pacific are as follows:

(a) Receive all applications for research at the University which involve people or animals as subjects of research, judge whether the proposed research follows all pertinent ethical principles;

(b) Actively promote all ethical principles outlined above (in Section 2);

(c) Provide advice on ethical challenges in research and teaching at the University;

(d) Assess research and teaching developments within the University and its member states, periodically make recommendations, and contribute to the preparation of guidelines on ethical issues important to the University and its member states;

(e) Develop guidelines for addressing conflicts that may arise within the University;

(f) Recommend sanctions and penalties consistent with other University discipline procedures to be imposed in cases of ethical infringements; and,

(g) Advise on appropriate appeals processes that are also consistent with those existing within the University.

In association with the Office of the Pro Vice-Chancellor (Research and Innovation), the University Research Ethics Committee will also spearhead training in ethical practices for researchers at the University and others.

4. Ethical responsibilities of researchers at the University

Staff researchers should be aware of the ethical principles they are required to bring to all their research activities, including those of the students whose research they oversee. Staff researchers should also communicate to research collaborators from outside the University the nature and scope of its ethical principles, and the importance that the University attaches to their adherence.

In particular, every researcher at the University should acknowledge and understand the Pacific context within which they are working. They should be sensitive to the needs and aspirations of Pacific communities and states, they should evince respect for Pacific knowledge systems and methodologies, and they should be bound as far as possible by all traditional protocols when dealing with Pacific peoples. Researchers who are unfamiliar with Pacific cultures should seek advice from appropriate persons before developing research proposals dealing with human subjects.

Every staff and student researcher at the University who is proposing research involving people must receive approval (in writing) from the University Research Ethics Committee before commencing that research. No researcher from the University should begin a research project involving humans unless an appropriate agreement with the persons/communities to be studied has been reached.

5. Procedures for applying for ethical clearance of proposed research

Any research project dealing with human subjects that is proposed to be undertaken under the auspices of the University of the South Pacific, whether by full-time or affiliate staff or students, is required to have ethical approval before commencing. Procedures are essentially the same for academic staff and for students.

Researchers at the University of the South Pacific, whether staff or students, whether full-time, temporary or affiliate, are required to complete the Screening Questionnaire for every new research project that they propose to undertake. Where several staff and students of the University are involved in a single project, only the lead researcher needs to complete the Screening Questionnaire.

A sample **Screening Questionnaire** is given in Appendix 1 for information only. Researchers should always download the current Screening Questionnaire from www.usp.ac.fj/research/ethics in case it has changed from that in Appendix 1.

The Screening Questionnaire is intended to ascertain whether or not a researcher needs to have their proposed project given ethics approval. Researchers should answer all questions honestly, and should seek advice if they are in doubt about what to answer. Once the Screening Questionnaire is complete, it should be submitted to the appropriate Faculty representative on the University Research Ethics Committee.

If all answers are NO, then generally there is no further need for human ethics approval, and the project can proceed. A decision on this will be approved by the Faculty Research Committee. The Screening Questionnaire will be kept on file, and the researcher should indicate in their full proposal that no ethics approval was required given the results of this exercise. If any answers on the Screening Questionnaire are YES, then the researcher must complete a full submission to the University Research Ethics Committee on the **Application for Human Ethics Approval** form provided (sample in Appendix 2).

This form requires a lot more information about the proposed project from the researcher and should be submitted, when complete, to the appropriate Faculty representative on the University Research Ethics Committee who will then make a recommendation, perhaps liaise directly with the researcher, before passing it on to the full Committee for their review. Researchers should note that the University Research Ethics Committee does not wish to discourage research involving humans, but is mandated to ensure that all such research is ethically sound.

Where research involving human subjects/participants is proposed by a researcher at the University of the South Pacific, agreement must be obtained from a fraction of those subjects or their spokespersons in advance of the proposal being submitted to the University Research Ethics Committee, who will require written evidence of such an agreement. This is best accomplished by the production of an **Information Sheet** which explains the nature of the proposed research to potential participants (model in Appendix 3). Where appropriate, this must be translated into a language that is readily comprehended by potential participants. The rights of participants must be emphasised, their questions all satisfactorily answered. Under no circumstances should participants be paid a fee for their involvement in the research project, although any expenses they incur, including subsistence costs, and any costs of traditional gifts appropriate in particular cultural contexts are allowed.

Potential participants who agree to be involved in the study must all complete a **Consent Form** (model in Appendix 4). Where a community is the subject of research, it is acceptable in a Pacific Islands context for a recognised leader or spokesperson for that group to sign a consent form on behalf of the group. Where possible, all completed consent forms must be obtained before the research commences but the University Research Ethics Committee will accept a fraction of these so long as it is clear that the rest will be forthcoming before research commences.

Persons other than the Lead Researcher who are associated with a research project involving humans that requires ethical approval must sign a **Confidentiality Agreement** whereby they agree to keep confidential all information concerning the project (model in Appendix 5). This agreement must be signed by each co-researcher who will have access to personal data before they begin work on the project.

Researchers should destroy personal data (including biological samples) collected for research projects involving humans after a maximum of ten years from the start of the project unless specific permission is given by the University Research Ethics Committee.

The University Research Ethics Committee will provide guidance and support to satisfactorily address any conflicts that may arise between the student, the supervisor, research participants and communities in the course of research. Deliberate or avoidable breaches of the ethical principles for human research of the University of the South Pacific will be reported by the University Research Ethics Committee for appropriate action.

Appendix 1. Screening Questionnaire for Human Ethics (sample)

The purpose of this questionnaire is to determine whether or not your proposed research project requires approval by the University Research Ethics Committee. Once completed, it should be passed to your Faculty Representative on the University Research Ethics Committee who will advise you of the next step.

Name/Section:

Project Title:

I certify that with respect to this research project I have read the Human Ethics Handbook and understand the ethical principles listed therein. My answers to the following questions are informed by my understanding of these principles.

Signed _____(Lead Researcher)

Date

If you are a student, your supervisor must sign below to indicate that they have counselled you about human ethics issues in your research, and agree that you have completed this Screening Questionnaire as accurately as you can.

Signed _____(Student's supervisor)

Date

Does your Project involve any of the following?

(Please circle YES or NO for each question)

1.	Situations in which the researcher may be at risk of harm from human participants	**YES NO**
2.	Use of questionnaire of interview (anonymous or not) which might reasonably be expected to cause discomfort, embarrassment, or psychological or spiritual harm to the participants	**YES NO**
3.	Processes that are potentially disadvantageous to a person or group, such as the collection of information which may expose the person or group to discrimination	**YES NO**
4.	Collection of information about illegal behaviour gained during the research which could place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, professional or personal relationships	**YES NO**
5.	Collection of any blood, body fluid, tissue samples, or other samples	**YES NO**
6.	Any form of exercise regime, physical examination, deprivation (e.g. sleep, dietary)	**YES NO**
7.	The administration of any form of drug, medicine, placebo	**YES NO**
8.	Physical pain, beyond mild discomfort	**YES NO**
9.	Any demonstration of procedures or phenomena having a potential for harm which involves the participation of students of the University of the South Pacific	**YES NO**
10.	Participants whose identity is known to the researcher giving oral consent rather than written consent (if participants are anonymous, you may answer No)	**YES NO**
11.	Participants who are unable to give informed consent	**YES NO**
12.	Research on your own students	**YES NO**
13.	The participation of children younger than 7 years	**YES NO**
14.	The participation of children younger than 16 years where parental consent is not being sought	**YES NO**
15.	Participants who are in a dependent situation, such as people with a disability, residents of a hospital, nursing home or prison, or persons highly dependent on medical care	**YES NO**
16.	Participants who are vulnerable	**YES NO**
17.	The use of previously collected information or biological samples for which there was no explicit consent for this research from the participants	**YES NO**
18.	Any evaluation of the services or organisational practices of the University of the South Pacific where information of a personal nature may be collected and where participants may be identified	**YES NO**
19.	Deception of the participants, including concealed and covert observations	**YES NO**
20.	Conflict of interest situation for the researcher (e.g. is the researcher also the lecturer/teacher/colleague or treatment provider or employer of the research participants, or is there any other power relationship between the researcher and research participants?)	**YES NO**
21.	Payments or other financial inducements (other than reasonable reimbursement of travel expenses or time) to participants	**YES NO**
22.	A requirement by an outside organisation (e.g. a funding organisation or a journal in which you wish to publish) for approval by the University Research Ethics Committee	**YES NO**

If you answered YES to any of these questions, then you need to submit an Application for Human Ethics Approval (available at www.usp.ac.fj/research/ethics, sample shown in Appendix 2).

Even if you answered NO to all the questions above, this Screening Questionnaire must still be submitted to your Faculty representative on the University Research Ethics Committee who reserves the right to discuss your research with you and, in some cases, may require you to complete an Application for Human Ethics Approval.

Appendix 2. Application for Human Ethics Approval (sample)

The University of the South Pacific

Office of the Pro Vice-Chancellor

(Research and Innovation)

Faculty:

Application No: _____/_____

This number is assigned when your application is accepted. Quote on all documentation to participants and the Committees

HUMAN ETHICS APPLICATION

FOR APPROVAL OF PROPOSED RESEARCH INVOLVING LIVE HUMANS

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

SECTION A

1. Project Title _____

Projected start date for data collection _____

Projected end date _____

Approval will not be given if recruitment and/or data collection has already begun

2. Applicant Details (Select either ACADEMIC STAFF or STUDENT APPLICATION and complete details)

ACADEMIC STAFF APPLICATION (excluding staff who are also students)

Full name of Staff Applicant	
Faculty/School/Division	
Campus where you are based (name one only)	
Telephone	Email Address

STUDENT APPLICATION

Full Name of Student Applicant	
Employer (if applicable)	
Telephone	Email Address
Postal Address	
Full Name of USP Supervisor(s)	
School/Division/Institute	
Campus where supervisor is based (name one only)	
Supervisor's Telephone	Supervisor's Email Address

3. Type of Project (tick one only)

❍ Academic staff research

❍ Student Research (Masters or PhD)

❍ Student Research (in-course or independent)

If other, please specify:

4. Summary of Project

Please outline in no more than 200 words in lay language why you have chosen this project, what you intend to do, and the methods you will use. Be sure to name all the countries in which you will gather data from human subjects.

5. List any attachments to your Application,

e.g. Completed "Screening Questionnaire (if not already submitted), Information Sheet/s (indicate how many), Consent Forms (indicate how many completed), Questionnaire, Interview Schedule, Evidence of Consultation, Confidentiality Agreement, Other (please specify).

Applications that are incomplete or lacking the appropriate signatures will not be processed. This will mean delays for the project. Please refer to the Ethics website (www.usp.ac.fj/research/ethics) for details of where and how to submit your application.

SECTION B: PROJECT INFORMATION

General

6. For staff research, is the applicant the only researcher? ❍ Yes ❍ No

   If no, list the names and affiliations of all members of the research team.

7. State concisely the aims of the project

8. Give a brief background to the project to place it in perspective and to allow the project's significance to be assessed. (no more than 200 words in lay language)

9. Outline the research procedures to be used, including approach/procedures/manipulations for collecting data.

10. Where will the project be conducted? Include information about the physical location/setting.

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

12. Describe the process that has been used to discuss and analyze the ethical issues present in this project.

Participants

13. Describe the intended participants

14. How many participants will be involved?

What is the reason for selecting this number?

15. Describe how potential participants were identified and recruited?

16. Who made the initial approach to potential participants?

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

Data Collection

18. Does the project include use of participant questionnaire/s? ❍ Yes ❍ No

(If yes, attach a copy of the Questionnaire/s to the application form and include this in your list of attachments (Q5))

If yes: i) Indicate whether the participants will be anonymous, ❍ Yes ❍ No
(i.e their identity will remain unknown to the researcher).

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

19. Does the project involve observation of participants? ❍ Yes ❍ No

If yes, please describe the precise nature of this.

20. Does the project include the use of focus group/s? ❍ Yes ❍ No

If yes, describe the location of the focus group and time length.

21. Does the project include the use of participant interview/s? ❍ Yes ❍ No

(If yes, attach a copy of the Interview Questions/Schedule to the application form, and, describe the location of the interview and time length).

22. Does the project involve sound recording? ❍ Yes ❍ No

23. Does the project involve image recording, e.g. photo or video? ❍ Yes ❍ No

If yes, describe.

24. If recording is used, will the record be transcribed? ❍ Yes ❍ No

If yes, state who will do the transcribing.

25. Does the project involve any other method of data collection not covered in Questions 18-24 ❍ Yes ❍ No

If yes, describe.

26. Who will carry out the data collection?

SECTION C: BENEFITS/RISK OF HARM

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

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

29. Describe the strategies you will use to deal with any of the situations identified in Q28?

30. What is the risk of harm (if any) of the project to the researcher?

31. Describe the strategies you will use to deal with any of the situations identified in Q30.

32. 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?

33. Describe the strategies you will use to deal with any of the situations identified in Q32?

34. Is ethnicity data being collected as part of the project? ❍ Yes ❍ No

If yes, will the data be used as a basis for analysis? ❍ Yes ❍ No

If yes, explain.

35. 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)*

SECTION D: INFORMED AND VOLUNTARY CONSENT

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

37. 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.

38. Will participants include persons under the age of 16? ❍ Yes ❍ No

If yes, i) indicate the age group and competency of giving consent.

ii) indicate 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)

39. Will participants include persons whose capacity to give informed consent may be compromised? ❍ Yes ❍ No

If yes, describe the consent process you will use.

40. Will the participants be proficient in English? ❍ Yes ❍ No

If no, all documentation for the participants (Consent Forms/Questionnaire etc) should be translated into the participants' first language(s).

(Attach copies of the translated forms to the application form)

SECTION E: PRIVACY/CONFIDENTIALITY ISSUES

41 Will any information be obtained from any source other than the participant? ❍ Yes ❍ No

If yes, describe how and from whom.

42. Will any information that identifies participants be given to any person outside the research team? ❍ Yes ❍ No

If yes, indicate why and how.

43. Will the participants be anonymous (i.e. their identity unknown to the Researcher?) ❍ Yes ❍ No

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

44. 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 have made the institution aware of this?

45. Outline how and where:

i) the data will be stored, and (pay particular attention to identifiable data, e.g. tapes, videos and images)

ii) Consent forms will be stored.

(note that Consent Forms should be stored separately from data)

46. i) Who will have access to the data/Consent Forms?

ii) How will the data/Consent Forms be protected from unauthorized access?

SECTION F: DECEPTION

47. Is deception involved at any stage of the project? ❍ Yes ❍ No

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

SECTION G: CONFLICT OF ROLE/INTEREST

48. Is the project to be funded in any way from sources external to the University of the South Pacific ❍ Yes ❍ No

If yes: i) state the source(s)

ii) does the source(s) of the funding present any conflict of interest with regard to the research topic? ❍ Yes ❍ No

49. Does the researcher/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

50. Describe any professional or other relationships between the researcher and the participants? (e..g. employer/employee, lecturer/student, practitioner/patient, researcher/family member). Indicate how any resulting conflict of role will be dealt with.

SECTION H: COMPENSATION OF PARTICIPANTS

51. Will any payments 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 attached to this application).

SECTION I: CULTURAL ISSUES

52. Are there any aspects of the project that might raise specific cultural issues? ❍ Yes ❍ No

If yes, explain. Otherwise, proceed to Section J.

53. What ethnic or social group/s does the project involve?

54. Does the researcher speak the language of the target population? ❍ Yes ❍ No

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

55. Describe the cultural competence of the researcher for carrying out the project.

(Note that where the researcher is not a member of the cultural group being researched, a cultural adviser may be necessary)

56. 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 the application form)

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

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

SECTION J: SHARING RESEARCH FINDINGS

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

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

SECTION K: INVASIVE PROCEDURES/PHYSIOLOGICAL TESTS

60. Does the project involve the collection of tissues, blood, other body fluids or physiological tests? ❍ Yes ❍ No

(If yes, complete Section L, otherwise proceed to Section M)

61. 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.

62. Will the material be stored? ❍ Yes ❍ No

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

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

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

64. 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? ❍ Yes ❍ No

(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.

65. Will any samples be imported into the country where you are based? ❍ Yes ❍ No

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

66. Will any samples go out of the country where you are based? ❍ Yes ❍ No

67. Describe any physiological tests/procedures that will be used.

68. Will participants be given a health-screening test prior to participation? ❍ Yes ❍ No

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

Reminder

Attach the completed Screening Questionnaire (if not already submitted) and other attachments listed in Q5

SECTION L: DECLARATION (Complete appropriate section)

ACADEMIC STAFF RESEARCH

Declaration for Academic Staff Applicant

I have read the Human Ethics Handbook of the University of the South Pacific. I understand my obligations and the rights of the participants. I agree to undertake the research as set out in the Human Ethics Handbook. My Head of Division/School/Institute (delete as appropriate) knows that I am undertaking this research. The information contained in this application is to the best of my knowledge accurate and not misleading.

Staff Applicant's Signature _____ Date _____

STUDENT RESEARCH

Declaration for Student Applicant

I have read the Human Ethics Handbook of the University of the South Pacific and discussed the ethical issues surrounding my project with my Supervisor. I understand my obligations and the rights of the participants. I agree to undertake the research as set out in the Human Ethics Handbook. The information contained in this application is to the best of my knowledge accurate and not misleading.

Student Applicant's Signature _____ Date _____

Declaration of 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 accordingly to the Human Ethics Handbook of the University of the South Pacific.

Supervisor's Signature _____ Date _____

Print name _____

Appendix 3. Information Sheet (model)

An Information Sheet is targeted at each group of potential research participants and is intended to give them all the information they need to make an informed decision about whether or not to participate in your research project.

The Information Sheet must be understandable by the target group; it must be written in readily understandable language appropriate to the general educational level; it must be in a language that the target group understands and, in some situations in the Pacific Islands, this may not be English.

The Information Sheet must be separate from the Participant Consent Form. The intention is to inform potential participants what the project is about and what will be required of them should they consent to be involved. Sufficient time must be allowed for potential participants to digest the information in the Information Sheet, to discuss it and reach a decision about whether or not to become involved, before Consent Forms are handed out.

A typical Information Sheet might be in the following form, but adapt this as needed for your project.

1. **Information Sheet**

   Give project title.

2. **Researcher(s)**

   Give the names of the researcher(s), affiliations, supervisors (if student researcher), and relevant experience and qualifications.

3. **Project Description and Invitation**

   Give a brief summary of the project, and an invitation to participate in it.

4. **Participant Role**

   Give details of the number of participants and whether or not identities will be collected. Give details of any discomforts or risks involved. Give details of any compensation offered to participants for their participation.

5. **Project Procedures**

   Describe what will the participants be expected to do, the time involved, and other pertinent details.

6. **Data Management**

   Explain how the data gathered will be used, stored and disposed. Explain how participants will be able to access the project findings after the project is complete.

7. **Participant's Rights**

   Where participants will be identified, the following Statement of Rights must be included.

   "You are under no obligation to accept this invitation. If you decide to participate, you have the right to:

   - decline to answer any particular question;
   - withdraw from the study (specify timeframe);
   - ask any questions about the study at any time during participation;
   - provide information on the understanding that your name will not be used unless you give permission for this to the researcher;
   - be given access to a summary of the project findings when the project is concluded."

If recording interviews, include the statement:

- "ask for the recorder to be turned off at any time during the interview."

If an anonymous questionnaire is being used, replace the above Statement of Rights with the following:

- Completion and return of the questionnaire implies consent. You have the right to decline to answer any particular question.

8. Project Contacts

Include the names and contact details of the researcher.

Appendix 4. Participant Consent Form (model)

The University of the South Pacific and Faculty/School letterhead

Researcher's name

Contact address

Date

CONSENT FORM

Name of Project

I have read and understood the Information Sheet pertaining to the above-named project. On this basis I agree to participate as a subject in the project. I consent to publication of the results of the project on the understanding that my anonymity is preserved.

I understand that at any time I may withdraw from the project, as well as withdraw any information that I have provided.

I note that this project has been reviewed and approved by the University Research Ethics Committee at the University of the South Pacific.

NAME (please print)

Signature

Date

(where appropriate) I am signing this Consent Form on behalf of the

whom I represent in the capacity of

(where appropriate) I am signing this Consent Form as parent/caregiver on behalf of

Age (_____years)

to allow her/him to participate in this project.

Appendix 5. Confidentiality Agreement (model)

The University of the South Pacific and Faculty/School letterhead

Researcher's name

Contact address

Date

CONFIDENTIALITY AGREEMENT

Name of Project

I agree to keep confidential all information concerning this project. I shall not retain or copy any information about this project.

NAME (please print)

_____

Signature

_____

Date

_____