**Screening Questionnaire for Human Ethics**

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:** Click here to enter text.

**Project Title:** Click here to enter text.

**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:** Click here to enter a 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: [Principal Supervisor]**

**Date:** Click here to enter a date.

Does your Project involve any of the following?

(Please choose either 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 behavior 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.**

**The University of the South Pacific**

**Office of the Deputy Vice-Chancellor [Research, Innovation, and International]**

**Faculty:** Choose an item.

**Application Number:** Click here to enter text.

**HUMAN ETHICS APPLICATION**

**FOR APPROVAL OF PROPOSED RESEARCH INVOLVING HUMANS**

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

**Section A**

1. **Project Title:** Click here to enter text.

**Projected start date for data collection:** Click here to enter a date.

**Projected end date:** Click here to enter a date.

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

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

ACADEMIC STAFF APPLICATION (excluding staff who are also students)

**Full Name of Applicant:** Click here to enter text.

**Faculty/School/Division:** Click here to enter text.

**Campus Location:** Click here to enter text.

**Telephone Contact:** Click here to enter text. **Email:** Click here to enter text.

STUDENT APPLICATION

**Full Name of Applicant:** Click here to enter text.

**Employer Name [if applicable]:** Click here to enter text.

**Telephone Contact:** Click here to enter text. **Email:** Click here to enter text.

**Postal Address:** Click here to enter text.

**Full Name of USP Supervisor(s):** Click here to enter text.

**School/Division:** Click here to enter text.

**Faculty:** Click here to enter text.

**Campus Location of the Supervisor:** Click here to enter text.

**Supervisor’s Telephone:** Click here to enter text. **Supervisor’s Email:** Click here to enter text.

1. **Type of Project (tick one only)**

[ ] **Academic staff research**

[ ] **Student research [Masters or PhD]**

[ ] **Student Research [in-course or independent]**

[ ] **Teaching**

**If other, please specify:** Click here to enter text.

1. **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.**

1. **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).**

**Section B**

**General**

1. **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.**

1. **State concisely the aims of the project**
2. **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)**
3. **Outline the research procedures to be used, including approach/procedures/manipulations for collecting data.**
4. **Where will the project be conducted? Include information about the physical location/setting.**
5. **Describe the experience of the researcher and/or supervisor to undertake this type of project?**
6. **Describe the process that has been used to discuss and analyze the ethical issues present in this project.**
7. **Describe the intended participants**
8. **How many participants will be involved? What is the reason for selecting this number?**
9. **Describe how potential participants will be identified and recruited?**
10. **Who will make the initial approach to potential participants?**
11. **How much time will participants have to give to the project?**

**Data Collection**

1. 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:

1. indicate whether the participants will be anonymous [ ] Yes [ ]  No
2. describe how the questionnaire will be distributed and collected.
3. Does the project involve observation of participants? [ ] Yes [ ]  No

If yes, please describe the precise nature of this:

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

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

1. 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).

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

If yes, describe:

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

If yes, state who will do the transcribing

1. Does the project involve any other method of data collection not covered in Questions 18-24? [ ] Yes [ ]  No
2. Who will collect the data?

SECTION C: BENEFITS/RISK OF HARM

1. What are the possible benefits (if any) of the project to individual participants, groups, communities and institutions?
2. What discomfort (physical, psychological, social), incapacity or other risk of harm are individual participants likely to experience as a result of participation?
3. Describe the strategies you will use to deal with any of the situations identified in Q28?
4. What is the risk of harm (if any) of the project to the researcher?
5. Describe the strategies you will use to deal with any of the situations identified in Q30.
6. 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?
7. Describe the strategies you will use to deal with any of the situations identified in Q32?
8. 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:

1. 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

1. By whom and how, will information about the proposed research be given to potential participants?
2. Will consent to participate be given in writing? [ ]  **Yes** [ ]  **No**

If no, justify the use of oral consent

1. 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 when children are competent. Ensure Information Sheets and Consent Forms are in a style and language appropriate for the age group)

1. Will participants include persons whose capacity to give informed consent may be compromised? [ ] **Yes** [ ]  **No**

If yes, describe the consent process you will use

1. Will the participants be proficient in English? [ ] **Yes** [ ]  **No**
2. If no, all documentation for the participants (Consent Forms/Questionnaire etc.) should be translated into the participants’ first language(s).

SECTION E: PRIVACY/CONFIDENTIALITY ISSUES

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

If so, give details:

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

If yes, indicate why and how:

1. Will the participants be anonymous (i.e. their identity unknown to the Researcher)?

[ ]  **Yes** [ ]  **No**

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

1. Will an institution (e.g. school) to which participants belong to 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 information will be stored.

1. the data will be stored, and (pay particular attention to identifiable data, e.g. tapes, videos and images)
2. 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 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 the varying out the project. (Note that where the researcher is not a member of the cultural group being researched, a cultural adviser may be necessary)

SECTION J: CONSULTATION

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 group/s consulted.

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 K, 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 the storage period).

(Note that the wishes if 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? (Attach evidence of this to the application form) [ ]  **Yes** [ ]  **No**

If no, describe how consent will be obtained. Where the samples have been anonymized 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

SECTION L: DECLARATION (Complete appropriate section)

**ACADEMIC STAFF RESEARCH**

Declaration by Academic Staff Applicant

I have read the Human Ethics Handbook of The University of the South Pacific. I understand my obligations and rights of the participants. I agree to undertake the research as set out in the obligations and 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 by 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 rights of the participants. I agree to undertake the research as set out in the obligations and 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.

Staff Applicant’s Signature Date

**INFORMATION SHEET**

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.

Participant Consent Form (model)

The University of the South Pacific and Faculty/School letterhead

**Researcher Name**

**Contact Address**

**Date**

CONSENT FORM

**Name of Project**

I have read and understood the Information Sheet describing the above-named project. I agree to participate as a subject in the project. I consent to publication of the results of the project/the information given to me 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)

Click here to enter text.

Signature Date

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

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.

Confidentiality Agreement (The University of the South Pacific and Faculty/School letterhead)

**Researcher 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)

Click here to enter text.

Signature Date