**PROPOSAL APPLICATION FORM**

**FOR ETHICAL APPROVAL OF HEALTH RESEARCH INVOLVING ABORIGINAL PEOPLE**

**A. RESEARCHERS INFORMATION**

**\* If there is more than one researcher, please indicate who should receive correspondence.** Do this by double-clicking on the small box (i.e. [ ]  ). A dialogue box will appear. Under the ‘Default Value’ sub-heading click in the ‘Checked’ option.

**\*\* PRINCIPAL RESEARCHER**

**Title:** Click here to enter text. **First Name:** Click here to enter text.**Family Name:** Click here to enter text.

**Organisation:** Click here to enter text. **Check box to receive correspondence\*** **[ ]**

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

**Phone:** Click here to enter text. **Fax:** Click here to enter text. **Email:** Click here to enter text.

**OTHER RESEARCHERS/SUPERVISORS**

***Researcher 2 or* *Principal Supervisor***

**Title:** Click here to enter text.**First Name:** Click here to enter text. **Family Name:** Click here to enter text.

**Organisation:** Click here to enter text. **Check box to receive correspondence\* [ ]**

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

**Phone:** Click here to enter text. **Fax:** Click here to enter text. **Email:** Click here to enter text.

***Researcher 3 / Supervisor***

**Title:** Click here to enter text.**First Name:** Click here to enter text. **Family Name:** Click here to enter text.

**Organisation:** Click here to enter text. **Check box to receive correspondence\* [ ]**

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

**Phone:** Click here to enter text. **Fax:** Click here to enter text. **Email:** Click here to enter text.

*\*\*If there are more researchers/supervisors involved in the project please add their names and contact details into Appendix A.*

**B. TITLE, LOCATION & TIME FRAME**

**B1. Title:**

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**B2. Location of research:**

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**B3. Period for which approval is sought:**

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| --- | --- |
| Date data collection is planned to commence:  | / / |
| Important Note – data collection *cannot* commence until final ethics approval has been granted by the AHREC. | Or following approval:  |  |
| Date data collection is expected to be completed: |  |
| Date project is expected to be completed: |  |

**C. RESEARCH DETAILS - *(Note: Maximum 300 words)***

**C1. What are the hypothesis / aims and objectives of the research?** *What research hypothesis is being investigated? What benefits does the study aim to produce?*

**C1.1 Hypothesis / Aims:**

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 **C1.2 Objectives:**

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**C2. Why is this research significant?**

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 **C3.** **What benefits will it provide to Aboriginal people?**

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**D. ABORIGINAL ORGANISATION(S), CONSULTATION PROCESS, PERMISSIONS & CAPACITY BUILDING**

**D1. What consultation process and permissions has occurred to fully inform Aboriginal organisation(s) and/or relevant** **Aboriginal community Elders, leaders and/or community-recognised spokespersons about the research project?**

*As an Appendix provide a list of the Aboriginal organisations and their contact details, as well as the number (but no names or contact details) of Elders, leaders and/or spokespersons that have been consulted. Permissions should be sought, in the first instance, from the Chief Executive Officer or Head of an organisation or governing body unless adequate justification can be provided that contextual circumstances require a different approach.*

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**D2. Indicate any other permissions required from, or involvement of, other people (employers, school principals, teachers, parents, guardians, carers, etc.) and attach letters requesting permission as well as copies of permission letters.**

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**D3. Will this study seek to employ and/or train Aboriginal people as members of the study team?**

**Yes [ ]  No [ ]**

**D3.1. If NOT, please tell us why not.**

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**D3.2 If YES, how many Aboriginal people will there be employed and/or trained in this study?**

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**D3.3 Describe the role Aboriginal people will play as members of the study team?**

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 **D3.4 If training is being provided, please describe the type of training and who is providing it?**

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**E. HEALTH RESEARCH INVOLVING THE PRIVACY ACT 1988**

**E1 Is the research related to medical or health matters?**

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| --- | --- | --- |
| Yes |  | *Noting that this is a question in relation to health research involving the Privacy Act 1988, place letter ‘X’ in the relevant box.*  |
| No |  |

If **YES** to **E1** above, go to question **E1.1** below; if **NO**, please ensure that the scope of the study is health related before submission and go to item **F1**.

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| **E1.1** Will the research involve the collection of ‘personal information’ (information or an opinion from which the identity of a person is evident, or could reasonably be ascertained, including by combining the information collected with other information). |
| Yes |  | *Place letter ‘X’ in the relevant box.* If **YES**, complete **Appendix B ‘Privacy Legislation Matters’** that relates to compliance with the Guidelines under the Privacy Act 1988.If NO, *go to item* ***F1****.*  |
| No |  |

**F. STUDY PLAN & DESIGN – *(Note: Maximum 300 words)***

**F1. Outline the study plan and design.**

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**F2. Provide a detailed description of all planned interactions between researchers and study participants.**

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**F3. How are data to be obtained primarily? Please check the relevant response box.** ***Interview guide(s), questionnaire(s), survey(s) (etc.) that will be used are to be included in the Appendices.***

**Data Type** *Place letter ‘X’ in the relevant box*

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| --- | --- | --- | --- | --- | --- |
| Is DATA to be obtained primarily | **Quantitative**  |  | **Qualitative**  |  |  |
| Is information to be sought by | Questionnaire  |  | Interview  |  | If OTHER, please state: |
|  | Experiment  |  | Computer / Online  |  |
|  | Focus Group  |  | Secondary analysis of data  |  |
|  |  |  | Other |  |

**Recording / Observation**

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| --- | --- | --- | --- | --- |
| Will participants be video, audio recorded, photographed or observed? | Video |  |  |  |
| Audio |  |  |  |
| **If YES,** please place a letter ‘x’ in the relevant response box or boxes and outline what will be recorded or observed. | Photographed |  |  |  |
| Observed |  |  |  |

**Will case-notes be accessed for the purpose of this research?**

|  |  |  |
| --- | --- | --- |
| Yes |  | *Place letter ‘X’ in the relevant box* |
| No |  |

**If YES,** who owns the case-notes?

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 **G. PARTICIPANTS & RECRUITMENT - *(Note: Maximum 300 words)***

**G1. Who will be the participants?**

* **Source:**
* **Number:** *Please specify the* ***number*** *or an approximation if the exact number is not known.*Click here to enter text.
* **Age range:** Click here to enter text.

**G2. What are the selection and exclusion criteria for recruitment to the study?**

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**G3. Are any participants under 18 years of age?** \*Please refer to instructions described above.

**Yes** **[ ]  If YES, what is the age range?** Click here to enter text. **No** **[ ]**

**G4. Do participants have the ability to give informed consent?**

**Yes [ ]  No [ ]**

**If NOT, please explain why not.**

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**G5. Are there likely to be any issues with language?** *For example, is it likely participants will be approached who do not speak English or speak English as a second or third language?*

**Yes [ ]  No [ ]**

**If YES, please provide more information.**

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**G6. Do the forms or participant information need to be presented in a language other than English?**

**Yes [ ]  No [ ]**

*Please note: If YES, the translated documents should be submitted to the AHREC with a footnote, signed by the researcher/supervisor stating that it is an accurate translation.*

**G7. Please provide a detailed explanation of how participants are to be contacted and recruited?** *For example, if making direct contact how will contact details be obtained, how will participants indicate willingness to be involved in the study? Any advertisements, flyers or other recruitment materials that will be used should be included as an Appendix.*

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**G8. What information will be given to participants?** *For example, letter of introduction, Consent Form, Information Sheet, questionnaire or other documentation. Please outline when this information will be provided to participants.**Include the letter of introduction, Consent Form, Information Sheet, questionnaire or other documentation as Appendices.*

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**G9. Describe procedures for obtaining free and informed consent from those who wish to participate in your research.** *Please note: If participants will be recruited verbally ensure that the verbal script to be used to recruit participants is provided. For more information on ensuring informed consent see section 2.2.6 under General Requirements for Consent in the National Statement on Ethical Conduct in Human Research. Include the Consent Form and/or verbal script as an Appendix.*

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**G10. Does recruitment involve a direct personal approach to potential participants by the researchers?**

**Yes [ ]  No [ ]**

**If yes, how will the researchers address any real or perceived coercion felt by potential participants?**

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**G11. Indicate how assurances for confidentiality and anonymity will be given to participants.**

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**G12. Indicate the expected time commitment by participants, and proposed location, if being interviewed or required to complete a survey.** *This information should be included in the Letter of Introduction to participants.*

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**G13. Provide details of and the rationale for any payment or reimbursement to participants.**

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**G14. Provide a clear description of any potential risks to participants (including physical, emotional, social or legal) and the steps that will be taken to address these risks.**

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**G15. Outline the protocol that will be followed in the eventuality of any adverse event(s).**

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**H. DATA STORAGE & RETENTION**

**H1. Indicate what you will do with the recorded data once it has been analysed.** *Please check all the boxes that apply to this research project.*

 **H1.1 On completion of the project, data will be stored:**

|  |  |  |  |
| --- | --- | --- | --- |
| In writing | [ ]  | On computer disk | [ ]  |
| On audio tape/CD | [ ]  | On video tape/DVD | [ ]  |
| Other (please indicate): Click here to enter text. |

 **H1.2 Data will be stored in a de-identified form:**

**Yes [ ]  No [ ]**

 **If NO, explain how anonymity and confidentiality standards will be met for data storage.**

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**H1.3 Where will data be stored, how long will it be stored for and what will happen to the data once the storage period has expired?**

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**H2. Specify who apart from yourself (and your supervisors, if applicable) will have access to the research data and results, and any conditions to be placed on that access.**

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**I. DATA OWNERSHIP**

**I1. Detail who will own the data collected during the research.**

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1. **REPORTING PROCESS**

**J1. How will the results be reported back to participants, Aboriginal organisations and/or relevant** **Aboriginal community Elders, leaders and/or community-recognised spokespersons?**

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**J2. Publication of results**

 Yes or No

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| Publication | Intend to publish results?(e.g., article, book, thesis) |  |

**How will the results be published?**

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**K. OTHER MATTERS**

**K1. Indicate any other centres involved in the research and any other Ethics Committee(s) being approached for approval of this project (if applicable), including the approval status of each. Please ensure that copies of all approval letters/notices from other Ethics Committees are sent the AHREC with this application.**

**Please note: If other Ethics Committees request amendments to your project after the AHREC has already provided approval, you will need to submit a request to modify your project using the Modification Request form available from** <http://ahcsa.org.au/research-overview/ethical-review-ahrec/>

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**K2. Has funding been received/applied for?**

**Yes [ ]  No [ ]**

**If YES, how much?**

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**Name of funding body**

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**Please declare any affiliation of financial interest.**

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**L. CERTIFICATION & SIGNATURES**

**The Researcher and/or Supervisor whose signature(s) appear below certify that the Application Form is complete and they have read the *National Statement on Ethical Conduct in Human Research* and *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* and accept responsibility for the conduct of this research in respect of those guidelines and any other conditions specified by the Aboriginal Health Research Ethics Committee.**

**Principal Researcher’s name:** Click here to enter text.**Principal Researcher’s signature:** Click here to enter text.

**or, if applicable:**

**Principal Supervisor's name:** Click here to enter text.**Principal Supervisor’s signature:** Click here to enter text.

**APPENDIX A: ADDITIONAL RESEARCHERS / SUPERVISORS**

***Researcher 4 / Supervisor***

**Title:** Click here to enter text.**First Name:** Click here to enter text. **Family Name:** Click here to enter text.

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

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

**Phone:** Click here to enter text. **Fax:** Click here to enter text. **Email:** Click here to enter text.

***Researcher 5 / Supervisor***

**Title:** Click here to enter text.**First Name:** Click here to enter text. **Family Name:** Click here to enter text.

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

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

**Phone:** Click here to enter text. **Fax:** Click here to enter text. **Email:** Click here to enter text.

***Researcher 6 / Supervisor***

**Title:** Click here to enter text.**First Name:** Click here to enter text. **Family Name:** Click here to enter text.

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

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

**Phone:** Click here to enter text. **Fax:** Click here to enter text. **Email:** Click here to enter text.

***Researcher 7 / Supervisor***

**Title:** Click here to enter text.**First Name:** Click here to enter text. **Family Name:** Click here to enter text.

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

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

**Phone:** Click here to enter text. **Fax:** Click here to enter text. **Email:** Click here to enter text.

***Researcher 8 / Supervisor***

**Title:** Click here to enter text.**First Name:** Click here to enter text. **Family Name:** Click here to enter text.

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

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

**Phone:** Click here to enter text. **Fax:** Click here to enter text. **Email:** Click here to enter text.

**APPENDIX B: PRIVACY LEGISLATION MATTERS**

**If your research involves collecting information about individuals, and that information could identify any individual (or be re-identified so as to identify an individual), you must complete this checklist.**

**Section 1 – COLLECTION OF INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Question** | **Answer** | **Action or Decision** |
|  | Is the researcher’s organisation an APP entity (see note 1.1)?  | YES | 🞏 | Proceed to question 2. |
| NO | 🞏 | Privacy Act does not apply. |
|  |
|  | Is the information being collected ‘personal information’ (see note 2.1)?  | YES | 🞏 | Proceed to question 3. |
| NO | 🞏 | Privacy Act does not apply. |
|  |
|  | Does the researcher’s organisation have an up-to-date Privacy Policy (see note 3.1) about how the ‘personal information’ is to be managed? | YES | 🞏 | Proceed to question 4. |
| NO | 🞏 | Ensure this is complete before proceeding to question 4. |
|  |
|  | Is the collection of ‘personal information’ necessary for the research? | YES | 🞏 | Proceed to question 5. |
| NO | 🞏 | The personal information cannot be collected without an exemption. Proceed to question 8. |
|  |
|  | Will individuals be given the option of not identifying themselves, or of using a pseudonym as part of the research? | YES | 🞏 | Proceed to question 6. |
| NO | 🞏 | Unless it is impractical to do this, or a law/Court order permits you not to do so, you must give this option. If allowing people to respond anonymously/under a pseudonym would be impractical, select “no” and continue to question 6. |
|  |
|  | Is it possible to do the research by collecting information that is ‘de-identified’? (See note 6.1) | YES | 🞏 | This must be done in order to comply with privacy legislation. |
| NO | 🞏 | Proceed to question 7. |
|  |
|  | Will each individual give consent to the researcher collecting the personal information? | YES | 🞏 | Skip to question 15. |
| NO | 🞏 | Proceed to question 8. |

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| --- | --- | --- | --- |
| **#** | **Question** | **Answer** | **Action or Decision**  |
|  | Is the research: ‘medical research’; or research relevant to public health or safety or the managing of a health service?  | YES | 🞏 | Proceed to question 9 – you may still be able to collect despite having no individual consent. |
| NO | 🞏 | You cannot collect the information without the consent of the individual. It is unlikely that ethics approval can be granted without good reason. |
|  |
|  | Is it *impractical* to obtain the individual’s consent (through lack of legal capacity of individual, scale/size of project etc.)? | YES | 🞏 | Proceed to question 10. |
| NO | 🞏 | You cannot collect the information without the consent of the individual. It is unlikely that ethics approval can be granted without good reason. |
|  |
|  | Is the personal information to be collected from an Agency? (see note 10.1) | YES | 🞏 | Proceed to question 11. |
| NO | 🞏 | Skip to question 12. |
|  |
|  | Will the collection be made in accordance with the set of Medical Research Guidelines published by the National Health and Medical Research Council, and does your application contain all of the information required by the guidelines? (see note 11.1) | YES | 🞏 | Skip to question 15. |
| NO | 🞏 | You cannot collect the information without the consent of the individual. It is unlikely that ethics approval can be granted without good reason. |
|  |
|  | Is the personal information to be collected from an Organisation (i.e. not from the individual directly)? | YES | 🞏 | Proceed to question 13. |
| NO | 🞏 | You cannot collect the information without the consent of the individual. It is unlikely that ethics approval can be granted without good reason. |
|  |
|  | Is the personal information being collected ‘sensitive information?’ (see note 13.1) | YES | 🞏 | Proceed to question 14 – you may be able to collect under a ‘Permitted Health Situation’ (see note 13.2) |
| NO | 🞏 | You cannot collect the information without the consent of the individual. It is unlikely that ethics approval can be granted without good reason. |
|  |
|  | Will collection been made in accordance with the set of Medical Research Guidelines published by the National Health and Medical Research Council (see note 14.1)? | YES | 🞏 | Proceed to question 15. |
| NO | 🞏 | You cannot collect the information without the consent of the individual. It is unlikely that ethics approval can be granted without good reason. |

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Question** | **Answer** | **Action or Decision**  |
|  | Will the researcher notify the individual that their personal information (including sensitive information) has been collected, as well as what it’ll be used for and if it’ll be disclosed to other parties? | YES | 🞏 | Your collection of personal (including sensitive) information has complied with the privacy legislation.  |
| NO | 🞏 | You must do this before you can say your collection of personal (including sensitive) information has complied with the privacy legislation. |
|  |
| 16. If you believe that your research justifies the collection of Sensitive Information without consent, please indicate the justification (tick those that apply), and provide a brief statement to support your statement.* Will scientific defects result if the research is conducted using de-identified information?
* Does the proposed research involve linkage of data?
* Is the purpose for which the information will be used included in existing consent relating to the collection, use or disclosure of personal information?
* Is the proposed research an extension of, or closely related to, a previously approved research project? Please provide project number……
* Is it impossible or difficult to obtain consent due to the age of the records or lack of up-to-date contact details.
* Is the proposed research minimally intrusive on the privacy and well-being of the individuals involved.
* Other, please describe………………………………………………………..
 |
| Statement of justification: |

**Notes**

1.1 Almost all health research institutions will be APP entities. If you think you might not be subject to the Privacy Act, please check with your legal department and provide us with written confirmation of this fact.

2.1P*ersonal information* means information or an opinion about an identified individual, or an individual who is reasonably identifiable:

1. Whether the information or opinion is true or not; and
2. Whether the information or opinion is recorded in a material form or not.

Personal information includes sensitive information (see note 13.1).

3.1 If you are working for a research organisation or university, they probably have a Privacy Policy. You should check with the legal department to make sure that you have an up to date copy of this policy. Your organisation may be exempt from the Privacy Policy. If it is, you should provide the AHREC with confirmation of this from your organisation’s legal team.

6.1 In this checklist, ‘de-identified’ means that all identifying characteristics have been removed from the information and that there is no possibility for any person (including the research team) to re-identify that information, including where this becomes possible through accessing separately stored information.

10.1 Agency means Minister, Department, statutory body, federal Court, federal Police etc.

11.1 These are published under s95 of the Privacy Act. A link appears [here](http://www.nhmrc.gov.au/guidelines/publications/pr1). To comply with the Guidelines, your application must contain an explanation of:

1. The aims or purpose of the research
2. The credentials and technical competence of the researcher
3. The data needed and how it will be analysed
4. If sensitive information\* is to be used, why it is necessary
5. The source of the data
6. The study period
7. The target population
8. The reasons why de-identified\* information, cannot achieve the relevant purpose of the research activity
9. The reasons why it is impracticable to seek consent from the individual for the use or disclosure of the personal information.

[Note: Any genetic research should be conducted in accordance with the guidelines in ‘Chapter 3.5 of the National Statement on Ethical Conduct in Human Research, 2007.]

1. The specific uses or disclosures that will be made of the personal information
2. The proposed method of publication of results of the research and a statement that any health information\* to be used or disclosed will not be published unless in de-identified form
3. The estimated time of retention of the personal information
4. The identity of the custodian(s) of the personal information used during the research
5. Security standards to be applied to the personal information. In particular, that personal information will be retained in accordance with Chapter 2 of the Australian Code for the Responsible Conduct of Research, 2007, and in a form that is at least as secure as it was in the sources from which the personal information was obtained unless more stringent legislative or contractual provisions apply
6. A list of personnel with access to the personal information including any contractors or subcontractors
7. The standards that will be applied to protect personal information disclosed by an agency. These should include the:
	1. Terms of any disclosure agreement between the agency and the researcher to govern the limits on use and disclosure of that personal information
	2. Proposed methods of disposal of the personal information on the completion of the research, and that these are in accordance with the Archives Act 1983 for Commonwealth records and legislative requirements of a State or Territory
	3. Standards that will be applied to protect privacy of personal information where it is made available to other researchers or third parties if that is proposed
8. Any proposal to send data overseas for the purpose of the research project including the names of the countries to which it is proposed the data be sent and how the research project will comply with Australian Privacy Principle 8 of the Privacy Act.

13.1 ***Sensitive information*** includes:

1. Health information about an individual; or
2. Genetic information about an individual that is not otherwise health information; or
3. Biometric information that is to be used for the purpose of automated biometric verification or biometric identification; or
4. Biometric templates.

***Health information*** means:

1. Information or an opinion about:
2. The health or a disability (at any time) of an individual; or
3. An individual’s expressed wishes about the future provision of health services to him or her; or
4. A health service provided, or to be provided, to an individual;

that is also personal information; or

1. Other personal information collected to provide, or in providing, a health service; or
2. 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
3. Genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual.

13.2 ‘Permitted Health Situation’ allows the collection of ‘sensitive information’ when consent has not been given by an individual. It will arise where it is not possible to do the research by collecting information that is ‘de-identified’ and the answer YES is given to questions 8, 9, 13 and 14.

14.1 These guidelines are published under s95A of the Privacy Act. A link appears [here](http://www.nhmrc.gov.au/guidelines/publications/pr2). If the guidelines are complied with, this is classified as a ‘permitted health situation’, and you can apply to the AHREC for an exemption from the Act. You must make sure that each item listed below is addressed in your application:

1. The aims or purpose of the collection
2. The credentials and technical competence of the collector(s) of the data
3. The data needed
4. The study period
5. The target population
6. The reasons why de-identified information cannot achieve the relevant purpose of the research activity
7. The reasons why it is impracticable to seek consent from the individual for the collection of health information
8. The estimated time of retention of the health information
9. The identity of the custodian(s) of the health information collected
10. The security standards to be applied to the health information.
11. A list of personnel within the collecting organisation or organisations with access to the health information collected
12. The level of protection that will be applied by the collector(s) to protect health information disclosed to the collector(s) by the disclosing organisation. These should include:
	1. Terms of any release agreement between the disclosing organisation and the collector(s) to govern limits on the use and disclosure of collected health information
	2. Proposed methods of disposal of the health information on the completion of the research activity, as required by APP 11.2 (security of personal information).
13. Any proposal to send data overseas for the purpose of the research project including the names of the countries to which it is proposed the data be sent and how the research project will comply with APP 8 (cross border disclosure of personal information) of the Privacy Act.

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| **Section 2 – USE AND DISCLOSURE OF PERSONAL INFORMATION** |
| **#** | **Question** | **Answer** | **Action or Decision**  |
|  | Will the researcher use or disclose the personal information for a different purpose to which it was collected? | YES | 🞏 | Proceed to question 2. |
| NO | 🞏 | The researcher has complied with the new Privacy legislation. |
|  |
|  | Will individuals consent to this secondary use or disclosure? | YES | 🞏 | Skip to question 10. |
| NO | 🞏 | Proceed to question 3. |
|  |
|  | Would the individual have reasonably expected the researcher to use or disclose the personal information for this secondary purpose? | YES | 🞏 | Proceed to question 4. |
| NO | 🞏 | Skip to question 7. |
|  |
|  | Is the personal information ‘sensitive information’? | YES | 🞏 | Proceed to question 5. |
| NO | 🞏 | Skip to question 6. |
|  |
|  | Sensitive information - is the secondary use/disclosure *directly related* to the purpose for collection? | YES | 🞏 | Skip to question 11. |
| NO | 🞏 | Skip to question 7. |
|  |
|  | Non-sensitive personal information - is the secondary use/disclosure *related* to the purpose for collection? | YES | 🞏 | Skip to question 11. |
| NO | 🞏 | You must not use or disclose the personal information for this purpose. |
|  |
|  | Is the use or disclosure necessary for research or the compilation of statistics relevant to public health or public safety? | YES | 🞏 | Proceed to question 8 - you may be able to use or disclose under a ‘Permitted Health Situation’ (see note 7.1) |
| NO | 🞏 | You must not use or disclose the personal information for this secondary purpose. |
|  |
|  | Is it impractical to obtain the individual’s consent (through lack of legal capacity of individual, scale/size of project etc.)? | YES | 🞏 | Proceed to question 9. |
| NO | 🞏 | You must not use or disclose the personal information for this purpose. |

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Question** | **Answer** | **Action or Decision**  |
|  | Is the use or disclosure in accordance with the set of Medical Research Guidelines published by the National Health and Medical Research Council (see note 9.1)? | YES | 🞏 | Proceed to question 10. |
| NO | 🞏 | You cannot use or disclose the information without the consent of the individual. Ethics approval is unlikely to be granted. |
|  |
|  | If the researcher is disclosing this sensitive information, is the information de-identified so that there is no way it can be re-identified by anyone (including the researcher) before it is disclosed?  | YES | 🞏 | Proceed to question 11. |
| NO | 🞏 | You cannot disclose this information unless this is done. |
|  |
| 11. | Is the researcher disclosing information to someone overseas? | YES | 🞏 | Proceed to question 12. |
| NO | 🞏 | The researcher has complied with the new Privacy legislation. |
|  |
| 12. | Has the researcher taken steps to ensure the recipient does not breach Australian privacy laws or is bound by privacy laws of equal strength? | YES | 🞏 | The researcher has complied with the new Privacy legislation. |
| NO | 🞏 | Proceed to question 13. |
|  |
| 13. | Has the individual consented to the researcher not monitoring how the personal information is dealt with by the overseas recipient? | YES | 🞏 | The researcher has complied with the new Privacy legislation. |
| NO | 🞏 | You cannot disclose this information unless you answer yes to either question 12 or question 13. |

**Notes**

7.1 ‘Permitted Health Situation’ allows the use or disclosure of ‘sensitive information’ when consent has not been given by an individual and the use/disclosure is not directly related to the primary purpose for collection. It will arise when the answer YES is given to questions 7, 8 and 9.

9.1 These guidelines are published under s95A of the Privacy Act. A link appears [here](http://www.nhmrc.gov.au/guidelines/publications/pr2). If the guidelines are complied with, this is classified as a ‘permitted health situation’, and you can apply to the AHREC for an exemption from the Act. See note 14.1, above, for details.

**APPENDIX C: CONSENT FORM**

*The form is only an example and should be modified and adapted by researchers for their specific needs*

*(Delete if not applicable)*

**SAMPLE CONSENT FORM**

**Project Title:**

**Researcher’s name:**

**Supervisor’s name:**

(If the researcher is a student)

* I have received information about this research project.
* The research project has been explained to me and I fully understand the purpose and my involvement in it.
* I understand that I may withdraw from the research project at any stage.
* I understand that I may not directly benefit from taking part in the project.
* I understand that while information gained during the study may be published, I will not be identified and my personal results will remain confidential. If other arrangements have been agreed in relation to identification of research participants this point will require amendment to accurately reflect those arrangements.
* I understand that I may be audiotaped / videotaped during the interview. The tapes will be destroyed once they are summarised and at completion of the project. Omit this point if the interview will not be taped.

Participants under the age of 18 normally require parental or guardian consent to be involved in research. The consent form should allow for those under the age of 18 to agree to their involvement and for a parent or guardian to give consent.

**Name of participant:**

**Signed:**  **Date:**

**I have explained the research project to the participant and believe that he/she understands what is involved.**

**Researcher’s signature and date:**

**APPENDIX D: Distress/Referral/Unexpected Finding Protocol**

*The form is only an example and should be modified and adapted by researchers for their specific needs, (Delete if not applicable)*

**Protocol for participants for the project …**

Distress

* A participant indicates that they are experiencing a high level of emotional stress
* Or a participant exhibits behaviours which suggest that the interview is stressful such as crying or shaking
* **STOP** the interview
* Offer immediate support
* Assess the participant’s mental status;
* Tell me what you are feeling?
* Do you feel able to go on about your day?
* Do you feel safe?
* Tell me what thoughts you are having?

Stage 1 response

* If the participant feels able to carry on resume the interview
* If the participant is unable to carry on go to stage 2
* Notify the researcher

Review

* Discontinue the interview
* Ask the participant if he or she would like the interviewer to contact any family members
* Ask the participant if the interviewer can contact the [INSERT NAME] for support
* With participant consent contact a member of the health care team treating them for further advice/support

Stage 2 Response

* If the participant consents, the interviewer will contact the participant with a courtesy call to check on their well-being
* Provide the participant with the interviewer’s phone number and encourage the participant to call if she experiences increased distress in the hours/days following the interview
* Notify the researcher

Follow up

**Possible support services**

|  |  |  |
| --- | --- | --- |
| [INSERT NAME OF CONTACT PERSON] | TITLE ADDRESS***The CONTACT PERSON is able to refer the participant for long term counselling and support*** | Tel:  |
| [INSERT NAME OF CONTACT PERSON] | TITLE ADDRESS***The CONTACT PERSON is able to refer the participant for long term counselling and support*** | Tel:  |
| Contact the researcher who will assist in taking appropriate action to care for the [participant]  | Researcher’s details |  |

**Note**: The researchers are required to notify possible support services and ensure support as per their mandate throughout the course of the research project.

**APPENDIX E: ATTACHMENT CHECKLIST**

**Note:** The researcher should provide all information required for review on the application form and attachments listed below. Study protocol should only be attached to the original signed hard copy and a soft copy should be emailed to the Executive Officer. **Do not attach** the study protocol to the additional 14 hard copies.

[ ]  **1.** **Letter of Introduction** (From the principal researcher - place before the application form)

[ ]  **2. Privacy Legislation Matters – Part A and/or Part B** (if applicable)

[ ]  **3. Letter(s) of Support**

Support should be sought from the Aboriginal organisation or community council where the research study will be conducted before submitting the project for ethical review. This should be in the form of written support on the organisation’s letterhead and signed by the Director(s) / Manager(s).

[ ]  **4. Information Sheet for participants** (Information sheets should be readily understandable by the participant and are written in plain English (Grade 8 reading level or below).)

 It should describe:

* + - The purpose of the study
		- What benefits or value it will have to participants
		- An invitation to take part in the study
		- What it will involve for the participant and how long it will take
		- Any inconveniences
		- What information the researcher is interested in obtaining
		- What equipment will be used
		- Participant’s rights in regard to the information they share and copyright issues (if applicable)
		- How confidentiality will be assured
		- How privacy will be assured
		- Freedom to withdraw from study without prejudice
		- Name and telephone number of at least one member of the research group.

[ ]  **5. Consent Form(s) for participation in research by:**

* Interview
* Focus Group
* Experiment
* Other (please specify)….

Explicit consent must be obtained from participants if material is to be audio or videotaped or photographed.

[ ]  **6. Consent Form for Children**

**[ ]  7. Consent Form for Observation of Professional Activity**

[ ]  **8.** **Appendices**

* Questionnaire or survey instruments
* Interview questions, or list of topics to be discussed, as appropriate
* Advertisement for recruitment of participants
* Debriefing material or video/DVD to be viewed by participants