**Instructions**

This form should be accompanied by the HREC application and proof of the HREC decision.

**Part A** – to be completed by the responsible researcher

**Part B** - to be completed by the responsible researcher

**Part C** – to be completed by two Barwon Health HREC Members

**Part D** – to be completed by the approving HREC Chairperson

**Part E** – both the researcher and the Chairperson are required sign the declaration at Part E.

## **Part A – Addressing National Statement Chapter 2.3**

### Researcher to complete

|  |  |
| --- | --- |
| **Barwon Health Reference Number** |  |
| **Project Title** |  |
| **Principal Investigator** |  |

|  |  |
| --- | --- |
| **Type of Data Items Sought for the Purpose of the Research** |  |
| **Number of Records Involved** |  |

**Chapter 2.3 of the National Statement expands on waiver of consent and includes criteria that the HREC must consider before granting the request. The HREC must be satisfied that the research protocol adequately addresses the following criteria (Paragraph 2.3.10). To assist the HREC in its consideration, please address each item below.**

|  |  |
| --- | --- |
| A | Involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7) to participants |
|  |
| B | The benefits from the research justify any risks of harm associated with not seeking consent |
|  |
| C | It is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records) |
|  |
| D | There is no known or likely reason for thinking that participants would not have consented if they had been asked |
|  |
| E | There is sufficient protection of their privacy |
|  |
| F | There is an adequate plan to protect the confidentiality of data |
|  |
| G | In case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media) |
|  |
| H | The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled |
|  |
| I | The waiver is not prohibited by State, federal, or international law |
|  |

**If the research aims to expose illegal activity please also address the following by responding under each point**:

|  |  |
| --- | --- |
| A | The value of exposing the illegal activity justifies the adverse effects on the people exposed (see paragraph 4.6.1) |
|  |
| B | There is sufficient protection of their privacy |
|  |
| C | There is sufficient protection of the confidentiality of data |
|  |
| D | The waiver is not otherwise prohibited by State, federal, or international law |
|  |

## **Part B – Australian Privacy Principle Guidelines**

**Researcher to complete**

**Under paragraph 2.3 of the s95 Guidelines, when research may involve a breach of one or more APPs, the proposal for that research to be submitted to an HREC must contain a reference to the APP(s) and must also state reasons for believing that the public interest in the research outweighs, to a substantial degree, the public interest in complying with the APP(s). Please identify the APPs which may be breached by the proposed research and provide your reasons below:**

**APP1** **- open and transparent management of personal information**

Reason(s)

|  |
| --- |
|  |

**APP2** **— anonymity and pseudonymity**

Reason(s)

|  |
| --- |
|  |

**APP3 — collection of solicited personal information**

Reason(s)

|  |
| --- |
|  |

**APP4 — dealing with unsolicited personal information**

Reason(s)

|  |
| --- |
|  |

**APP5 — notification of the collection of personal information**

Reason(s)

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| --- |
|  |

**APP6 — use or disclosure of personal information**

Reason(s)

|  |
| --- |
|  |

**APP7 — direct marketing**

Reason(s)

|  |
| --- |
|  |

**APP8 — cross-border disclosure of personal information**

Reason(s)

|  |
| --- |
|  |

**APP9 — adoption, use or disclosure of government related identifiers**

Reason(s)

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| --- |
|  |

**APP10 — quality of personal information**

Reason(s)

|  |
| --- |
|  |

**APP11 — security of personal information**

Reason(s)

|  |
| --- |
|  |

**APP12 — access to personal information**

Reason(s)

|  |
| --- |
|  |

**APP13 — correction of personal information**

Reason(s)

|  |
| --- |
|  |

**Part C – Barwon Health HREC Review**

### Barwon Health HREC Members to complete

The [Guidelines under Section 95 of the Privacy Act 1988](https://www.nhmrc.gov.au/guidelines/publications/pr1) (s95 guidelines) set the current standard for the protection of privacy in the conduct of medical research involving human participants in Australia. The s95 guidelines provide a framework for the conduct of medical research using information held by Commonwealth agencies where identified information needs to be used without consent. In these situations, a Commonwealth agency may collect or disclose, in identifiable form, records for medical research purposes without infringing the Privacy Act if the proposed medical research has been approved by a properly constituted HREC in accordance with the s95 guidelines.

When research may involve a breach of one or more Australian Privacy Principles (APPs) the proposed research must be reviewed and approved by a HREC. In undertaking ethical assessment of research proposals, HREC members must apply the [S95 or S95A guidelines](https://www.nhmrc.gov.au/guidelines/publications/pr1).

In reaching a decision under these guidelines, HREC members must consider each of the following matters and weigh up if the public interest, in the proposed research, outweighs or does not outweigh to a substantial degree, the public interest in the protection of privacy (refer to Section 3 of the s95 Guidelines).

The following guide has been developed to assist HREC members in their considerations.

|  |
| --- |
| **Instructions for HREC Members** |
| 1. Indicate by putting a cross (X) in each applicable box below to show that each of the following matters have been considered in relation to the application 2. Provide a comment documenting your decision for each matter below 3. Provide a final comment on whether it is reasonable for the research to proceed without the consent of the individuals to whom the information relates |

Consider each of the following matters and weigh up if the public interest, in the proposed research, outweighs or does not outweigh to a substantial degree, the public interest in the protection of privacy.

|  |  |  |
| --- | --- | --- |
| **Matter for HREC Member to Consider/Decide** | **Yes** | **No** |
| (a) the degree to which the proposed collection, use or disclosure of health information is necessary to the functions or activities of the organisation |  |  |
| (b) the degree to which the research, or compilation or analysis of statistics activity is relevant to public health or public safety |  |  |
| (c) the degree to which the medical research is likely to contribute to:   1. the identification, prevention or treatment of illness or disease |  |  |
| 1. scientific understanding relating to health |  |  |
| 1. the protection of the health of individuals and/or communities |  |  |
| 1. the improved delivery of health services |  |  |
| 1. scientific understanding or knowledge |  |  |
| 1. enhanced knowledge of issues within the fields of social science and the humanities relating to public health or public safety |  |  |
| (d) any likely benefits to individuals, to the category of persons to which they belong, or the wider community that will arise from the medical research being undertaken in the manner proposed |  |  |
| (e) in considering benefits to the category of persons to which the individual(s) belong, specific consideration should be given to any likely benefits to individuals that belong to certain categories where the information may be of a particularly personal or sensitive nature; for example:   1. children and young people; or |  |  |
| 1. persons with intellectual or psychiatric disability; or |  |  |
| 1. persons highly dependent on medical care; or |  |  |
| 1. persons in dependent or unequal relationships; or |  |  |
| 1. persons who are members of collectivities; or |  |  |
| 1. Aboriginal and Torres Strait Islander peoples; or |  |  |
| 1. persons whose information relates to their mental or sexual health |  |  |
| (f) whether the medical research design can be satisfied without risking infringement of an APP and the scientific defects in the medical research that might arise if the medical research was not conducted in the manner proposed |  |  |
| (g) the financial costs of not undertaking the medical research (to government, the public, the health care system, etc.) |  |  |
| (h) the public importance of the medical research |  |  |

|  |  |  |
| --- | --- | --- |
| **Matter for HREC Member to Consider/Decide (Continued)** | **Yes** | **No** |
| (i) the extent to which the data being sought are ordinarily available to the public from that agency;   1. whether the medical research involves use of data in a way which is inconsistent with the purpose for which the data was made public |  |  |
| 1. whether the medical research requires an alteration of the format of the data of a kind that would, if used by an agency, involve a breach of an APP |  |  |
| (j) whether the risk of harm to a person whose personal information is to be used in proposed research is minimal, having regard to the elements of that research provided in response to paragraph 2.3 of these guidelines |  |  |
| (k) the standards of conduct that are to be observed in medical research, including:   1. the study design and the scientific credentials of the researchers |  |  |
| 1. if the research involves contact with participants, the procedures or controls which will apply to ensure that participants are treated with integrity and sensitivity, including whether questions to be asked or procedures to be employed are intrusive |  |  |
| 1. whether access to personal information is restricted to appropriate researchers |  |  |
| 1. the risk that a person or group could be identified in the published results |  |  |
| 1. the procedures that are to be followed at the completion of the research to ensure that all data containing personal information are at least as secure as they were in the sources from which the data were obtained, including the date when the data will be destroyed or returned |  |  |

**Final Decision**

Please provide comment on whether it is reasonable for the research to proceed without the consent of the individuals to whom the information relates by ticking the appropriate box and signing below.

|  |
| --- |
| **HREC Member Comment on Waiver Application** (please provide comment on whether it is reasonable for the research to proceed without the consent of the individuals to whom the information relates and tick the appropriate box and sign below) |
|  |
| **HREC Member Recommendation** |
| *Approved*  *Not approved*  *Researcher to provide further information* |

**HREC Member Signature**

*Print name:*

*Signature:*

(E-signature or email signature is acceptable)

*Date:*

**Part D – Weighing the public interest**

### HREC Chairperson to complete

The HREC must ensure that the committee has the competence to determine if the public interest in the proposed research outweighs, or does not outweigh, to a substantial degree, the public interest in the protection of privacy (refer to Section 3 of the s95 Guidelines).

|  |  |
| --- | --- |
| Has the HREC considered: |  |
| (a) the degree to which the proposed collection, use or disclosure of health information is necessary to the functions or activities of the organisation | **Y  N** |
| (b) the degree to which the research, or compilation or analysis of statistics activity is relevant to public health or public safety | **Y  N** |
| (c) the degree to which the medical research is likely to contribute to:   1. the identification, prevention or treatment of illness or disease | **Y  N** |
| 1. scientific understanding relating to health | **Y  N** |
| 1. the protection of the health of individuals and/or communities | **Y  N** |
| 1. the improved delivery of health services | **Y  N** |
| 1. scientific understanding or knowledge | **Y  N** |
| 1. enhanced knowledge of issues within the fields of social science and the humanities relating to public health or public safety | **Y  N** |
| (d) any likely benefits to individuals, to the category of persons to which they belong, or the wider community that will arise from the medical research being undertaken in the manner proposed | **Y  N** |
| (e) in considering benefits to the category of persons to which the individual(s) belong, specific consideration should be given to any likely benefits to individuals that belong to certain categories where the information may be of a particularly personal or sensitive nature; for example:   1. children and young people; or | **Y  N** |
| 1. persons with intellectual or psychiatric disability; or | **Y  N** |
| 1. persons highly dependent on medical care; or | **Y  N** |
| 1. persons in dependent or unequal relationships; or | **Y  N** |
| 1. persons who are members of collectivities; or | **Y  N** |
| 1. Aboriginal and Torres Strait Islander peoples; or | **Y  N** |
| 1. persons whose information relates to their mental or sexual health | **Y  N** |
| (f) whether the medical research design can be satisfied without risking infringement of an APP and the scientific defects in the medical research that might arise if the medical research was not conducted in the manner proposed | **Y  N** |
| (g) the financial costs of not undertaking the medical research (to government, the public, the health care system, etc.) | **Y  N** |
| (h) the public importance of the medical research | **Y  N** |
| (i) the extent to which the data being sought are ordinarily available to the public from that agency;   1. whether the medical research involves use of data in a way which is inconsistent with the purpose for which the data was made public | **Y  N** |
| 1. whether the medical research requires an alteration of the format of the data of a kind that would, if used by an agency, involve a breach of an APP | **Y  N** |
| (j) whether the risk of harm to a person whose personal information is to be used in proposed research is minimal, having regard to the elements of that research provided in response to paragraph 2.3 of these guidelines | **Y  N** |
| (k) the standards of conduct that are to be observed in medical research, including:   1. the study design and the scientific credentials of the researchers | **Y  N** |
| 1. if the research involves contact with participants, the procedures or controls which will apply to ensure that participants are treated with integrity and sensitivity, including whether questions to be asked or procedures to be employed are intrusive | **Y  N** |
| 1. whether access to personal information is restricted to appropriate researchers | **Y  N** |
| 1. the risk that a person or group could be identified in the published results | **Y  N** |
| 1. the procedures that are to be followed at the completion of the research to ensure that all data containing personal information are at least as secure as they were in the sources from which the data were obtained, including the date when the data will be destroyed or returned | **Y  N** |

**Part E – Declaration**

By signing below, the researcher and HREC Chairperson are making the declaration that the information provided in this form is true and correct – e-signature or email signature is acceptable.

**Researcher**

Print name

Signature

Date

**HREC Chairperson**

Print name

Signature

Date