Application Guidelines

Justice Human Research Ethics Committee

TRIM ID: CD/15/132566
Date: 03 May 2018
Version: 1.1

FINAL

VICTORIA State Government | Justice and Regulation

Contents

1 Getting Started

The purpose of these guidelines is to assist researchers complete the JHREC application form for the ethical review of projects with more than a low level of risk.

All projects that are deemed to have more than a low level of risk are required to submit an application to the Justice Human Research Ethics Committee (JHREC) for approval, prior to project commencement.

These guidelines provide detailed information and instructions on how to answer the questions in the JHREC application form.

2 National Statement on Ethical Conduct in Human Research

Ethical review of your project by a Human Research Ethics Committee (HREC) is required under the *National Statement.* The *National Statement* is available on the NHMRC website at http://www.nhmrc.gov.au

The *National Statement* sets out principles for the conduct of research involving humans, and gives a clear indication of the issues that HRECs will consider in determining the scientific merit of, and ethical issues raised by, your project proposal.

Applicants need to read and understand both these Guidelines and the *National Statement*. Familiarity with the *National Statement* helps to understand the purpose of the questions in the JHREC application form and makes it easier to answer the questions posed.

Note: Researchers are asked at the end of the application form to sign a Researcher Declaration that they have read the *National Statement.*

3 Types of Applications

3.1 New Application

Any project that has not yet undergone JHREC review is a new application. Approval may be granted for a maximum of three years.

3.2 Renewal Application of a Long-Term Project

If a JHREC approved project is nearing the maximum three year approval period, and it is anticipated the project will need to continue into the future, then the researcher may submit a renewal application for a long term project. The application to renew the approval of a project must be made **before** the current JHREC approval expires. Please use the JHREC application form and state that it is a renewal application.

3.3 Amendment Request

An amendment request may be made to seek approval for minor changes to JHREC approved projects. Examples include the addition of a researcher, an extension to the completion date or the addition of a new data set.

Substantial additions or changes to the project methodology, such as the addition of focus groups may not be made as an amendment request. These substantial changes must submitted through a new JHREC application (such as a second phase of the project).

4 Essential Steps in making a JHREC application

4.1 Register with the JHREC Secretariat

All applicants that intend to submit to the JHREC must notify the JHREC Secretariat **at least three months** prior to submission. Early registration with the JHREC Secretariat will ensure your application is reviewed in line with your own project timelines.

JHREC Secretariat

Email: ethics@justice.vic.gov.au Phone:

(03) 8684 1514

4.2 Does the project require JHREC review?

An application for ethics approval must be made to the JHREC for all research or evaluation, conducted by or for the Department of Justice & Regulation or its agencies, or done under its auspices, if it involves more than a low level risk for:

- people for whom the Department is responsible or people associated with or affected by the activities of the Department
- involves the use of or access to information relating to any of the above groups.

4.3 Risk Assessment

The JHREC only considers applications for projects above a low level of risk. Researchers are responsible for assessing the level of risk for their research or evaluation by referring to Chapter 2.1 'Risk and Benefit' of the National Statement.

If you identify that your project involves more than a low level of risk, an ethics application must be submitted for review by the JHREC at a meeting. Please see the JHREC website for meeting dates and submission deadlines.

4.4 Letters of Support

Letters of support provide the JHREC with an assurance that any DJR business areas and external agencies involved in a research project or evaluation have been contacted and are supportive of the proposed research or evaluation (including the amount of their time and resources that will be required to support the project).

All submissions must:

- Provide a letter of support from each non-DJR agency involved in the project. The letter must state that the signatory has reviewed the JHREC research application.
- Provide a letter of support from each DJR business unit involved in the project. The letter of support must be from Director level or equivalent within the relevant business area of DJR, and state that the signatory has reviewed the JHREC research application.

4.5 Approval from University HRECs

Researchers affiliated with a University must seek approval from their University's HREC before submitting an application. Applications without this approval will not be accepted. Note: Streamlining arrangements have been developed with Monash University, The University of Melbourne, Deakin University and RMIT. See details below.

4.6 Streamlining with other HRECs

The JHREC and the following agencies have established a streamlined review process pursuant to the National Statement requirement to minimise the duplication of review.

Eligible projects are only required to complete a JHREC Application form and will not be required undergo full HREC review by the other organisation.

Researchers are required to contact the relevant HREC to confirm whether their project is suitable for streamlining.

Deakin University
Email: research-ethics@deakin.edu.au

Monash University HREC
Email: MUHREC@monash.edu

RMIT University
Email: SEH-Human-Ethics@ems.rmit.edu.au

Swinburne University HREC
Email: resethics@swin.edu.au

The University of Melbourne HREC
Email: research-integrity@unimelb.edu.au

Victoria Police HREC
Email: ethics.committee@police.vic.gov.au

4.7 Preparation of Application

Complete the JHREC application form on the DJR website at
http://www.justice.vic.gov.au/utility/data+and+research/making+a+jhrec+application

Prepare attachments as required. Note that the finalised version of research instruments such as participant information sheets, consent forms and interview questions are required.

Ensure that the signature pages of the Researcher Declaration and Checklist form are signed by the Principal Researcher (not a Student Researcher).

Give sufficient detail: Include all relevant information so that your application can be assessed without unnecessary delay. Fill in all sections of the application. If a section does not apply to your research, write not applicable (N/A) in the space provided. Do not leave it blank.

Researchers must provide a current professional indemnity certificate.

4.8 Participant Information

It is important to ensure all documents for participants are clear and informative. Below are key inclusions for research involving participants

- *Participant Information & Consent Forms*: All forms and correspondence relevant to the application must be on the letterhead of the Researcher's institution.
- *Explanations for research participants*: must be written in plain language.
- *Warning of non-adjudicated m*atters: The Participant Information Sheet must contain a plain language warning to participants about disclosure of non-adjudicated offences where applicable.
- *Sufficient explanation of the limits to confidentiality*: Applicants must explain to potential participants any circumstances in which confidentiality cannot be guaranteed. There are mandatory reporting requirements, depending on the circumstances of the research.
- *Counselling and safety*: Research involving participants must have arrangements in place for the counselling and safety of participants and researchers. Provision of a phone number to participants for counselling is not sufficient. Researchers must explain how they will facilitate access to counselling for participants. Sufficient measures must also be in place to ensure the safety of the researchers.

4.9 Presentation

Write in clear, plain language so that the members of the JHREC who do not have a background in the field of the project can easily understand the content of the application. Define all terminology and abbreviations.

Check applications thoroughly to avoid misspelling and grammatical errors, particularly in attached information for participants, consent forms or questionnaires.

4.10 Submission of application

Email one electronic copy of your application to ethics@justice.vic.gov.au by the submission closing date.

Applications must be submitted in one PDF file and include all documents in the following order:

- Cover letter
- Letters of support
- JHREC application form
- Recruitment documentation eg poster or flyer
- Participant information sheet
- Participant consent form
- Survey instrument eg interview questions
- Current Professional Indemnity certificate
- Signed researcher declaration

The document file name must comply with the following: JHREC - Project title - researcher's family name - institution - year of the project (e.g. JHREC - Victims of Crime - Jones – Monash – 2013)

Applications not in the above format will be asked to resubmit. Hard copies of the signature pages **only** are to be sent in the post.

Note that submission closing dates are strictly adhered to.

5 Outcomes of JHREC review

Researchers will be informed of the JHREC's decision within one week of the JHREC meeting. The review outcome will be one of the following:

- *Full Approval*: If the project has been fully approved, complete the Undertaking Form and send it to the JHREC Secretariat.
- *Provisional Approval*: If the project has received provisional approval, attend to the JHREC requests and send through your response to the JHREC Secretariat. Your response will be considered out of session as soon as possible. Your response will require a cover letter in which your must provide a response to the JHREC requests, cross-referencing so that the reviewers can easily check where the issues have been attended to.
- *Not Approved*: If you have been invited to resubmit the application it will need to be revised according to the JHREC's request, and considered at the next JHREC meeting. Note that an invitation to resubmit is not necessarily a reflection on the quality of the submission and can occur for research or evaluation which covers complex or sensitive issues. The revised application will require a covering letter in which you provide a response to the JHREC requests, cross-referencing to documents within the application so that the reviewers can easily check where the issues have been attended to in the revised application.

6 JHREC Reporting

All fully approved projects must adhere to the reporting requirements outlined below:

- *Amendment Request Form -* An Amendment Request Form must be completed when any alterations are made to the project such as staff changes and changes to the methodology or research instruments. If a DJR letter of support was attached to your application, the signatories of the letters need to be informed of the amendment prior to submission to the JHREC.
- *Annual Report Form*: Annual Report Forms are to be submitted every 12 months on the anniversary of the full JHREC approval being granted (for projects which extend beyond 12 months in duration).
- *Completion Form*: The Completion Form must be submitted on the conclusion of the research phase of the project. A copy of the research findings are also required on finalisation of the project.
- *Three Year Phase Completion of Long Term Projects:* Long term or ongoing projects are required to submit a Completion Form at the end of each three-year period and renew by submitting a new application.
- *Adverse Event/Incident Report:* Any adverse events or incidents must be reported to the JHREC in writing via email within 48 hours.

7 Information privacy

These guidelines, and the various sets of Statutory Guidelines for research described below, indicate the information researchers must include in their application.

Researchers are responsible for identifying the relevant privacy Act and associated Statutory Guidelines under which an application for approval of a project is made.

Completion of this section will assist the JHREC in assessing the project from a privacy perspective but researchers should also note any impact of specific provisions relating to confidentiality or secrecy obligations, as contained in other legislation.

General Considerations

The privacy principles contained in Victoria's state privacy legislation and the federal *Privacy Act 1988* are fairly consistent, so if the project is compliant with the privacy principles in Victoria's *Privacy and Data Protection Act 2014*, for example, then it is likely to be consistent with the federal *Privacy Act 1988* . Other states and territories have more varied privacy requirements.

Matters such as the source of personally identifying information, and the purpose for which that information was originally collected by the relevant agency or organisation can have implications for privacy compliance. Researchers should also consider the type and general sensitivity of the information involved in research, and why the collection, use or disclosure of that information is justified.

With the exception of privacy protection for 'Health Information' across all Australian jurisdictions, the legislated privacy protection framework is designed to ensure that only one privacy statute will be applicable to a given information handling act or practice by a person or organisation.

Researchers should review ALL Privacy Principles in the relevant legislation identified in Q28(b), to ensure that their project is fully compliant with them.

Researchers should be aware that HRECs have a statutory reporting requirement in relation to information that is provided in this section of the application. Failure by the Researcher to provide all this information will delay the review of the application.

Data Security

Provide sufficient details about how and where data will be stored, in both electronic and hard copy form. It is not sufficient to simply state that data will be kept in a locked office. Reference also needs to be made to how the data (electronic and hardcopy) will be secured and then disposed of at the end of the research period.

8 Application Form Guidance

8.1 Question 1: Full Project Title

Give the full technical or scientific project title

8.2 Question 2: Brief Project Title

Provide a brief descriptive title in no more than 50 words. If the Full Project Title is already fewer than 50 words applicants may write "as above" in Brief Project Title.

8.3 Question 3: Broad Category of Research

This question is included to provide reporting information for HRECs. Indicate the category that best describes the application.

8.4 Question 4: Project Proposal/Outline Summary

Researchers should note that HRECs are specifically required by the National Statement to consider all aspects of the project, including the scientific and statistical validity and the overall methodology, in addition to any ethical issues (National Statement 2.1.3 and 2.1.8).

Provide a succinct summary of no more than two pages. The summary should include the following elements:

- Justification of project
- Describe how the proposed research will complement, enhance, or contribute to existing knowledge, including an analysis of previous literature and studies.
- Explain why this research is necessary given existing knowledge in this field.
- Note that replication of previous studies in the field is acceptable if, for example the aim is to confirm or extend existing results, using more rigorous experimental criteria.
- Primary hypothesis and/or research questions
- Project design, including scientific description
- Include a description of how the findings or outcomes of the project will be published or made publicly available.

Provide sufficient detail to enable the HREC to determine the project's methodological rigour. Indicate any limitations of the project design and any potential sources of bias and how these matters will be dealt with.

Refer to the National Statement, Section 3 for further information about qualitative research approaches (Chapter 3.1) and the use of databanks (Chapter 3.2).

8.5 Question 5: Aims and Hypothesis

The aims should be summarised in such a way as to make it clear to the JHREC why the project is in the public interest and that any imposition on public resources or on participants is justified. Comment on the relevance of your proposed research project to current criminological or social problems and its potential to contribute to existing knowledge, treatment, or social improvement. Limit the answer to 150 words.

Clearly state the hypothesis or hypotheses being tested. If the project does not involve testing a hypothesis, write "not applicable". Limit the answer to 100 words.

8.6 Question 6: Reporting of Results

6 a) Restrictions on publications

Indicate whether the researchers will be restricted in any way in terms of publication of results. If any type of limitation or restriction will occur, give details, e.g. who will impose the restriction, for how long the restriction will apply, etc.

6 b) Report details

If a public report will be available at the end of the project, what form will it take and how will members of the public be able to access it? If a public report will not be made available, this must be justified to JHREC.

If the project involves participants (see definition of 'participant' under Section 3 of these guidelines), explain how the findings will be made directly available to the participants and in what form. **6 c)**

Reports and participants

At the end of the project, it is useful to give all participants a final report of meaningful group data. Providing a report can assist with recruitment and compliance, as many participants appreciate receiving feedback and are rewarded by knowing the results of their participation.

If a final report is to be made available to participants, inform them of this at the start of the project. Also, advise whether group or individual results (or both) will be reported.

Include information in the Participant Information Form on how participants can gain access to the final report.

8.7 Question 7: Victoria Police

Indicate whether the project will utilise any Victoria Police data or involves Victoria Police members.

8.8 Question 8:

8 a) Researchers

The National Statement (1.1 e.) stipulates that research must be "conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research". The JHREC is responsible for ensuring that the research proposal meets this requirement.

All researchers directly involved in the project must be listed and have appropriate credentials. Indicate the role of each researcher in the project. The roles include Principal Researcher, Associate Researcher, Student Supervisor and Student.

The Principal Researcher is the person at this site with overall responsibility for the project. If the project will be undertaken by a student, the student's supervisor must be the Principal Researchers. The Principal Researcher must have input into the proposal and review the final application.

If another party on behalf of the research team is conducting interviews, then the interviewers must also be listed.

Provide full details of the qualifications and relevant research experience of each researcher concerning the proposed research. If any of the researchers require training to enable them to participate in the project, give the name of the person(s) who will carry out this training.

Please provide the most direct contact phone number available. Do not provide the Institution's central inquiry phone number. Include contact details of the person to whom the JHREC Secretariat is to direct correspondence concerning the project.

If there is not enough room on the form, please provide the details of additional researchers as an attachment.

8 b) Departmental Contact

Provide details of the Department of Justice & Regulation business unit or agency contact. This must be the contact that has facilitated the business unit or agency letter of approval.

8.9 Question 9: Project Summary

9 a) Participants

Indicate whether the project involves participants.

9 b) Use or disclosure of information

Indicate whether the project involves the use or disclosure of information.

8.10 Question 10: Sites where the project will be conducted

The questions below satisfy National Statement paragraph 5.3.4, which states that, at the time of submitting a research project, the Principal Researcher must inform the JHREC of all other Australian sites where the research project is proposed or conducted and the name and location of any other body that will conduct an ethical review of the research.

For the purposes of this application, the term 'site' is equivalent to a **type** of location or institution, such as hospital, school, care facility, correctional facility, university, government department, etc. Sites do not refer to the number of individual locations.

10 a) Type of sites

Indicate the type(s) of sites where the project will be conducted. For example if children are to be tested for various learning parameters, the category of site might be schools or childcare centres or possibly a learning laboratory. Projects may involve more than one category of site and all sites should be listed.

10 b) JHREC sites

Indicate whether all sites at which the project will be conducted are covered by the application to this HREC. For example the project may be conducted at two government departments, one of which is covered by the JHREC and one of which is covered by another HREC.

The answer to this question assists the JHREC to know precisely whom this application is meant to cover, and it prompts the researcher to determine whether this application is sufficient to cover all sites involved in the project.

10 c) Other HREC sites

If this application does not cover all of the sites involved in the study, then it is very likely that an application to another HREC will be required. Researchers should determine what the arrangements are for ethical review of research projects for each site at which the project is to be conducted.

There may be situations where the project involves several categories of participants, the responsibility for whom falls under different HRECs. An example would be a project that will test the learning capabilities of able versus youth with a mild intellectual disability, being conducted by a university researcher. Ethical review of the project by the university HREC may cover the able participants, but the participants with a disability, with the involvement of the Office of the Public Advocate, may be covered by an application to the JHREC.

10 d) All HREC sites

The answer to this part should include all Australian HRECs to which this project has been or will be submitted, including the JHREC. If one HREC has responsibility for a large number of sites at which the project is to be conducted, indicate the number of sites (e.g. 36 child care centres) under the 'Site' column for that particular HREC.

8.11 Question 11: Anticipated duration of the project

State the number of months it is expected to take to complete the research project. In general, the duration of a project starts soon after the date of JHREC approval and ends on the date of completion of the research phase.

Since the analysis of data is considered to be part of the research project, the ongoing analysis of data requires ethics approval. Therefore, if the ethics approval expires before data analysis is complete, an extension for the approval will have to be sought from the JHREC.

8.12 Question 12: Anticipated commencement date

State when the research project is anticipated to start. The date must be later than the date of consideration of the JHREC application.

8.13 Question 13: Anticipated completion date

State when research project is expected to finish. JHREC will approve projects for a maximum of three years. At the end of three years a new application will need to be submitted. Applications will not be given 'open' or 'ongoing' approval.

8.14 Question 14: Literature search strategy

Describe the literature search strategies used. If the literature search was obtained from another source, and the search strategy is not known, indicate that this is the case. Please limit content to half a page. Do not include a bibliography.

8.15 Question 15: Participants

Indicate whether the project involves participants. If 'yes', complete section 3, if 'no' proceed to section 4.

8.16 Question 16: Participants - numbers

16 a) Total numbers

Indicate the total number of participants to be recruited.

16 b) Multi-site project participants

This question only applies to multi-site projects. A multi-site project is a project being conducted at several locations, e.g., more than one school or more than one hospital. A project involving three focus groups held at different community centres is not a multi-site project, but instead should be considered as a single-site project involving three project groups. If the project is not a multi-site project, answer "n/a" for not applicable.

For projects being conducted at more than one site, indicate how many participants in total this HREC is responsible for in the first part of this question, and the break down of that number across all sites for which this HREC has responsibility in the second part of this question. For example, the project may be conducted at 15 sites, two of which are covered by this HREC. The total number of participants for the whole project may be 150 (answer to part a). The two sites under this HREC may have a total of 20 participants (answer to first question in part b) and each of those sites may have 10 participants (answer to second question in part b).

16 c) Participant groups

If the research involves more than one project group, e.g. a test group and a control group or three different focus groups, indicate the number of participants in each group.

8.17 Question 17: Participants - details

17 a) Participant categories

Indicate all categories of participants that are to be recruited. The recruitment might be quite nonspecific (e.g. "members of the general public") or it might be very specific (e.g. "Female parolees with children"). If control groups are to be recruited, include this as one of the categories of participants to be recruited.

17 b) Participant age

Indicate the range of ages of participants.

17 c) Participant consent

Indicate how the competence of participants to give consent will be determined. Refer to National Statement Chapter 2.2 and apply this to your response.

17 d) Participant groups

Indicate whether the study includes any of the categories of vulnerable participants listed. Do this by checking either the 'yes' or 'no' box for each category. Clarify whether or not the research has this category of participants as a specific focus, at Q17(c). **17 e) Child participants**

If the research involves contact with young people under the age of 18, researchers must hold a current Working with Children Check. **17 f) ATSI participants**

All research that specifically involves Aboriginal or Torres Strait Islander (ATSI) participants, or is likely to have a significant number of ATSI participants, must be endorsed by the Koori Justice Unit. This unit will assess the application based on a number of key objectives. For further information, contact the Manager, Evaluation and Monitoring, Koori Justice Unit, on (03) 8684 1744. **17 g) CALD participants**

If the research specifically involves people from Culturally And Linguistically Diverse (CALD) backgrounds, tick yes and provide details of how the participant documents and recruitment processes will be customised to suit these participants. The use of translators should also be considered.

8.18 Question 18: Recruitment of participants

18 a) Recruitment procedure

Describe the recruitment procedure, including information about where participants will be recruited from (e.g. prisons, treatment clinics, etc) and how the recruitment will occur.

Provide samples of each form of recruitment material to be used. This may include printed advertisements, transcripts of radio or television advertisements and telephone calls, copies of photographs or other images to be used, posters and letters of invitation.

18 b) Participation rate

Provide details of the expected participation rate and any follow up procedures to be used for people who respond and who do not respond.

18 c) Dependent or unequal relationships

This question concerns the possibility that participants may be recruited in situations where they are in some way dependent upon the person doing the recruiting. The National Statement (2.2.9) indicates that the person's consent to participate in research must not be subject to any coercion.

In the first part of the question, indicate the nature of the unequal or dependent relationship (e.g. police officer/offender, counsellor/client, etc).

In the second part of the question, indicate how potential problems arising from unequal or dependent relationships between recruiters and participants will be handled. Refer also to Section 3 of the National Statement.

18 d) Dual relationships

This question deals with the possibility that the researcher may, in some instances, have more than one relationship with some or all of the participants in the research. For example the researcher may also be a colleague of the research participants or may have responsibility for the program area being studied. This situation is referred to as a 'dual relationship' and does not necessarily involve an unequal or dependent relationship, although it may.

In the first part of this question, indicate the nature of any dual relationship (e.g. the researcher is a work colleague of the participants).

In the second part of the question, indicate how potential problems arising from dual relationships between researchers and participants will be addressed (also refer to the National Statement Chapter 4.3).

18 e) Reimbursement or payment of participants

This question covers the issue of reimbursement, payment or other incentives to be made to participants.

A payment should not be too large or it risks becoming an inducement to participate and potentially biasing the project's results.

Inducement involves the offer of excessive and inappropriate reward in order to obtain compliance from potential research participants. Examples of inducements may include payment for research participation, offers of subject credits to students, or promises of leniency to prisoners. (Refer to 2.2.10 of National Statement)

In answering this question, researchers should explain:

- What the type and level of the payment or reimbursement is
- Whether it is necessary, and if so why.

8.19 Question 19: Information to participants

19 a) Deception of participants

This question concerns research involving deception of participants. This issue is discussed in Section 2.3 of the National Statement.

19 b) Written information

Although the National Statement stipulates that obtaining informed consent must involve provision of information to participants, at their level of comprehension, about the research (National Statement 2.2.1 and 5.2.16), there may be circumstances where use of written participant information is not feasible. If written participant information will not be used, explain the reasons for this.

19 c) Provision of information to participants

Describe how information (whether written or not) will be given to participants (e.g. " an Information sheet will be distributed to prisoners at a meeting at the prison"). Note: The Information Sheet should be attached as an appendix on the appropriate institution/organisation letterhead. Additional information about Participant Information Sheets, together with Consent Forms, is provided in the next section of these guidelines.

NOTE: Copies of all the participant information documents must be issued to participants for their retention and be separate from the consent form.

8.20 Question 20: Consent

Before giving approval, the JHREC must be satisfied as to how the researcher(s) will obtain evidence that a participant has given valid consent to participate in the project (National Statement 2.2.4-2.2.7). HRECs generally require that written consent will be obtained from all participants and the Consent Form is evidence that valid consent has been obtained.

Indicate whether written consent to participate is to be obtained.

20 a) Children and young people

Research involving children and young people raises particular ethical concerns about their capacity to understand what the research entails, the possible coercion by parents, peers, researchers and others, and conflicts between parent/guardian and child.

Indicate if a child or young person's consent will be sought (in the case that the child is capable of providing such consent) or a parent or guardian or primary care giver will be asked to provide consent. For further information see the National Statement 4.3.6 and 4.2.7.

20 b) Alternative consent processes

In some circumstances, it may be ethical to rely on verbal consent, with written consent being unnecessary or even undesirable. In these cases, consent may be recorded by another means.

Examples include video or audio-taping or Researcher's notes of a conversation, or verbal consent by telephone before a telephone interview.

Indicate how consent will be achieved. If written consent will not be obtained, give reasons and explain how consent will be obtained and recorded.

20 c) Participants unable to give consent

Research involving people with cognitive impairment, intellectual disability or a mental illness raises concern about their understanding of the research and ongoing capacity to be involved. (See the National Statement 4.5.5-4.5.10). If the participant is unable to give consent, explain how consent will be achieved, for example from the person's legal guardian.

20 d) Waiver of consent

Any waiver of consent for research using personal health or sensitive information must be approved by JHREC. Before deciding to waive the requirement of consent, ensure that consideration is made to sections 2.3.10 and 2.3.11 of the National Statement.

8.21 Question 21: Consequences of participation

21 a) Potential or actual harms of participation

Explain any risks to participants compared to those people who do not participate. Include psychological and physical risks and any risks to participants' quality of life or potential invasion of privacy.

21 b) Inconvenience to participants

Describe any possible inconvenience to participants.

21 c) Counselling or debriefing

Describe the arrangements that are in place should any participants require counselling or debriefing. Describe the form this counselling/debriefing will take, name the person(s) who will conduct the counselling/debriefing and give details of their qualifications to provide this support. Explain how the researcher will facilitate access to the counselling (it is not acceptable to provide participants with only a list of telephone numbers on their information sheet). Please note that a person independent of the project must conduct the counselling or debriefing.

21 d) Denial of access to treatment or services

Explain whether participants will be denied access to any other interventions, treatments or therapies as a result of participating. If yes, explain the consequences for participants and explain how the researchers will ensure that participants receive care equivalent to or above the current standard practice.

21 e) Benefits of participation

Explain whether there are any potential benefits of participation to the participants.

8.22 Question 22: Summary of ethical issues raised by applications

The purpose of this question is to summarise and address any ethical issues raised by this application.

The *National Statement* (Section 4) provides further details on ethical issues in relation to participants. Applicants are asked to familiarise themselves with these issues before completing this question. Provide details of any other ethical issues not described above and how these issues will be addressed. Issues may include:

- Monitoring and reporting illegal activities (see *National Statement 4.6)*
- Aboriginal, Torres Strait Islander or other special community or cultural groups (*see National Statement 4.7)*
- Risk to third parties. If the project presents risk to third parties (e.g., illegal activity), explain how these risks will be addressed and participants informed of risk minimisation procedures
- Potential participant distress.

8.23 Question 23: Adverse events

Explain the monitoring, reporting and other procedures set up to manage adverse, or unforeseen events.

Adverse events may include adverse responses from participants or other bodies (including media) in reaction to forms or methods of questioning. These adverse events may have longer-term implications for the data collection process or the organisations involved in the research, including the institution responsible for the research and/or the DJR.

The Principal Researcher is responsible for reporting all adverse events, signing all correspondence regarding adverse events, and forwarding updates on adverse events to the HREC.

For serious adverse events, the Principal Researcher must report to the JHREC as soon as possible and, if practicable, within 24 hours of awareness of the event.

In reporting an adverse event, the Principal Researcher must provide written notification to the JHREC via email detailing:

- the adverse event
- events leading to the adverse event
- what action was taken to manage the adverse event
- whether they believe it is appropriate to continue or discontinue the project
- any participant information sheets or consent forms should be changed. A copy of any changes must promptly be forwarded to the JHREC.

8.24 Question 24: Research Involving Collection, Use or Disclosure of Information

If the project does not involve the collection, use or disclosure of ‘personal information’, ‘sensitive information’, or ‘health information’, then you do not need to answer Section 4. Go to Section 5.

8.25 Question 25: Type of activity proposed

Indicate all types of activity for which this proposal is seeking approval.

8.26 Question 26: Collection of information directly from individuals

Information collected directly from an individual will generally, by implication, only be collected with their consent. However, in any event, when collecting the information, the researcher is responsible for taking reasonable steps to inform the participants about the following matters:

- the purpose for which the information about the participant being collected (i.e. research)
- any planned disclosures of that information to other persons or organisations
- any law that requires the information to be collected (this is highly unlikely to arise in the context of consensual research)
- the main consequences for the participant (if any), if they do not provide the information sought
- their ability to access the information about them, collected for the research, where possible

These obligations can be read subject to the two sets of guidelines made under the Privacy Act (Cth), and the Guidelines made under the *Health Records Act 2000 (Vic)*, as applicable.

For example, if a researcher subject to section 95A of the Privacy Act 1988 proposed to collect health information without consent of, or notice to, the research subject, the Guidelines made under section 95A state that the researcher should explain why they are unable to comply with the 'collection' Privacy Principle.

Note that from 12 March 2014, as a result of the Privacy Amendment (Enhancing Privacy Protection) Act 2012 (Cth) researchers covered by the Privacy Act 1988 (Cth) are required to take reasonable steps to give participants notice about additional matters, when collecting personally identifying information, again, subject to their adherence to applicable Statutory Guidelines relating to research. These additional matters, are, relevantly as follows:

If the researcher proposes to collect information about the participant from another source, advise of this fact and the circumstances

That the researcher's (or institution's) privacy policy contains information about how:

- Participants can access or correct personal information collected
- Participants can complain about a breach of privacy, and how the researcher will deal with such a complaint;

Whether the researcher is likely to disclose personal information to overseas recipients, and if so, the countries in which such recipients are likely to be located.

These are matters that can generally be set out in the Participant Information Sheet (PIS) and in some cases can be implied from the overall information provided, however if participants will not be informed about these matters in the PIS, please give reasons why this is the case in Q26. For further notice requirements, see also Consent of Consent Form, in these guidelines.

8.27 Question 27: Collection of Information about individuals from a third party

27 a) Information from a source other than the individual

If you answer 'yes' to this part, you will need to answer at least parts (b)-(e) of this question.

27 b) Source of information

Specify the source of the information that is to be collected. Check as many boxes as are relevant (i.e. if the information is to be collected from more than one source). In the box at the end of part (b), list the organisations by name (or by category if there are a large number, e.g. “child care centres”) and clearly indicate precisely what information will be obtained from each source.

Commonwealth agencies with recordkeeping functions, frequently approached by researchers for data are listed below (see Australian Health Ethics Committee (AHEC), Report on Use of Section 95 Guidelines).

Australian Law Reform Commission	Australian Electoral Commission (not State Electoral Offices)
Australian Archives	Australian National University
Australian Bureau of Statistics	Australian Sports Commission
Australian Institute of Health and	Health Insurance Commission Welfare

27 c) Agreement from institutions

Indicate whether the organisations from which you intend to collect information have agreed to provide that information and supply written evidence of the agreement to disclose information. If the agreement of the disclosing organisation has not yet been obtained, explain why not and how/when the agreement will be obtained.

27 d) Separate HREC approval for use of information

Indicate whether the organisation from which information will be collected will be seeking separate HREC approval for disclosure of the information. Federal and State privacy laws do not require a disclosing organisation to apply separately for JHREC approval. If separate approval is sought, researchers should supply a copy of that approval when it is available. If separate approval will not be sought, then the researcher should supply a copy of this HREC’s approval (and any conditions associated with it) to the organisation disclosing the information.

27 e) Identifiable information

Indicate whether the information provided may identify a person or people when it is received by the researcher. Information that may identify an individual includes name, address or other contact details, date/place of birth, Medicare number, etc. Identifying information can include other information, if that information is unique in some way or highly specific. For example, “employee of the Victorian DJR” is not sufficient information to identify an individual. However, “employee of organisation X” which only employs three people may be sufficient information to identify someone, particularly in conjunction with other information.

Consider the situation where information is disclosed to a researcher without information that could identify the individual, but coded so that it may be linked with other data, to be re-identified if necessary. If the researcher does not have access to the code, then the information collected and subsequently used by the researcher is de-identified. If the researcher is given the code, as well as the information, then the information is potentially identifiable, as long as the code remains associated with the information. Privacy laws treat ‘potentially identifiable’ information the same as ‘identifiable information’

If the information will be identifiable (or potentially identifiable) and will be collected without consent of the individual to whom it relates, then the specific Statutory Guidelines on privacy requirements for research may need to be applied, depending on which privacy Act is applicable (see the Guidelines below).

If the answer to either part (e) or part (f) is "No", then no further parts of Q27 need to be answered. In this case, go directly to Q28.

27 f) Information collected without consent from individual

Indicate whether identifiable information will be collected without consent. If the information will be identifiable (or potentially identifiable) and will be collected without consent of the individual to whom it relates, the Statutory Guidelines relating to research may have to be applied, depending on which Privacy Principles apply. This part of Q28 assists Researchers to identify which Privacy Principles apply to the collection of information. This will be determined by:

- The type of information being collected;
- The type of organisation that holds the information; and
- The type of organisation that is collecting the information.

27 g) Privacy principles

Tick as many boxes as apply. For example, if both health information and other personal information is being collected, tick both boxes. Then, within each category of information, tick the box next to the type of organisation that holds the information and the type of organisation that is collecting the information. E.g., the researcher may be a Victorian public sector organisation, but may be collecting information held by a Commonwealth Agency. In this case, both the 'Victorian public sector' and 'Commonwealth public sector' boxes should be ticked.

Note that even though the researcher's activities are not covered by the Commonwealth legislation, the Commonwealth legislation does apply to this project, since the information is held by the Commonwealth public sector. The right-hand column for each row that has been ticked will identify the Privacy Principle(s) relevant to that situation.

The relevant Statutory Guidelines are:

- For Health Privacy Principles (HPPs) under the Health Records Act 2001 (Vic) – Statutory Guidelines on Research issued for the purposes of Health Privacy Principles 1.1 (e)(iii) & 2.2(g)(iii). Download from the Office of the Health Services Commissioner's website: http://www.health.vic.gov.au/hsc

- For Australian Privacy Principles (APPs) under the Privacy Act 1998 as applicable to the Commonwealth public sector– Guidelines Under Section 95 of the Privacy Act 1988 (Cth). http://www.nhmrc.gov.au/publications/synopses/e26syn.htm
- For APPs as applicable to the private (business) sector – Guidelines Approved under Section 95A of the Privacy Act 1988 (Cth). http://www.nhmrc.gov.au/publications/synopses/e43syn.htm
- Note that there are no Guidelines on research that have been issued under the Information Privacy Act 2000 (Vic).

27 h) Identifiable information

Explain why the information will not be collected in a de-identified form, for example because identifiers are required for data linkage, etc. This question is not requesting an explanation of why the information is considered to be identifiable or potentially identifiable (e.g. because names and birth dates will be included).

27 i) Waiver of consent

Explain why consent will not be obtained, for example because the number of records is so large that obtaining consent is not practicable. This question is **not** seeking an explanation of why the researcher's actions constitute 'not seeking consent' (e.g. because the researcher won't be contacting the individuals).

27 j) Justification for access to information

Clarify how the collection is in the public interest. The answers provided by the researcher to questions 27 h) i) and j) will in large part determine whether the JHREC comes to the conclusion that the public interest in the project (whether it is research or another activity) substantially outweighs the public interest in protecting the privacy of individuals.

8.28 Question 28: Use or disclosure of information about individuals

28 a) Use of identifiable information

Indicate whether the project will involve the use of identifiable or potentially identifiable information. If the answer is 'no' continue to question 30.

28 b) Disclosure of identifiable information

Indicate whether the project will involve the disclosure of information about an individual. If the answer is 'no' continue to question 30.

28 c) Use of information without consent

Indicate whether the project will involve the use of information without the consent of the individual whose information it is. If the answer is 'no' continue to question 30. **28 d) Privacy Principles**

Tick as many boxes as apply, then within each category of information, tick the box next to the type of organisation that is using or disclosing the information.

28 e) Purpose for use of information

Specify how the information will be used. Privacy Principles generally require that personally identifying information is used or disclosed for the primary purpose it is originally collected by an organisation.

28 f) Use of information different to original purpose

If the information is to be used or disclosed for a purpose other than the primary purpose for which the information was collected, explain the purpose for which the information will be used. **28 g) Disclosure of information to organisations**

Identify any organisations to which the information will be disclosed if applicable. List the organisations by name and clearly indicate what information will be disclosed to each one.

28 h) Reason for disclosure of identifiable information

Explain why the information will not be disclosed in a de-identified form, for example because identifiers are required for data linkage, etc.

28 i) Reason for consent not being obtained for disclosure of information

Explain why consent will not be obtained for the disclosure of information.

28 j) Public Interest

Clarify how the use and disclosure of the information is in the public interest.

8.29 Question 29: Security of information

29 a) Number of records

Indicate the total number of records that will be collected used or disclosed.

29 b) Type of information

Specify the type of information that will be collected, used or disclosed, for example hard copy coronial files, date of birth data, videos of participant interviews.

29 c) Security arrangements

Explain the security arrangements for the storage of the information. Be specific and ensure each type of data is included, for example 'all hard copy files will be stored in locked cabinets, and all electronic data will be stored on an encrypted USB and password protected computer'. **29 d) Storage**

Explain the location at which the information will be stored, for example 'all information will be stored on campus in the principal researcher's office'.

29 e) Access

List all individuals that will have access to the information and their role in the project. Ensure that each individual also has their information provided at Questions 8. **29 f) Retention**

Specify the maximum time the information will be retained. The committee will not approve openended retention timeframes. Researchers may not retain information for use other than that specified in the application, and any use of information outside that specified will require a new JHREC application.

29 g) Disposal

Explain how the information will be disposed of at the end of the retention period. Provide specific information for the destruction of each type of information, for example ' all hard copy data will be shredded securely on site, and all electronic data will be deleted off computers and servers'. **29 h) Publications**

Specify how the privacy of individuals will be respected in any publications arising from the project, for example 'all information will be presented in aggregate form in publications **29 i) Trans-border data flow**

If the project involves data moving interstate, or overseas, you must tick 'yes' and explain how the information will be transferred and how this will be in accordance with relevant Privacy Principles.

29 j) Unique identifiers

If the project involves the adoption of unique identifiers assigned to other individuals by other agencies or organisations, you must tick 'yes' and explain how the identifiers will comply with the relevant privacy principles.

8.30 Question 30: Adverse events - information management

Procedures must be in place to manage any adverse or unforseen events in relation to information collection, use or disclosure. Ensure that all relevant HRECs will be notified, including JHREC.

8.31 Question 31: Other ethical issues

This question must be answered. Explain any potential ethical issues, and the steps taken to address these. If you believe there are no other ethical issues, then state this and explain your rational.

8.32 Question 32: Conflict of interest

If there are any affiliation or financial interest for researchers in this project or its outcomes you must tick 'yes'. Provide details of the conflict of interest, and how any issues will be managed.

8.33 Question 33: Project budget

Provide a budget if one is available and tick the appropriate boxes. If a budget is not being provided, please explain the reason.

8.34 Question 34: Source of funding

Provide details of the funding sources for this project.

8.35 Question 35: Funds coverage

If all funds presently available or applied for cover all requirements to conduct the project, tick 'yes', If there is a short fall in funds, please explain how this will be dealt with.

8.36 Question 36: Indemnity

All researchers must be covered by suitable professional indemnity insurance. Please attach a copy of your institution's current professional indemnity certificate.

9 Application Checklist

This section must be completed and signed.

10 Attachments

10.1 Recruitment poster or flyer

Attach a copy of any recruitment posters or flyers. The institution, researcher and project objectives must be clearly stated. Do not include information stating that the project has been approved by any HRECs.

10.2 Participant information sheet

Attach a copy of the participant information sheet. The participant information sheet must be clear and written at an appropriate level for the audience. For example, if the participant information sheet is for prisoners, then ensure a plain language version is available, and arrangements are in place for participants with no, or low literacy ability. Ensure the JHREC phone number and email address is included (do not include the JHREC postal address).

Clarify the research and the involvement required at the beginning of the document. Ensure it is clear that the participant may withdraw from the project at any time up until the specific point in time their information will be de-identified in the project (ensure this point in time is clear).

If any sensitive of potentially distressing information is involved in participation, warn the participant of this in the participant information sheet.

The participants must be given this document to retain for their information.

10.3 Participant consent form

Attach a copy of the consent form. Ensure the form is clear, and written at an appropriate level for the audience. Include bullet points ensuring the participant understands what their participation in the project involves, including the use of their information and any details regarding withdrawal from the project. This form must be separate to the participant information sheet.

10.4 Survey instrument

Attach any survey instruments to be used in the project, for example questionnaires or interview questions. Ensure the questions are clear and written at an appropriate level for the participants.

Ensure the length of any questionnaires or interviews are realistic and not overly burdensome on the participants.