Application Guidelines

Justice Human Research Ethics Committee

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State Government Victoria
Department of Justice & Regulation

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1 Getting Started

The purpose of these guidelines is to provide detailed information and instructions to assist researchers in completing a JHREC application form for the ethical review of projects with more than a low level of risk.

Where a researcher deems any project to have more than a low level of risk, the researcher is required to submit an application to the Justice Human Research Ethics Committee (JHREC) for approval, prior to project commencement.

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 the principles for the conduct of research involving humans, and gives a clear indication of the issues that HRECs consider in determining the scientific merit of, and ethical issues raised by, project proposals.

It is important that applicants 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 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 of risk for:

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

3.1 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 and are referred to the *National Statement* Chapter 2.1 'Risk and Benefit' for guidance.

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

4 Types of Applications

4.1 New Application

Any project that has not yet undergone JHREC review is a new application. See the table below for application approval duration.

4.2 Renewal Application of a Long-Term Project

If a JHREC approved project is ongoing and will exceed the maximum five year approval period, 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.

4.3 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).

NOTE: The JHREC reserves the right to decide the manner in which applications need to be presented to the Committee for review, whether it be as a new application, renewal or amendment.

4.4 Application Approval Duration

Type of Application	Approval Period
New Application (standard)	Maximum 3 years
New Application (justification must be provided)	Greater than 3 years Less than 5 years
Long-term Application	Renew every 5 years

5 Essential Steps in making a JHREC application

5.1 Note the Submission Deadlines and Meeting Dates

All applicants need to be aware of the submission deadlines and meeting dates when making an application. It is important to note that **submission deadlines are strictly applied**. Should you have any queries regarding meeting a submission deadline, please contact the JHREC Secretary at:

Email: ethics@justice.vic.gov.au
Phone: (03) 8684 1514

5.2 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 (e.g. National Coronial Information System, Corrections Victoria Research Committee or Koori Justice Unit). 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.

5.3 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 established with Monash University, The University of Melbourne, Deakin University and RMIT. See details below.

5.4 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.

Researchers should first contact the relevant HREC below to confirm whether their project is suitable for streamlining.

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

Deakin University
Email: research-ethics@deakin.edu.au
Monash University HREC
Email: muhrec@monash.edu
RMIT University
Email: humanethics@rmit.edu.au
The University of Melbourne HREC
Email: HumanEthics-Enquiries@unimelb.edu.au

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

6 Preparation of an Application

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

All necessary attachments must accompany the completed application form including letters of support and approval letters from university HRECs (where applicable). Note that the finalised version of research instruments such as participant information sheets, consent forms and interview questions are also required.

Ensure that the signature pages of the Researcher Declaration and Checklist form are signed by **all** researchers involved in the project.

Please ensure sufficient detail is provided including all relevant information so that your application can be assessed without unnecessary delay. Please complete all sections of the application. If a section does not apply to your research, please write not applicable (N/A) in the space provided (do not leave it blank).

Researchers must provide a current professional indemnity certificate.

6.1 Participant Information

It is important to ensure all documents for participants are clear and informative. Please ensure the following:

- *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 matters*: 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 support and safety of the researchers.

6.2 Presentation

Applications must be written in clear, plain language so that JHREC members who do not have a background in the field of the project can easily understand the content of the application. Please define all terminology and abbreviations.

Please check applications thoroughly to avoid misspelling and grammatical errors, especially participant information sheets, consent forms and/or questionnaires.

6.3 Submission of application

Please email a single electronic copy of your application and attachments 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 e.g. poster or flyer
- Participant information sheet
- Participant consent form
- Survey instrument e.g. 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.

NOTE: The JHREC no longer accepts hard copies of applications. Electronic PDF submissions, in the format stated above, are sufficient for JHREC requirements.

7 Outcomes of JHREC Review

The JHREC aims to inform researchers of their decision within one week of the JHREC meeting. The review outcome will be one of the following:

- *Full Approval*: Upon a project receiving full approval, researchers are required to complete an Undertaking Form provided by the JHREC and return it to the JHREC Secretariat.

- *Provisional Approval*: Where a project receives provisional approval, researchers are required to address any concerns raised by the JHREC.

  A table will be provided to researchers by the JHREC which includes a column that outlines the Committee's comments/concerns that need to be addressed, and a column in which researchers are required to provide their responses. In addition to completing this table, the responses provided in the response column must also be reflected in an amended application form which is to be resubmitted by researchers with the completed table. Any changes to the resubmitted

application form must be highlighted in yellow so that the JHREC can easily identify these changes. The resubmitted application must be provided to the JHREC Secretariat **in full as one pdf document** and include the signed declaration and checklist, letters of support, professional indemnity certificate and any other supporting documentation.

- *Not Approved*: Where a project is not approved, the researcher might be invited to resubmit the application, upon addressing any concerns raised by the JHREC. 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. A resubmitted application must contain the amendment table (outlined above) to be provided by the JHREC indicating where the changes have been made to the application. The resubmitted application will then be considered at a future JHREC meeting according to the respective submission closing date.

8 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 (e.g. NCIS, Corrections Victoria Research Committee).

- *Annual Report Form*: Annual Report Forms are to be submitted every 12 months on the anniversary of full JHREC approval being granted (for projects which extend beyond 12 months in duration). Annual Report Forms should also be accompanied with evidence of publications or presentations, where applicable (no more than two are required).

- *Completion Form*: Completion Forms are to be submitted upon conclusion of the research phase of the project. A copy of the research findings are also required on finalisation of the project.

- *Five Year Phase Completion of Long Term Projects:* Long term or ongoing projects are required to submit a Completion Form at the end of each five-year period.

- *Adverse Event/Incident Report:* Any adverse event or incident must be reported to the JHREC in writing via email within 48 hours that summarises the adverse event and indicates what steps have been/will be taken to address the issue.

9 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.

9.1 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(d), 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.

9.2 Data Security

Researchers are required to 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.

10 Application Form Guidance

10.1 Question 1: Full Project Title

Provide the full technical or scientific project title

10.2 Question 2: Brief Project Title

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

10.3 Question 3: Broad Category of Research

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

10.4 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 (refer National Statement 2.1.3 and 2.1.8).

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

- justification of the project;
- description of how the proposed research will complement, enhance, or contribute to existing knowledge, including an analysis of previous literature and studies;
- explanation of 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 by using more rigorous experimental criteria);
- primary hypothesis and/or research questions; and
- project design, including scientific description.

Researchers are required to provide sufficient detail to enable the HREC to determine the project's methodological rigour. It is important that researchers also 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).

10.5 Question 5: Aims and Hypothesis

The aims should summarise clearly why the project is in the public interest and that any imposition on participants or public resources is justified. Please provide 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. Please limit your response to 150 words.

Please clearly state the hypothesis or hypotheses being tested, limiting your answer to 100 words. If the project does not involve testing a hypothesis, write “not applicable”.

10.6 Question 6: Reporting of Results

6(a) Restrictions on publications

Please indicate whether there is any restriction regarding the publication of results. If any type of limitation or restriction exists, please provide details (e.g. who will impose the restriction, how long does the restriction apply?).

6(b) Report details

Please describe what type of publication(s) will be made available at the end of the project and how members of the public will be able to access it? If a publication will not be made available, please provide the JHREC with justification.

NOTE: Where applicable, researchers should consider providing a summary report of findings to stakeholders and participants that is specifically crafted to meet their needs, as opposed to providing a peer reviewed journal article, thesis or a major report.

6(c) Reports and participants

At the end of a project, it is useful to provide participants a final report on the outcomes of the research which will assist with future recruitment and compliance, as many participants appreciate receiving feedback and are rewarded by knowing the results of their participation.

Where a project involves participants, please explain how the research outcomes will be made directly available to the participants and in what format they will be provided.

If a final report is to be made available to participants, please inform them prior to the commencement of the project that a final report will be available to them at the conclusion of the study. This information can be indicated in the Participant Information Sheet.

10.7 Question 7: Victoria Police

Please indicate whether the project will utilise any Victoria Police data or involves Victoria Police officers.

10.8 Question 8: Researchers and contact details

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 therefore be listed and have appropriate credentials indicating the role of each researcher in the project. Researcher roles include Principal Researcher, Associate Researcher, Student Supervisor and Student.

The Principal Researcher is the person with overall responsibility for the project. Where a project is being undertaken by a student, the student's supervisor must be the Principal Researcher(s). It is important the Principal Researcher has input into the proposal and reviews the final application.

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

Please 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) and contact details of the person to whom the JHREC Secretariat is to direct correspondence concerning the project (this is normally the Principal Researcher).

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

8(b) Departmental Contact

Please 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.

10.9 Question 9: Project Summary

9(a) Participants

Please indicate whether the project involves participants.

9(b) Use or disclosure of information

Please indicate whether the project involves the collection, use or disclosure of information.

10.10 Question 10: Sites where the project will be conducted

The questions below satisfy the National Statement paragraph 5.3.4 that the Principal Researcher must inform the JHREC of all other Australian sites where the research project will be conducted as well as the name and location of any other body that will conduct an ethical review of the research.

10(a) Category of sites

Please indicate the category(s) of sites where the project will be conducted. For example, if your research was being conducted at multiple prisons throughout Victoria, the category of site would be prisons. Projects may involve more than one category of site and all categories should be listed.

10(b) Number of sites

Please indicate the number of sites where the project will be conducted. Using the previous example, if you were conducting research at three separate prisons, then the number of sites would be three.

10(c) JHREC sites

Please indicate how many of the sites (nominated under Q10(b)) will be covered by your application to the JHREC. There are some instances where part of a project may be conducted at a different category of site that falls outside the scope of the JHREC, which would require the approval of another HREC. For example, the project might be conducted at two government departments, one of which is covered by the JHREC and one of which is covered by another HREC. This is most common where a project involves multiple categories of participants, the responsibility for whom falls under different HRECs.

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(d) 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.

10(e) Listing all HREC sites

Where applicable, please list all Australian HRECs to which your project has been or will be submitted, including the JHREC. Where a HREC has responsibility for a site(s) at which the project is to be conducted, please indicate the number of sites (e.g. 3 hospitals) under the 'Site' column for that particular HREC.

10.11 Question 11: Anticipated duration of the project

Please 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.

If your project is not long term/ongoing and you anticipate the duration of your project will exceed three years and less than five years, please provide justification why you will need longer than three years to complete your project. Approval of applications greater than three years and less than five years will only be granted in exceptional circumstances. Refer also to 4.4 Application Approval Duration in these Guidelines.

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, approval of an amendment seeking the extension is required to be sought from the JHREC.

10.12 Question 12: Anticipated commencement date

Please state when the research project is anticipated to start. The date must be later than the date your application is reviewed by the JHREC.

10.13 Question 13: Anticipated completion date

Please state when your research project is expected to finish. Refer to 4.4 of these Guidelines regarding application approval duration. It is important to note applications will not be given 'open' or 'ongoing' approval.

10.14 Question 14: Literature search strategy

Please describe the literature search strategies used for your project. 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 and do not include a bibliography.

10.15 Question 15: Participants

Please indicate whether your project involves participants. If 'yes', please complete section 3. If 'no', you may proceed to section 4.

10.16 Question 16: Participants - numbers

16(a) Total numbers

Please indicate the total number of participants to be recruited for your project, including those for whom the JHREC would not have responsibility for.

16(b) Multi-site project participants

Please indicate whether your project is a multi-site project. A multi-site project is a project being conducted at several locations (e.g. more than one prison). More specifically, a site is considered the physical location where the data collection occurs as opposed to where it might be analysed. The National Coronial Information System is an example of a single site project.

For projects being conducted at more than one site, please indicate in total how many participants for whom the JHREC will be responsible.

In the second part of the question, please provide a breakdown of the number of participants involved at each site for whom the JHREC has responsibility.

For example, the project may be conducted at 15 sites, two of which are covered by the JHREC. The total number of participants for the whole project may be 150 (answer to Q16(a)). The two sites under the JHREC may have a total of 20 participants (answer to first question under Q16(b)) and each of those sites may have 10 participants (answer to second question under Q16(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 at a particular site), please indicate the number of participants in each group.

10.17 Question 17: Participants - details

17(a) Participant categories

Please indicate all categories of participants that are to be recruited. The recruitment might be quite non-specific (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

Please indicate the age range of the participants.

17(c) Participant consent

Please 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

Please indicate whether the study includes any of the categories of vulnerable participants listed. This can be done by checking either the ‘yes’ or ‘no’ box for each category. It is important to clarify at Q17(c) whether or not your research has a category of participants as a specific focus.

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 (WWCC). All researchers must provide evidence that they hold a WWCC (i.e. provide the WWCC number or a scanned copy of the WWCC identification card).

17(f) Aboriginal and Torres Strait Islander participants

All research that specifically involves Aboriginal or Torres Strait Islander (ATSI) participants must be endorsed by the Koori Justice Unit within the Department of Justice and Regulation.

NOTE: Given ATSI people are overrepresented in prison populations, it is likely that your research might involve ATSI participants whether or not that is your specific intention. If your research is likely to have a significant number of ATSI participants (greater than ¼ of all participants), then your research must also 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) Culturally and Linguistically Diverse participants

If the research specifically involves people from Culturally and Linguistically Diverse (CALD) backgrounds, mark the yes box 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.

10.18 Question 18: Recruitment of participants

18(a) Recruitment procedure

Please describe the recruitment procedure, including information about where participants will be recruited from (e.g. prisons, courts etc) and how the recruitment will occur.

Please provide a copy 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

Please provide details of the expected participation rate and any follow up procedures that might be used to ensure a sufficient participation rate.

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. Please also refer to Chapter 4.3 of the National Statement for further guidance on dependent or unequal relationships.

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

In the second part of the question, please specify how potential problems will be handled arising from identified unequal or dependent relationships between recruiters and participants.

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 participant(s) 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, please 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, please 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 that it risks becoming an inducement for participation leading to potential bias in 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 the National Statement).

In answering this question, researchers should:

- describe what payment or reimbursement is being provided to participants; and
- provide justification of why reimbursement is appropriate/necessary.

10.19 Question 19: Information to participants

19(a) Deception of participants

This question concerns research involving deception of participants. There may be legitimate reasons for research to provide limited disclosure of the research aims or methods to participants. Please refer Chapter 2.3 of the National Statement for guidance. Sufficient justification why the research involves deliberate deception of participants is required in order to obtain approval.

19(b) Provision of written information to participants

Although the National Statement stipulates that obtaining informed consent must involve the provision of information to participants about the research that is easy to understand (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, sufficient justification is required in order to obtain approval.

19(c) Provision of information to participants

Please describe how information (whether written or not) about the research will be provided to participants (e.g. “Participant Information Sheets will be distributed to prisoners at a meeting at the prison”).

NOTE: Participant Information Sheet(s) must be attached as an appendix to your application on the appropriate institution/organisation letterhead. Additional information about Participant Information Sheets and Consent Forms is required at Q20, Q21 and Q26.

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

10.20 Question 20: Consent

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

Please 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 whether a parent, guardian or primary care giver will be asked to provide consent. Refer to sections 4.2.7 and 4.3.6 of the National Statement for further guidance.

20(b) Written and 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.

Please indicate whether written consent to participate will be obtained. If written consent will not be obtained, please provide justification why 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 (Refer to the National Statement Chapter 4.5). If the participant is unable to provide consent, please explain how consent will be obtained (e.g. 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, please ensure that you give due consideration to sections 2.3.10 and 2.3.11 of the National Statement.

10.21 Question 21: Consequences of participation

21(a) Potential or actual harms of participation

Please explain any risks or potential harm to participants involved in the research and how you intend to manage such issues. This includes psychological and physical risks, as well as any risks to participants' quality of life or potential invasion of privacy.

21(b) Inconvenience to participants

Please describe any possible inconvenience to participants.

21(c) Counselling or debriefing

Please describe the arrangements for counselling or debriefing participants, should this be required. This includes what counselling/debriefing will be available to participants, the name(s) of the person(s) who will conduct the counselling/debriefing providing details of their qualifications to provide this support. Please explain how researchers will facilitate access to the counselling. It is not acceptable to only provide participants with a list of telephone numbers on their participant information sheet.

NOTE: A person independent of the project must conduct the counselling or debriefing.

21(d) Denial of access to treatment or services

Please indicate 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

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

10.22 Question 22: Summary of ethical issues

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

The *National Statement* (Section 4) provides further guidance on ethical issues specific to participants. Applicants are asked to familiarise themselves with these issues before completing this question. Please 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; and/or

10.23 Question 23: Adverse or unforseen events

Please explain the process of how you will monitor, report and manage any adverse or unforeseen events involving participants. A response indicating "no adverse or unforseen events are anticipated" is not acceptable. Researchers should describe the actions they will take, should an adverse or unforseen event occur.

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 Department of Justice and Regulation.

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

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 you believe it is appropriate to continue or discontinue the project; and
- any participant information sheets or consent forms that require amendment. A copy of any changes must be promptly forwarded to the JHREC.

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

If the project does not involve the collection, use or disclosure of identifiable 'personal information', 'sensitive information', or 'health information', then you may proceed to Question 29.

10.25 Question 25: Type of activity proposed

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

10.26 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, 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 is 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 2001 (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 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, which are 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 participants of this fact and the circumstances;
- the researcher's (or institution's) privacy policy must contain 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.

10.27 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) Sources of the information being collected

Please specify the source of the information that is to be collected, checking all relevant boxes (i.e. if the information is to be collected from more than one source). In the box at the end of part (b), please 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.

Examples of Commonwealth agencies with recordkeeping functions frequently approached by researchers for data are listed below.

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 Welfare	Health Insurance Commission

27(c) Agreement from institutions

Please indicate whether the organisations from which you intend to collect information have agreed to provide that information. You are required to provide written evidence of your agreement. 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

Please indicate whether the organisation from which information will be collected will be seeking separate HREC approval to disclose 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

Please 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, particularly 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.

It is important to note that privacy laws treat 'potentially identifiable' information the same as 'identifiable information'. To illustrate the types of identifiable information, say for example information was disclosed to a researcher without information that could identify individuals, but coded so that it may be linked with other data, and later re-identified if necessary. If the researcher was not provided access to the code, then the information collected and subsequently used by the researcher is considered de-identified. However, if the researcher is provided the code, as well as the information, then the information is potentially identifiable, as long as the code is held with the 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 you answer "Yes" to Q27(e), please explain why the information will not be collected in a non-identifiable form (e.g. because identifiers are required for data linkage). This question is not requesting an explanation why the information is considered identifiable or potentially identifiable (e.g. because names and birth dates will be included).

27(f) Information collected without consent from individual

Please 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 Q27 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 is collecting the information; and
- the type of organisation that holds the information.

If you answer "Yes" to Q27(f), please explain why consent will not be obtained (e.g. because the number of records is so large that obtaining consent is not practicable). This question is **not** seeking an explanation why the researcher's actions constitute 'not seeking consent' (e.g. because the researcher won't be contacting the individuals).

27(g) Privacy principles

Please 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/or 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).

It is important to 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 Privacy and Data Protection Act 2014 (Vic).

27(h) Justification for access to information

Please clarify how the collection of information for your project is in the public interest. The explanations provided by the researcher to questions 27(e)(f) and (h) will assist the JHREC in determining whether the public interest in the project (whether it is research or another activity) substantially outweighs the public interest in protecting the privacy of individuals.

10.28 Question 28: Use or disclosure of information about individuals

28(a) Use of identifiable information

Please indicate whether the project will involve the use of identifiable or potentially identifiable information. If the answer is 'No', proceed to question 29.

28(b) Disclosure of identifiable information

Please indicate whether the project will involve the disclosure of information about an individual. If the answer is 'No', proceed to question 29.

28(c) Use of information without consent

Please indicate whether the project will involve the use of an individual's information without his/her consent. If the answer is 'No', proceed to question 29.

28(d) Privacy Principles

Please 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

Please 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, please explain the purpose for which the information will be used.

28(g) Disclosure of information to organisations

If applicable, please identify any organisations to which the information will be disclosed. List the organisations by name and clearly indicate what information will be disclosed to each one.

28(h) Reason for disclosure of identifiable information

Please explain why the information will not be disclosed in non-identifiable form (e.g. because identifiers are required for data linkage). Please note that there are several parts to this question that all need to be answered, where information in identifiable (or potentially identifiable) form will be used or disclosed.

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

Please explain why consent will not be obtained from individual whose information will be used or disclosed.

28(j) Public Interest

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

10.29 Question 29: Security of information

29(a) Number of records

Please indicate the total number of records that will be collected, used or disclosed.

29(b) Type of information

Please specify the type of information that will be collected, used or disclosed (e.g. hard copy coronial files, date of birth data, videos of participant interviews).

29(c) Security arrangements

Please explain the security arrangements for the storage of the information. Be specific and ensure each type of data is included (e.g. '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

Please explain the location at which the information will be stored (e.g. 'all information will be stored on campus in the principal researcher's office').

29(e) Access

Please list all the 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(a).

29(f) Retention

Please specify the maximum time the information will be retained. It is important to note that the Committee will not approve open-ended retention timeframes. Researchers may not retain information for use other than that specified in the application. If researchers are considering using this information for similar but separate projects, they need to state they understand that any use of information outside that specified in the application will require a new JHREC application.

29(g) Disposal

Please explain how the information will be disposed at the end of the retention period. Provide specific information for the destruction of each type of information (e.g. 'all hard copy data will be shredded securely on site, and all electronic data will be deleted off computers and servers').

29(h) Publications

Please specify how the privacy of individuals will be respected in any publications arising from the project (e.g. '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, please tick 'Yes' and explain how the information will be transferred and how this will occur in accordance with relevant Privacy Principles.

29(j) Unique identifiers

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

10.30 Question 30: Adverse events - information management

It is important you describe the procedures in place to manage any adverse or unforseen events in relation to information collection, use or disclosure, ensuring that all relevant HRECs will be notified, including JHREC.

10.31 Question 31: Other ethical issues

A response to this question is required that explains any potential ethical issues and the steps taken to address these issues. If you believe there are no other ethical issues, then state this and explain your rationale.

10.32 Question 32: Conflict of interest

If there is any affiliation or financial interest for researchers in this project or its outcomes, please tick 'Yes'. Please provide details of the conflict of interest and how any issues will be managed.

10.33 Question 33: Project budget

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

10.34 Question 34: Source of funding

Please provide details of the funding sources for this project.

10.35 Question 35: Funds coverage

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

10.36 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.

11 Application Checklist and Researcher Declaration

The Application Checklist and Researcher Declaration is required to be completed and signed by all researchers listed under Q8(a).

12 Attachments

12.1 Recruitment poster or flyer

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

12.2 Participant information sheet

Please attach a copy of the participant information sheet (PIS). 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. Please ensure the JHREC phone number and email address is included (do not include the JHREC postal address).

The PIS should clarify the research and the involvement required at the beginning of the document. It needs to be clear that the participant may withdraw from the project at any time up until the specific point in time their information will be converted to non-identifiable form in the project. Please ensure this point in time is clear.

If any sensitive or potentially distressing information is sought from the participant, then make this clear to the participant on the participant information sheet.

Participants must be given this document to retain for their information.

12.3 Participant consent form

Please attach a copy of the consent form ensuring the form is clear, and written at an appropriate level for the audience. Please include bullet points that clearly articulate what the participant's involvement in the project entails, including the use of their information and any details regarding withdrawal from the project. This form must be separate to the participant information sheet.

12.4 Survey instrument

Please attach any survey instruments to be used in the project (e.g. questionnaires or interview questions) ensuring the questions are clear and written at an appropriate level for the participants.

The length of any questionnaires or interviews should be realistic and not overly burdensome on the participants.