

APPLICATION GUIDANCE DOCUMENT

This Human Research Application Guidance document should be used as a companion document as you complete your Human Research Ethics Application. It will provide you with guidance on how to complete your application form and the content you should include.

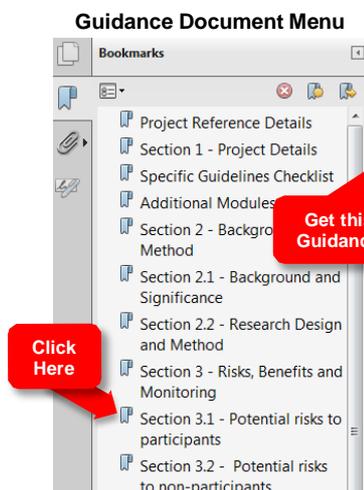
HOW TO USE THE APPLICATION GUIDANCE DOCUMENT

1. This document is designed to be opened whilst completing your application form.
2. This document has a 'Menu' on the left hand side window that contains links to specific guidance information for each section of the application form.
3. Click on the Section Number you require guidance for and you will be directed to the relevant section of this guidance document.

Example of Section 3.1 of Human Research Ethics Application Form

3. Risks, Benefits and Monitoring	
3.1 Potential Risks to Participants	<p>Does your research project pose any potential risks to participants? What are those risks? How will they be negated, minimised or managed? Refer to NS §2.1.</p> <p>Note that the risks you identify here should also be described in your Plain Language Statement (PLS). Attach a copy of any distress protocol or adverse event protocol (if applicable).</p>
<p>A) Potential Risks <i>[Identify, as far as possible, any potential risks to participants associated with the research project. Risks may arise from the nature of questions that participants are asked (such as discussing sensitive or distressing topics), or the tasks that participants will do, or the procedures that they will undergo. Potential risks might be physical, psychological, emotional, social, legal or economic in nature. (This list is not exhaustive). Risks also may be associated with the research setting (e.g. outdoors, in unsecure housing, or in countries other than Australia). If you believe that any potential risks are minimal, please state this and explain why.]</i></p>	
<p>B) Risk Management Strategy <i>[Describe what measures you have in place to negate, minimise or manage the potential risks you have identified. Depending on the type(s) of risks involved, participants may also need additional support (e.g. external counselling) during or after the study. Attach or include a copy of any distress protocol or adverse event protocol which you have developed.]</i></p>	

Example of Section 3.1 of Application Guidance Document



Guidance Information for Section 3.1

3. Risks, Benefits and Monitoring

3.1 Potential risks to participants

Risk involves the likelihood that a harm, discomfort or inconvenience will occur as well as the severity of that harm, discomfort or inconvenience, including its consequences. Assessment of risk involves identifying any risks, gauging their probability and severity, assessing the extent to which they can be minimized, and determining how they can be managed ([NS §2.1](#)).

You may find it useful to organise your answer into sections under the suggested sub-headings.

WHAT TO DO WHEN YOU HAVE COMPLETED YOUR APPLICATION

1. It is highly recommended that you have your application pre-reviewed by a trusted colleague experienced in preparing human ethics applications prior to submission.
2. Save your completed application as a PDF and upload it into Themis. Refer to your local Human Ethics Advisory group ([HEAG](#)) for detailed instructions on how and when to submit your application.

RESPONSIBILITY OF THE APPLICANT

1. Applicants should familiarise themselves with all relevant guidelines and legislation.
2. To ensure that reviewing bodies are provided with sufficient information to participate effectively in the assessment of the application, all responses must be given in plain English.
3. Responses should be clear and concise, and unnecessary or repetitive information should be avoided.
4. Ensure you have entered the Ethics ID number assigned to your project by Themis and the full title of your project, as well as the name of the ***Responsible Researcher** and the ***Application Type** being made.

***Responsible Researcher:** for staff research projects, the responsible researcher will generally be the principal investigator; for student research projects, the responsible researcher will generally be the student's academic supervisor.

***Application Type:** indicate whether you seek to have your project assessed as a minimal risk project or a standard project.

**ALL APPLICATIONS, REGARDLESS OF TYPE, WILL BE REVIEWED IN THE FIRST INSTANCE
BY A HUMAN ETHICS ADVISORY GROUP ([HEAG](#)).**

RESPONSIBILITY OF HEAGs and HESCs

1. HEAGs are composed of academic staff members from within a given department/school/centre/faculty, and are responsible for conducting technical and ethical reviews of all projects emanating from within their department/school/centre/faculty. HEAGs also have authority to approve minimal risk projects.
2. For a standard project, once the HEAG has completed the technical review, the application is then also reviewed by one of the three Human Ethics Sub-Committees (HESCs). Only a HESC can provide ethics approval for a standard project at The University of Melbourne.
3. The HEAG will ultimately determine whether your application is assessed as a minimal risk or a standard project.

1. PROJECT DETAILS

1.1 Project Summary

Provide a summary of the project in everyday language. This should be as short as an abstract (i.e. not more than 300 words long) but free of jargon, so that it will be intelligible to a lay person with no training in this discipline. You may find it helpful to organise your answer into sections under the suggested sub-headings.

SPECIFIC GUIDELINES CHECKLIST

Follow the instructions provided in the Application form.

The following supplemental information may help you determine which items apply to your project.

Children and/or young people (< 18 years old): if your research will be recruiting children and/or young people (under 18 years old) to participate, tick this box. You will need to familiarise yourself with the relevant chapter of the *National Statement* ([NS §4.2](#)) and ensure that your answers throughout the form address all the relevant guidelines contained in that chapter.

People in dependent or unequal relationships: For the purposes of this question, “dependent or unequal relationships” refers to pre-existing relationships between participants and researchers or between participants and others involved in facilitating or implementing the research. Such relationships may compromise the voluntary character of participants’ decisions, as they typically involve unequal status, where one party has or has had a position of influence or authority over the other. ([NS §4.3](#)) **If your research will be recruiting people in dependent or unequal relationships** to participate, tick the box. You will need to familiarise yourself with the relevant chapter of the *National Statement* ([NS §4.3](#)) and ensure that your answers throughout the form address all the relevant guidelines contained in that chapter.

People in countries other than Australia: if your research will be recruiting people in other countries to participate, tick the box. You will need to familiarise yourself with the relevant chapter of the *National Statement* ([NS §4.8](#)) and ensure that your answers throughout the form address all the relevant guidelines contained in that chapter.

Aboriginal and/or Torres Strait Islander individuals or peoples: tick this box if your research is

- a) about Aboriginal and/or Torres Strait Islander individuals or peoples, their health, or their culture(s), language(s) or histories; and/or
- b) about the impact(s) or effect(s) of some phenomenon or phenomena on Aboriginal and/or Torres Strait Islander individuals or peoples; and/or
- c) going to specifically target Aboriginal and/or Torres Strait Islander people to be recruited as participants; and/or
- d) going to be conducted in a geographical location where a significant number of the population are likely to be Aboriginal and/or Torres Strait Islander.

You will need to familiarise yourself with the relevant chapter of the *National Statement* ([NS §4.7](#)) and ensure that your answers throughout the form address all the relevant guidelines contained in that chapter.

It is strongly recommended that all researchers consult the *Guidelines for Ethical Research in Australian Indigenous Studies* ([GERAIS](#)), but it is mandatory for research funded by the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS).

For health research, you will *also* need to consult [Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders](#)

Note that if your research falls into this category, it is not eligible for review as a minimal risk project.

Women who are pregnant and/or the human foetus: tick the box if your research is

- a) going to **specifically target** women who are pregnant to be recruited as participants; and/or
- b) **focused** on women who are pregnant and/or the human foetus (including human foetal tissue or human embryos).

You will need to familiarise yourself with the relevant chapter of the *National Statement* ([NS §4.1](#)) and ensure that your answers throughout the form address all the **relevant** guidelines contained in that chapter.

Note that if your research falls into this category, it is not eligible for review as a minimal risk project.

People who may be involved in illegal activities will be recruited as participants, and the research could potentially expose such activities: if your research does not have the potential to discover participants' involvement in illegal activities, or is unlikely to do so, do not tick the box.

If your research *does* have the potential to discover participants' involvement in illegal activities, including if it is designed to discover participants' involvement in illegal activities, tick the box. You will need to familiarise yourself with the relevant chapter of the *National Statement* ([NS §4.6](#)) and ensure that your answers throughout the form address all the **relevant** guidelines contained in that chapter.

Note that if your research falls into this category, it is likely to be ineligible for review as a minimal risk project.

People with cognitive impairment, intellectual disability, or mental illness: if your research will be recruiting people with cognitive impairment, intellectual disability, or mental illness to participate, tick the box. You will need to familiarise yourself with the relevant chapter of the *National Statement* ([NS §4.5](#)) and ensure that your answers throughout the form address all the **relevant** guidelines contained in that chapter.

Note that if your research falls into this category, it is not eligible for review as a minimal risk project.

People highly dependent on medical care: for the purposes of this question, "people highly dependent on medical care" refers to people whose lives or wellbeing are at serious risk, and who may therefore have limited capacity to give consent. For example, research on patients in emergency care or neonatal intensive care would be considered to focus on people highly dependent on medical care.

If your research will be recruiting people highly dependent on medical care to participate, tick the box. You will need to familiarise yourself with the relevant chapter of the *National Statement* ([NS §4.4](#)) and ensure that your answers throughout the form address all the **relevant** guidelines contained in that chapter.

Note that if your research falls into this category, it is not eligible for review as a minimal risk project.

ADDITIONAL MODULES CHECKLIST

Follow the instructions provided in the Application form.

The following supplemental information may help you determine which items apply to your project.

Creation of a databank: for the purposes of this question, a databank is a systematic collection of data (such as a database) intended to be used again in future research. If your research will involve creating a databank, tick the box. **Note that if this describes your research, you will also need to complete and attach the Privacy and Databanks Module.**

You will need to familiarise yourself with the relevant chapter of the *National Statement* 1 ([NS §3.1](#)) and ensure that your answers throughout the form address all the **relevant** guidelines contained in that chapter.

Collection of information for a databank: for the purposes of this question, a databank is a systematic collection of data (such as a database) intended to be used again in future research. If your research will involve collecting information for a databank, tick the box. **Note that if this describes your research, you will also need to complete and attach the Privacy and Databanks Module.**

You will need to familiarise yourself with the relevant chapter of the *National Statement* 1 ([NS §3.1](#)) and ensure that your answers throughout the form address all the **relevant** guidelines contained in that chapter.

Accessing information from a databank: for the purposes of this question, a databank is a systematic collection of data (such as a database) intended to be used again in future research. If your research will involve accessing information from a databank, tick the box. **Note that if this describes your research, you will also need to complete and attach the Privacy and Databanks Module.**

You will need to familiarise yourself with the relevant chapter of the *National Statement* ([NS §3.1](#)) and ensure that your answers throughout the form address all the **relevant** guidelines contained in that chapter.

Obtaining personal information (including health information) about individuals without their consent: if your research will involve obtaining identifiable or potentially identifiable personal information about individuals without their consent, tick the box. According to the [Privacy Act \(1988\)](#), “personal information” means information or an opinion about an identified individual, or an individual who is reasonably identifiable, whether the information or opinion is true or not; and whether the information or opinion is recorded in a material form or not. For the purposes of this question, health information is considered to be personal information.

Note that if this describes your research, you will also need to complete and attach the Privacy and Databanks Module.

Collection and/or use of human biological samples or materials: if your research will involve the collection and or use of human biological samples or materials (e.g. blood, saliva, cheek swabs, hair, tissues, human embryonic or foetal tissue, et cetera), tick the box. You will need to **complete and attach the Body Tissue and Genetic Research Module**. You will also need to familiarise yourself with the relevant chapter of the *National Statement* ([NS §3.2](#)) and ensure that your answers throughout both the application form and the Body Tissue & Genetic Research Module address all the [relevant](#) guidelines.

Human Genetics: if your research will involve human genetics, tick the box. You will need to **complete and attach the Body Tissue and Genetic Research Module**. You will also need to familiarise yourself with the relevant chapter of the *National Statement* ([NS §3.3](#)) and ensure that your answers throughout both the application form and the Body Tissue & Genetic Research Module address all the [relevant](#) guidelines.

Note that if your research falls into this category, it is not eligible for review as a minimal risk project.

Medical interventions, therapies or trials: if your research will involve medical interventions, therapies or trials, tick the box. You will need to **complete and attach the Interventions, Therapies and Trials Module**. You will also need to familiarise yourself with the relevant chapter of the *National Statement* ([NS §3.3](#)) and ensure that your answers throughout both the application form and the Interventions, Therapies and Trials Module address all the [relevant](#) guidelines.

Note that if your research falls into this category, it is not eligible for review as a minimal risk project.

Administration of ionising radiation: if your research will involve the administration of ionising radiation, tick the box. You will also need to **complete and attach the Ionising Radiation Module**.

2. BACKGROUND AND METHOD

2.1 Background and Significance

Explain the significance of the project. Include a brief description of current research/literature in this field, and any expected benefits. It may be helpful to organise your answer into sections under the suggested headings provided in the form. You may include a few key references, but you do not need to provide your entire list of references here.

2.2 Research Design and Method

Describe the proposed methodology for your project. It may be helpful to organise your response into sections under the suggested headings provided in the form.

You will need to attach a copy of any measures/scales, questionnaires, survey instruments, interview questions/themes, and/or focus group topics/questions to be used.

For all quantitative research: ensure that you justify your participant numbers as being sufficient for your intended mode of data analysis (i.e. demonstrate that your sample size is large enough to provide statistically significant results).

For Fine Arts research: try to limit your answer to this question to 500 words.

For Health research: copy and paste your full research protocol in the space provided.

If your research will be conducted in schools during class time: use the space provided to give details of the alternate activity arranged for students in the class who will not be participating in the research. The *National Statement* stipulates that researchers should ensure there will be no disadvantage for those who decline to participate ([NS §2.2.19](#)).

3. RISKS, BENEFITS AND MONITORING

3.1 Potential risks to participants

Risk involves the likelihood that a harm, discomfort or inconvenience will occur as well as the severity of that harm, discomfort or inconvenience, including its consequences. Assessment of risk involves identifying any risks, gauging their probability and severity, assessing the extent to which they can be minimized, and determining how they can be managed ([NS §2.1](#)).

You may find it useful to organise your answer into sections under the suggested sub-headings.

3.2 Potential risks to non-participants

Identify any potential risks to non-participants associated with this research, and describe the measures in place to negate, minimise or manage these risks. Examples of risks to non-participants include the risk of distress to a participant's family member identified with a serious genetic disorder, the possible effects of a biography on family and friends of the subject, or infectious disease risks to the community. If the research poses no potential risks to non-participants, simply state that there are no known risks to people not involved in the research.

3.3 Risks, Benefits and Justification

According to the *National Statement*, risks to research participants are ethically acceptable only if they are justified by the potential benefits of the research ([NS §2.1.2](#)).

Describe the expected benefits of the project and explain how these benefits are sufficient to justify any risks to participants or third parties (e.g. by being of greater magnitude, or by being much more likely, or by being of a more significant type, et cetera.) You may find it helpful to separate your answer to this question into sections, using the suggested sub-headings.

3.4 Management & Monitoring

Explain how researchers will manage and monitor the conduct of the project, throughout the life of the project, to ensure that it complies with the protocols set out in the application, with the University's human ethics guidelines and with the *National Statement*. Be sure to address, in particular:

- Cases where several people are involved in recruiting, interviewing or administering procedures.
- If the research is being carried out at some distance from the responsible researcher (i.e. interstate or overseas), describe the systems in place to ensure compliance with the protocols.
- If this is a student research project, describe how the student will be supervised to ensure compliance with the protocols, including details of any local supervision to be organised for research conducted overseas or interstate.
- If any independent contractors will be carrying out any part of the research, provide details of the contractors involved, explaining their role and their qualifications/experience to fulfil this. For example, independent contractors might be involved in recruitment, data collection, sample testing, questionnaire design or analysis. Anyone somehow involved in the project, other than the listed researchers and the participants, is considered an independent contractor for the purposes of this question. Include details of any training that will be provided to the contractors regarding monitoring, data access and storage arrangements, incident reporting procedures, et cetera. Confirm that the Responsible researcher will provide the contractors with a copy of the approved ethics protocol and advise them of their responsibilities arising from this.

4. CONSENT

4.1 Obtaining Informed Consent

Regardless of the design of your research, you should familiarise yourself with the chapter of the *National Statement* concerning consent ([NS §2.2](#)). Tick as many of the options as apply to your research, then use the space provided to give a detailed explanation of your consent process. For instance, if your study will be recruiting young people of various ages as participants, you might need to tick "written consent" and "third parties will provide consent on behalf of participants", then use the space provided to explain that the older participants will not need to have consent provided by their parents.

Written consent: this is generally the ethics committee's strongly preferred method of obtaining consent from (or on behalf of) research participants. If you are proposing to use a written consent process, you do not usually need to provide justification for choosing this process; however, you should still use the space provided at the end of this question to describe in some detail how consent will actually be sought from (or on behalf of) research participants. In some cases, special arrangements may need to be made to accommodate potential participants with low literacy and/or limited comprehension of English (if applicable).

Verbal consent: this method of obtaining consent can be more suitable than written consent for certain research projects, but the ethics committee will generally expect you to provide some justification for proposing to use a verbal consent process. In addition to describing in detail how consent will actually be sought from (or on behalf of) research participants, you should also use the space provided at the end of this question to explain how this verbal consent will be recorded.

Consent will be implied: sometimes it is not necessary to seek explicit consent from participants, such as when the risk to participants is minimal and their consent is implied by their actions (e.g. by completing/returning an anonymous survey). If you are proposing to use an implied consent process, the committee will generally expect you to provide some justification for this choice, which you should include in the space provided at the end of this question.

Third parties (e.g. parents/guardians of minors) will provide consent on behalf of participants: if potential participants are not able or competent to provide their own informed consent, it may be appropriate to have others provide consent on behalf of participants. For instance, young children are generally not competent to provide consent, so it is appropriate to have a child's parent(s) or guardian(s) provide consent on behalf of the child.

Third parties (e.g. community elders, school boards) need to be involved in participation decisions: in some cases, third parties may need to be involved in participation decisions at the community level. From the *National Statement* ([NS §2.2.13](#)): "Within some communities, decisions about participation in research may involve not only individuals but also properly interested parties such as formally constituted bodies, institutions, families or community elders. Researchers need to engage with all properly interested parties in planning the research." In addition to explaining your consent process, you should use the space provided at the end of this question to explain which third parties need to be involved, why they need to be involved, and how this will be accomplished.

Waiver of consent: in some cases, neither explicit consent nor an opt-out approach to consent is appropriate, and a waiver of the consent requirement can be granted. If you are seeking a waiver of consent (and your research is not aiming to expose illegal activity), you will need to provide a convincing case by demonstrating that your research meets all of the criteria described in [NS §2.3.10](#) – i.e. that risks to participants are no greater than discomfort, that the benefits from the research justify any risks of harm associated with not seeking consent, that it is impracticable to obtain consent, that there is no known or likely reason for thinking that participants would not have consented if asked, that there is sufficient protection of participant privacy, that there is an adequate plan to protect data confidentiality, that (if practicable and the results have significance for participants' welfare) there is a plan to make research results available to participants, that participants will not be deprived of any financial benefits entitled them from commercial exploitation of research outcomes, and that the waiver is not prohibited by law.

If you are seeking a waiver of consent (and your research is aiming to expose illegal activity), you will need to provide a convincing case by demonstrating that your research meets all of the criteria described in [NS §2.3.11](#) – i.e. that the value of exposing the illegal activity justifies the adverse effects on the people exposed, that there is sufficient protection of their privacy, that there is sufficient protection of the confidentiality of data, and that the waiver is not prohibited by law.

Opt-out approach: this approach to consent may be appropriate when it is feasible to contact some or all of the participants, but the project is of such scale and significance that using explicit consent is neither practical nor feasible. If you are seeking to use an opt-out approach to consent, you will need to provide a convincing case by demonstrating that your research meets all of the criteria described in [NS §2.3.6](#) – i.e. that risks to participants are no greater than discomfort, that public interest in the proposed research substantially outweighs the public interest in protection of privacy, that the research is likely to be compromised if the participation rate is not near complete (and requiring explicit consent would compromise the necessary level of participation), that reasonable attempts are made to provide all prospective participants with appropriate plain language information explaining the study and the procedure to decline or withdraw ("opt-out"), that there is a reasonable opt-out window between the time information is provided to potential participants and the time their data is used, that a mechanism is provided for prospective participants to obtain further information and opt-out, that data collected will be managed according

to relevant security standards, that there is a governance process in place delineating specific responsibility for the project and the management of the data, and that the opt-out approach is not prohibited by law.

4.2 Limited Disclosure

For the purposes of this question, your research is considered to involve limited disclosure if **any** of the following conditions apply:

- The true aims and/or methods of the research will not be fully disclosed to participants beforehand
- The true identity and/or affiliations of the researcher(s) and/or sponsor(s) of the research will not be fully disclosed to participants beforehand
- The collection of data itself will be concealed from participants
- The research involves any deception or intentional misleading of participants

If none of the above conditions apply to your research, simply check “No” and proceed to the next question.

If your research will involve limited disclosure, concealment or deception, check “Yes” and use the space provided to give details about the type of limited disclosure proposed. You will need to justify the use of limited disclosure by reference to the guidelines in the *National Statement* ([NS §2.3](#)). Your answer should explain why the use of limited disclosure is necessary, as well as describe how participants will eventually be informed about the aims of the research and the necessity of the limited disclosure. If you will be debriefing participants, be sure to **attach a copy of the debriefing statement** to be used. If you will not be debriefing participants, your answer should explain why this is neither necessary nor practicable.

For research involving limited disclosure, but not active concealment or planned deception: ensure that your answer addresses the conditions set out in [NS §2.3.1](#).

For research involving active concealment or explicit deception, but not the aim to expose illegal activity: ensure that your answer addresses the conditions set out in [NS §2.3.1](#) and [NS §2.3.2](#). **Note that if your research falls into this category, it is not eligible for review as a Minimal Risk project.**

For research involving limited disclosure that aims to expose illegal activity: you must also demonstrate that the value of the exposure is sufficient to justify the adverse effects on those whose illegal activity is exposed ([NS §2.3.3](#); see also [NS §4.6](#)). **Note that if your research falls into this category, it is not eligible for review as a Minimal Risk project.**

4.3 Future Use of Data, Materials, or Tissues

Do you intend for the data and/or materials and/or tissues collected for this research project to be reused in future research? Select from the options provided, then use the space below to specify which data/materials/tissues will be reused, if any. (See [NS §2.2.14](#).)

4.4 Conflict of Interest

A conflict of interest in the context of research is discussed in [NS §5.4](#) and [Australian Code for the Responsible Conduct of Research](#). University researchers must disclose and manage conflicts of interest in accord with the provisions of the University's [Research Integrity and Misconduct Policy](#)

For the purposes of this question, there is considered to be a potential conflict of interest if there is any affiliation or financial interest for researchers in this research project or its outcomes, or any circumstances which might represent a perceived, potential or actual conflict of interest.

If there is no potential conflict of interest, simply check “No” and proceed to question 4.5.

If there is a potential conflict of interest, check “Yes” and use the space provided to give details of the potential conflict of interest and how it will be managed. You will also need to include an appropriate comment in the PLS and the Consent Form.

4.5 Information for Participants

Explain how relevant information will be provided to potential participants. You must also **attach copies of all recruitment materials** to be used, including Plain Language Statements, consent forms, advertisements (whether print, online, or social media), letters or emails, debriefing statements and/or telephone scripts.

Plain Language Statement: the Office for Research Ethics and Integrity's website has [guidance on composing your plain language statement](#). Refer to your [HEAG](#) for discipline-specific guidance on composing your PLS. Your PLS should also satisfy the requirements set out in the *National Statement* ([NS §2.2](#)). **Please take care to ensure that your PLS is written in plain language, and that the information contained in your PLS is consistent with the information in your application.**

Consent Form: the Office for Research Ethics and Integrity's website has [guidance on composing your consent form](#). Refer to your [HEAG](#) for discipline-specific guidance on composing your consent form. Your consent form should also satisfy the requirements set out in the *National Statement* ([NS §2.2](#)). **Please take care to ensure that your consent form is written in plain language, and that the information contained in your consent form is consistent with the information in your application.**

5. DISSEMINATION AND DATA MANAGEMENT

5.1 Providing Results to Participants

According to the *National Statement*, the principle of justice requires that research outcomes be made accessible to research participants in a timely and clear manner ([NS §1.5](#)). Since the outcome(s) of research are among its main benefits, and since participants' contributions to research are indispensable, a failure to provide this benefit to the participants would be unjust.

Describe how participants will be given access to the results of the research. (Typically these results are provided in the form of a summary report.) For example, results could be emailed to participants who have indicated their interest in receiving such a report by including their email address on the consent form. Another way to provide the results to participants would be for the report could be put online (once it is ready) at a pre-determined URL, so that the Plain Language Statement could include a statement along the lines of "Following the completion of the project, a summary report of the results will be available online at [pre-determined URL] from [date when the summary report will be available]."

5.2 Reporting Project Outcomes

The public reporting of project outcomes is important for research integrity. This involves a commitment on the part of researchers to publicly disseminate results, in order to facilitate scrutiny and contribute to public knowledge ([NS §1.3.d](#)).

You should describe the format and means by which the project's results will be made publicly available. This could include planned publication(s), conference poster(s)/presentation(s), et cetera. Note that the requirement to make results public does not mean you can only submit resulting papers to open-access journals. Also note that participants' privacy and the confidentiality of their data is to be respected, so identifying or identifiable data should not be made public unless participants have explicitly consented to the public release of such data. (One exception in this regard is in research aiming to expose illegal activity, for which you should refer to the information in [NS §4.6](#)).

5.3 Data Management

Research data and primary materials (including questionnaire responses, audio files, video recordings, photographs, etc.) should be maintained for as long as they are of continuing value to the researcher and as long as patent requirements, legislative and other regulatory requirements exist. The minimum retention period for research data and primary materials is five years after the *last* publication, or public release, arising from the research (see [Research Integrity and Misconduct Policy](#)). Other minimum retention periods apply to psychological testing/interventions with adults (7 years from end of intervention), clinical trials involving adults (15 years from conclusion of trial), and clinical trials involving children (25 years from conclusion of trial).

You may find it helpful to separate your answer to this question into sections, using the suggested sub-headings.

For detailed guidance and advice on data management planning, refer to [NS §3.1](#)

6. OTHER ISSUES

6.1 Other Ethical Issues

Use this space to address any additional ethical considerations relevant to your project but not addressed elsewhere in the application form or any attached modules. If there are no other issues relevant to the ethical review of your research, simply write "N/A".