ETHICS GUIDELINES

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HUMAN RESEARCH ETHICS GUIDELINES

CONTENTS

1. PART 1. BACKGROUND

1.1. NIODA and human research ethics

NIODA's purpose is 'the provision of education in systems psychodynamic approaches for the improvement of organisations, community and society'. The systems psychodynamic approach has grown out of a theoretical tradition integrating learning from psychoanalysis, systems theory, group relations theory and necessarily involves the study of human social phenomena.[1]

Systems psychodynamic methods attempt to work with covert, often hidden dynamics in social systems, through the bringing of unconscious phenomenon into conscious thought, such that underlying system patterns are able to be accessed.

A hallmark of the systems psychodynamic approach to research is that it is often emergent and iterative and anchored in the conscious and unconscious experience of any or all of the following: the individual, the group, and the researchers. The task of the researcher is to take up an interpretive stance to discover and negotiate the meanings that guide social behaviour and make sense of actions.

Ethically sound research that uses systems psychodynamic methods requires the researcher to think carefully about their approach to the research to ensure they do no harm. Particular attention should be given to selecting and recruiting participants, managing any risks associated with participation in the research and obtaining informed consent.

1.2. Why ethics regulation?

Currently academic research is subject to far greater examination than it ever has been before - from organisations, government bodies and the general public. Participants in research are also asking to be consulted, and are demanding that they not be taken for granted and wish to be active contributors in the construction of academic research.

In part this reflects a changing world overwhelmed by technology and depersonalisation, but it also reflects a positive shift in thinking within the research community. We now have a greater concern for the misuse and abuse of information and an acknowledgment that research cannot cut itself off from society. Research is now seen to be fully embedded into the fabric of our lived worlds, and inquirers are more conscious than ever that they must engage in ethical research and show that they are bound by a set of values open to scrutiny from the community in which they work.

1.3. Principles of quality research involving humans

Following the *Belmont Report* (1978), and subsequent *National Statements on Ethical Conduct in Research Involving Humans* the standards of good research involving people have been seen as proceeding from the following fundamental ethical principles:

Respect for persons: Individuals should be treated as self-directed, empowered agents, and persons with diminished independence are entitled to be safeguarded if they become participants in research. Therefore, research carried out with children and others deemed to be vulnerable requires adherence to additional principles of ethical behaviour.

Beneficence: This implies the obligation to minimise harm of all kinds, not just physical harm and to see that such harm as is caused in the activity of research is outweighed by benefits to the participating individuals and to the community generally.

[1] National Institute of Organisation Dynamics Australia Strategic Plan, 2016-2020 www.nioda.org.au

Justice: Researchers are obliged to distribute the burdens and benefits of research as fairly as possible. Research must be designed so that unfair burden of participation in research with particular groups who are likely to be "over-researched" is avoided.

Research merit and integrity: This implies a commitment to a form of research that values and exhibits honesty and transparency in the description of data and in the communication and dissemination of findings or "tellings". People with experience, competence and the qualifications appropriate to the research should supervise research. Quality research is judged by its attention to transparent reporting, thick description, methodological integrity, evidence of ethical interpersonal relationships, and its positive impact on participants and organisations within the research context.

1.4. Informed consent

Informed consent flows from the principles outlined above and especially from the first, that persons taking part in research must do so on the basis of *being fully informed on all aspects of the research in which they may choose to participate* and their decision to take part must be *voluntary* and *free of any coercion*. Where it is deemed appropriate to conduct research that involves participants with diminished capacity to give informed consent, then special arrangements, for instance, informed consent of a parent or guardian, must be made.

The research design will inform the nature of participation. Applicants are expected to give serious consideration to how they will obtain informed consent, consistent with the principles of quality research involving humans, outlined above, and allowing for flexibility to accommodate the research design. For example, approaches to obtaining consent of participants in a meeting which is observed by the researcher, may be influenced by the type of meeting, **the type of information the researcher intends to collect**, the roles of participants in the meeting, and the degree of regularity of participant attendance at the meeting.

1.5. How research ethics review is organised - an overview

In Australia the present state of this thinking is reflected in the *National Statement on Ethical Conduct in Research Involving Humans* issued by the National Health and Medical Research Council (NHMRC) in 1999. Acceptance of the National Statement obliges an institution to set up a Human Research Ethics Committee (HREC) for the purpose of reviewing all research undertaken by the institution and its members (including both staff and students) that involves humans.

Ethics review for research is a system of self-regulation, run by researchers for researchers; ethics committee decisions serve to protect the rights of legitimate research as well as the rights of human participants.

1.6. How research ethics review is organised at NIODA

The NIODA HREC membership includes an independent chairperson, academic and community persons experienced in evaluating the ethics of research proposals. The NIODA HREC schedule of meetings will be advertised at the commencement of each academic year via the official NIODA website.

Members of the NIODA HREC, including the Chairperson will be invited to participate, and be subsequently appointed by the Academic Board of Governance for a three-year period.

Students and staff should note that any research at NIODA conducted without ethics review might not be covered by the institution's indemnity insurance. NIODA may withhold the acceptance of research reports if the research lacks the necessary ethics approval, and students and staff should note that many journals require proof of ethics review before accepting an article for publication.

NIODA HREC recognises the complexity of the ethics procedural and practice implications in systems psychodynamic research and works to develop insights from its experiences in its institutional role when responding to student applications, to contribute to the growing body of knowledge of ethical research practice in this area.

1.7. What research must be reviewed?

As a general rule, **all** research projects involving human participants as subjects, or research that has an impact upon humans, require ethics approval.

This requirement applies to all members of NIODA, including visiting and honorary researchers, staff and students engaged in collaborative research with external institutions, contract research projects and all post-graduate research projects.

However, there are qualifications to this general rule:

1.7.1 Long-term experience and chance events and conversations may often influence research, but it is not necessary to require ethics review for them.

1.7.2 The collection and use of material that is on the public record does not require ethics review.

1.7.3 Ethics review is also not required for collecting and using material which is requested from an officer of an organisation where responding to such a request can reasonably be held to fall within the position description or role of the officer concerned.

1.7.4 Research that concerns the subjective, experiential data of the researcher and does not require data from others with whom he or she is in contact, may not require ethics review. Students undertaking this kind of heuristic research must provide their supervisor with a written outline of their project, the data to be included and the context in which the research is undertaken prior to the commencement of the research and discuss associated ethical issues. A decision taken to not undertake ethics approval must be approved in writing by the supervisor.

1.8. Managing approved projects

It is essential that research conducted over the life of a project conforms with the conditions in the original HREC approval. The following sets out the mechanisms that promote compliance in the ongoing management of research projects. Supervisors also have a critical role in monitoring student and doctoral candidate research.

1.8.1 Annual/Final Reporting

It is a condition of ethics approval at NIODA that researchers submit an annual or final report on the status of their project including progress to date, data management and compliance with the approved protocol. Ethics approval will be renewed for the next calendar year on receipt of a satisfactory report.

Requests for annual/final reports will be sent out by the NIODA HREC at the end of each year. Reports are required for all projects that are continuing into the next year, as well as those that were completed or abandoned in the present year. Failure to submit an annual report will mean that approval for the project will lapse.

- On completion of their research, Masters students are required to submit a Final Report on Human Research Ethics Projects for Masters Students [https://sites.google.com/nioda.org.au/internalplatform/ethics/hrec-forms-templates-examples?authuser=0]

- Doctoral candidates will be expected to receive ethics approval of their research by the end of their first year of candidature. Through years two to six of their candidature, doctoral candidates are required to complete an Annual Ethics Report [https://sites.google.com/nioda.org.au/internalplatform/ethics/hrec-forms-templates-examples?authuser=0] detailing progress and anticipated action for the next twelve months

- Other researchers are required to submit an Annual Ethics Report (as above) if their approved project continues from the calendar year to the next

- Doctoral candidates and other researchers are required to submit a Final Report upon completion of their research project.

All Final Reports (Masters) and Annual/Final Ethics Reports are to be submitted to hrec@nioda.org.au

1.9. Applying for ethics review

Ethics review is conducted on the basis of an application form that asks applicants to describe in detail the proposed research design and procedures, the prospective participants and the possible impact on them and others.

The form is comprehensive. It is important to remember that it is designed to cover eventualities that may occur in the course of undertaking experiential research, and that it is required to inquire into *potential for harm and risks*, not just what is expected to happen. The NIODA HREC also recognises that in the course of the research process, there will be many 'moments' of ethical decision making. Students are expected to keep these moments in conscious and constant appraisal. If necessary, they are able to seek NIODA HREC opinion on whether these 'moments' require a further amendment to ethics approval after the original approval has been granted and the research is underway.

Every question is designed to elicit information that may be of relevance to one of the principles described above in 1.2.

1.9.1 Application forms

Ethics application forms may be obtained from the NIODA administrator admin@nioda.org.au or downloaded from the NIODA website: http://www.nioda.org.au/

Researchers undertaking collaborative research with external institutions must submit their ethics application to the external institution in the first instance. Once approval is granted from this institution's relevant ethics committee, then this approval documentation including the applications is submitted to the NIODA HREC who may request further information if necessary.

All applications are to be submitted as word documents to the NIODA HREC hrec@nioda.org.au

1.9.2 Confidentiality of applications

NIODA has a Register of Human Ethics Applications. The Register is not a confidential document. Details included in the register include the name of the inquirers, affiliated institutions (if relevant), title of the project, and a brief summary of the project's aims.

Copies of applications are kept on NIODA file. While applications are generally treated as confidential and are not disclosed outside of the ethics committee, there are circumstances where applications are made available to persons outside of the committee. For example, an application may be subject to a court subpoena or a request for information under the Freedom of Information Act.

1.9.3 General advice to applicants

To avoid delays in the process of approving the application, please ensure that:

- it is typed
- lay language is used throughout
- all questions are answered
- the form is signed by all researchers
- there is a full description of what is required of all the participants and
- all relevant attachments are included with the application.

1.9.4 Form lodgement and approval process

The NIODA HREC* will review applications on a regular basis throughout the year. All applications must be submitted one week prior to HREC meetings and should be lodged at least six weeks prior to the date at which data collection is to begin. This time frame may alter where an application requires further consideration. Data collection must not commence without full written approval from the NIODA HREC. A copy of the application should be forwarded to hrec@nioda.org.au

*A schedule of HREC meetings is available on the NIODA website

1.9.5 Appeals procedures

If the NIODA HREC has rejected an application for ethics approval, the staff or student may lodge an appeal against this decision to the HREC for consideration. The Committee may co-opt expert advice in this situation. If the outcome is still considered unsatisfactory by the applicants, the NIODA Grievance Procedures may be instigated to review the procedures by which the Committee came to its decision. The Student Grievance Policy can be found on the NIODA drive www.nioda.org.au.

2. PART 2. GUIDELINES FOR COMPLETION OF THE APPLICATION FORM FOR ETHICS APPROVAL FOR RESEARCH PROJECTS.

2.1. Introduction

All NIODA staff and research students should become familiar with the guidelines contained in the National Health and Medical Research Council's (NHMRC's) *National Statement on Ethical Conduct in Human Research* prior to completion of the Application Form for Ethics Approval of Research Projects. *This statement can be found at:*

National Statement on Ethical Conduct in Human Research (2007) - Updated May 2015
https://www.nhmrc.gov.au/guidelines-publications/e72

2.2. Information Privacy Legislation

Researchers must become familiar with all information on privacy legislation and associated guidelines that may be relevant to their application for ethics approval. Information privacy legislation (including the *Health Records Act*) serves to protect individuals' personal information and to give them control as to how their personal information is collected, used and disclosed. Information on privacy legislation and guidelines that may be relevant to researchers are detailed in Attachment A.

It is important to note that Information Privacy Principles 2.1 and 10.2 (detailed in Attachment A) are of particular relevance to research where it is not proposed to obtain an individual's consent for the use, disclosure or collection of personal information. This might apply in workplace observation or unplanned attendance at meetings for example.

2.3. Specific guidelines to assist applicants to complete the application form

Each item numbered below corresponds with the numbered item on the NIODA ethics application form

ITEM 1: Project Title

Choose a short, simple and self-explanatory title that will identify for research participants and ethics committee members the essential point of the project. This title should be the same as the title that appears on all documentation provided to participants about the project.

Please note that this title may change during the course of the research. This change can be proceeded with (assuming the data collection and participant involvement has not changed substantially) after notifying the NIODA HREC of the changes.

ITEM 2: Lay summary of the project

Provide a two-sentence summary of the project that conveys the purpose and general method of the research in easily understood lay terms. This summary should be 50 words or less.

ITEM 3: Type of project

Identify the type of project: i.e. is it research by academic staff member, supervised postgraduate research, contract research or supervised undergraduate research?

ITEM 4: Is this project part of a larger project?

Is this project a part of a larger project(s)? If so describe both/all projects, relevant ethics approval from outside institutions and the details of all researchers involved in these research activities.

ITEM 5: Does this project involve multi-centre research?

If the research project is being conducted at more than one institution and may involve a research project where a researcher has joint affiliations, details of these affiliations must be provided.

ITEM 6: Details of researchers

Because all correspondence from the ethics committee is forwarded to all applicants, please ensure that full contact details are provided for each applicant.

ITEM 7: Period during which activities requiring ethics approval will occur

Please note that the recruitment of participants, access to participant records and data collection must not commence until full ethics approval is obtained. Note that ethics approval will be active only until the completion date specified. If it becomes evident that the project is likely to continue beyond the period approved, an application to extend the ethics approval will be required. The response to this item should also specify the expected date of completion of the project. Please note: completion does not mean that all reports, theses and journal papers have been published.

ITEM 8: Funding

Projects that receive funding from sources external to NIODA must gain ethics approval from the relevant body that auspice the project. Please note that, for the purposes of applications for ethics approval, student scholarships are not considered to constitute research funding.

ITEM 9: Description of project

State clearly and simply the aims and intentions of the project, the governance for the project, research activities, who the participants will be, what they are intending to do, how the data will be explored and why this particular project is worth doing.

The ethics committee needs to form a clear understanding of the aims and value of the project if it is to weigh the possible benefits of the proposed research against the burden for participants involved in the project. Burden for the participants includes discomfort, inconvenience, risk to psychological or physical health, social, legal and/or economic disadvantage and loss of privacy.

ITEM 10: Participant details

There are several reasons for asking for specific details of the participants. First, it is necessary to assess whether the principle of justice has been considered in the design of the project. Second, it is important to consider whether particular participants may have diminished ability to provide informed consent and/or increased risk of being harmed or coerced to participate because of an impairment or disability and therefore require special provisions in gaining informed consent.

10 a) Number of participants

If precise numbers of participants have not been established, indicate that numbers are 'approximate'. Researchers should provide justification for the number of participants involved in the research.

10 b) Age range of participants

Be as precise as possible about the age range of participants, at the very least use broad categories, e.g., 'infants', 'pre-adolescent children', 'adolescents', 'young adults', 'older adults' etc. For projects involving participants under the age of 18 years, please also note item (g) below.

10 c) Will any participants be ill or frail?

If you know of <u>any</u> participants may have <u>any</u> psychological, cognitive or physical impairment or disability, tick 'Yes' and state clearly the nature of the impairment or disability and how this might impact the research.

10 d) Participant inclusion and exclusion criteria

If there are any criteria that will determine whether participants are included in, or excluded from the research, please specify all the criteria that will be used and explain why each criterion is important to the purpose of the research. Inclusion/exclusion criteria may include, but are not limited to, factors based on a person's race, age, sex, health status, disability, religious, cultural or political beliefs, educational background, socio-economic group, and place of residence.

10 e) Recruitment method

Explain clearly how the participants will be contacted. For example, participants may be friends, family, patients, students, employees, professional colleagues or associates approached by the researchers.

Please note: If recruitment is to be through any form of advertisement, please identify the publications or media to be used and provide a copy of the text or script for the advertisement**.**

All advertisements must specify the staff/student's affiliations with NIODA and, where relevant, indicate the name of course of study for which the research is being conducted.

10 f) Compensation to participants

Because the *National Statement on Ethical Conduct in Research Involving Humans* states that the consent of a person to participate in research must not be subject to "any inducement or influence which could impair its voluntary character" (see section 1.10 of the statement), if compensation is to be provided to participants, it should not be so large as to create a clear inducement to participate. It is acceptable; however, to provide small amounts of compensation for things such as travel or child care.

10 g) Involvement of special groups

This section needs to be completed if participants are people in any of the following circumstances:

- People who are prisoners, Community Corrections offenders/parolees or wards of the state
- People who cannot provide informed consent because of an intellectual disability or mental illness
- People who are not legally competent to give informed consent
- People highly dependent on medical care
- Children or young people under the age of 18
- Aboriginal people and/or Torres Strait Islanders
- People from any other collectivity (as defined in the *National Statement on Ethical Conduct in Research Involving Humans*).

If the project involves participants from these special groups, please consult the *National Statement on Ethical Conduct in Research Involving Humans* chapters 4-8, and provide the following information:

- The nature of the special group
- Justification for the inclusion of people from this special group
- Details as to how the rights and welfare of participants from the special group will be protected in the research
- The persons and/or agencies from whom permission will be/ has been sought for these groups to participate in the research.

If Aboriginal people and or Torres Strait Islanders will participate in the research, applicants should also familiarise themselves with the NHMRC Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003). The application for ethics approval should detail the consultations undertaken with relevant community groups, committees and agencies.

The application for ethics approval should detail the consultations undertaken with relevant community groups, committees and agencies.

10 h) Participation of NIODA students

Because the *National Statement on Ethical Conduct in Human Research* states that an ethics committee should take special care in the review of applications involving people in perceived or actual dependent or unequal power relationships, applications for staff research involving the participation of students must satisfy the ethics committee that in this situation the inclusion of students is justified, that the rights and welfare of the students will be protected, and that the students' consent is both adequately informed and vol-

untary. In addition, the applicants must give an assurance that refusal to participate in, or withdrawal from the research, will not result in any discrimination or other penalty for the students.

10 i) Participants in dependent or unequal power relationships with the researchers

The researchers and the ethics committee must take special care if any of the participants are in a dependent or unequal (either perceived or actual) power relationship with each other or with any of the researchers.

Participants who might be considered to be in an unequal relationship within the workplace include:

- People in reporting lines e.g. Board/Manager/staff
- Peer relationships
- Staff/volunteers

Participants who might be considered to be in a dependent relationship with the researchers include:

- People under the care of a health professional or carer who is also a researcher
- People under the care of a health professional or carer who will assist in recruiting participants
- People whose superiors in their place of employment will assist in recruiting participants
- School students whose teachers or school principal will assist in recruiting participants
- People who are clients of a researcher or of any professional who will assist in recruiting participants.

Applications for research involving the participation of people in dependent or perceived or actual unequal power relationships must satisfy the ethics committee that inclusion of people in this situation is justified, that the rights and welfare of participants will be protected, and that the person's consent is both adequately informed and voluntary. In addition, the applicants must give an assurance that refusal to participate in, or withdrawal from the research, will not result in any discrimination, reduction in the level of care, or other penalty for the participant.

10 j) Disclosure of conflict of interest

The researchers must declare any actual or perceived conflicts of interest between them and the individuals and/or organisations involved in the research.

ITEM 11: Research using existing databases

Where the applicant intends to use existing records that may identify individuals and that are not normally available to the public, particular care must be taken to comply with all relevant privacy legislation (see Attachment A). In addition, the applicant must provide evidence that the relevant agency/organisation has agreed to provide or allow access to the existing records.

ITEM 12: Secondary use of data

Where the researcher plans to undertake analysis of data collected in a previous research project (including re-analysis of data the researcher has collected previously) (whether that data is written, electronic, audio/video, specimens or samples), the researcher must indicate the sources of the data and specify which of the following categories of personal information will be used:

- Identified (data that allow the identification of a specific individual/collectivity)
- Potentially identifiable (data which have had identifiers removed and replaced by a code so that the process of de-identification is reversible)

- De-identified (anonymous data and data for which the de-identification procedure is irreversible)

In cases where the data are de-identified, provided all Commonwealth and State/Territory legislation and policies dealing with the privacy and confidentiality of data are complied with, secondary use of the data is permissible. If, however, special groups are involved, (see 10g) permission or consultation may be required.

In cases where the data are identified or potentially identifiable, consent of participants should be obtained. However, the HREC may approve access to such data without obtaining consent, if the Committee can be satisfied that the research complies with all applicable Commonwealth and State/Territory privacy legislation and Guidelines (see Attachment A).

ITEM 13: Location of study

Please indicate where the research will take place. Give details such as the name and address of locations. Please also state whether the research will take place in the participant's home or workplace. If the research is to take place at an external organisation, researchers must provide evidence of permission to use those facilities.

ITEM 14: External approvals

If external approval is required to conduct the research, provide the details of the organisation, institution, ethics committee, authority, guardian or next of kin from which approvals are required. If approval is required but has not been sought, please explain why this has not occurred. If approval has been sought but not yet obtained, please specify when the approval is likely to be obtained. Please note that copies of approvals must be provided to the NIODA HREC at the time of application or made available as soon as possible thereafter. Copies of applications submitted to external agencies should be submitted to the NIODA HREC. Final approval from the NIODA HREC cannot be given until all relevant external approvals have been provided to the committee.

Ensure that external approvals are on the institution's or organisation's letterhead (except in the case of guardian or next of kin) and that all approvals are very specific as to the title of the project, the names of all researchers, and exactly what approval is given for. A general statement of permission to conduct project 'x' is not sufficient.

ITEM 15: Informed consent

Persons who are asked to participate in a research project must be properly informed as to what they are being asked to do and the likely consequences for them if they choose to participate. Researchers are required to provide potential participants with a statement describing the project and its probable/possible benefits, harms and risks (as far as can be foreseen) so that they may make an informed choice as to whether or not they will participate. What is required is a summary prepared from the participant's point of view, **in simple non-technical language**, of the essential points, which any reasonable person would wish to know before agreeing to participate. Potential participants should be given time to consider the proposal and to obtain further advice if they so wish prior to consenting to participate. The choice to participate must be made in the absence of any coercion.

In all cases, written consent of participants (and or parents/guardians) is required. For this reason, researchers are required to prepare a written Information and Consent Form (see below). Exceptions to the requirement for a written Information and Consent Form will be rare.

Participants must be provided with their own copy of the Information and Consent Form to keep. An outline of the required components of Information and Consent Forms is attached (see Attachment B). If the consent component of the form is to be provided as a separate document for participants, the title of the

project and the **Researchers are required to retain the consent forms separately from the data for a minimum period of seven years. Research data, conversely, must be retained for at least five years.**

For projects involving participants under 18 years of age, it is the responsibility of the researcher to ensure that each child or young person has parental/guardian consent prior to them participating in the project. In addition, it is the responsibility of the researcher to ensure that the child or young person is willing to participate. **Researchers should not assume a child's agreement to participate just because their parent or guardian has given consent.**

If research design includes workplace observation, how will consent for this be managed?

NIODA staff and HREC are very aware of the changing nature of research agreements as action research projects unfold and new insights, and perhaps even new participants, emerge. It is expected that students will be mindful of the impact of change on participants, particularly whether any new research risks to participants are exposed as the intervention proceeds. Renegotiation of ethical principles which come to light in incremental decision making, may be continual, particularly in fast moving projects in turbulent organisational climates. Students should keep a record of such incremental decision making, and share these insights with research participants. Significant changes in research processes may require alteration to Information and Consent forms, and a decision made about whether these changes require either a discussion with an HREC member, or full HREC review.

15 a) Consent for research in schools

In all circumstances, researchers must ensure that parental consent is obtained for children/adolescents participating in research at schools. Normally, no student may take part in research unless parental approval is clearly demonstrated.

See information on Department of Education and Training and Catholic Education Office requirements for research in schools in Victoria.

In all cases a signed agreement must be included along with the ethics application with both the participant and researcher to sign and date the form.

15 b) Withdrawal of consent

Where a participant wishes to withdraw consent, researchers are required to destroy, in a secure manner, the participant's data arising from their participation. The participant should be provided with a Withdrawal of Consent Form (Attachment C).

ITEM 16: Description of procedures

This section asks for a detailed description of the steps/stages, in plain language, of the research undertaken, including those that may have adverse consequences**.** Examples that should be specified here include:

1. face-to-face interview
2. telephone or email conversations
3. group workshops
4. audio-taping or video-taping
5. photography
6. writing a personal journal

7. being observed
8. creating art works
9. letters or any mail correspondence
10. noticing and documenting relevant emotional and interpersonal responses
11. creation of secondary data

PLEASE NOTE: Research involving deception

NIODA HREC deems that any research that is covert or deceptive is unethical and should not be undertaken.

ITEM 17: Identifying and managing risk

This section asks for an outline of any physical, emotional, social, legal or financial harm or risks of harm to the participants. Applicants are required to explain how those risks will be minimised and state what procedures will be in place to ensure the wellbeing of participants should the risk events occur.

Please complete and attach Risk Mitigation Table at Attachment D, in which you are to spell out, where you believe participants may be exposed to harm above the everyday norm, information that identifies all potential risks to participants, and explains how you intend to protect participants against those risks as far as possible.

Potential risks to subjects may be physical, social, psychological or legal. Breach of confidentiality, a common risk, could have both social and legal impact on a subject. Researchers should also describe what measures they may have in place in the event that there are any adverse effects to subjects arising from participation in the project (for example referral or access to medical or other specialist counselling services).

PLEASE NOTE: Duty of care

The HREC considers that researchers have a responsibility or 'duty of care' to human participants. This demands that all applicants carefully consider the potential impact of their procedures and findings on the rights and welfare of participants and identify strategies for dealing with consequences. It is important that researchers have sufficient training and access to supervision to recognise such situations and respond appropriately.

Other examples of studies where the researchers need to carefully consider the impact of their study or the need to act on their findings include:

- where research may reveal information about illegal activities,
- where there is the potential for procedures to result in harm (either physical or psychological).

Privacy of individuals must also be respected in accordance with both State and Commonwealth law. Studies involving the collection of data from individuals or collectivities should avoid identifying others who have not consented to participate in their own right, whether this is in text or any other form of identification.

Researchers should also be aware that where they hold identifying information, neither anonymity nor confidentiality can be guaranteed to participants, as researchers are not legally protected against testifying in court, or against the mandatory reporting provisions of the *Children and Young Persons Act 1989* if this is relevant to the researcher's profession. In any conflict of requirements between this Act and privacy legislation, the mandatory reporting requirements take precedence. If researchers are unclear about their obligations they should seek advice from the Chairperson of the HREC.

ITEM 18: Potential benefits

18a) To the participant

Explain how individual participants may benefit from participation in the study. If there is **no benefit** to participants, state here that this is the case.

18b) To humanity in general

How will the anticipated outcomes of the research benefit a population subgroup or the community in general? The answer to this question is particularly important because it will assist HREC to weigh the possible benefits of the proposed research against the burden for participants involved in the project.

ITEM 19: Recording and security of project documentation

19 a) How will data be recorded?

State whether data will be in the form of computer records, written records, photographic records, audiotapes, videotapes and/or CD-ROM. Please note that data collected for research purposes which would allow identification of individuals, cannot be used for teaching purposes unless participants provide explicit permission to do so. Please note that data must be kept in a medium that will be accessible for up to five years following completion of the project (see 20b below).

19 b) Will confidentiality of findings be maintained?

State if or how the data collection and recording procedures will maintain the participants' confidentiality. Confidentiality can be maintained by:

- not recording participant names or any other identifying information; or
- using participant codes for identification; and
- keeping and storing findings separately from lists of names and codes; and
- ensuring that no individual can be identified in any reports and publication arising from the research.

Some collaborative research may be undertaken where the participants agree to have their identifying details made public. This should be stated if it is the case. (See also guidelines for ethics mentoring.)

Particular care should be taken when conducting focus groups, or working in experiential groups in which sensitive information may be revealed. At the beginning of a group, the facilitator must provide clear guidance about confidentiality practices that must be observed by all group members. In addition, the facilitator should intervene whenever these practices are not followed by any group member, including the termination of the group if necessary.

19 c) Security of data

Project documentation should be stored in secure, lockable locations. Computer files should be password protected. Data, de-identified where appropriate, and Information and Consent Forms should normally be kept for a period consistent with the requirements of the *Public Records Office of Victoria Standard (PROS02/01)* (normally at least five years following publication/completion of the project). Please note that for certain types of research and for projects conducted in association with external agencies such as hospitals, data and consent forms may be required to be kept for longer periods than normally required by NIODA.

During the study: specify the precise location of the storage place and explain who will have access to the data. Give details such as the storage medium (e.g., locked filing cabinet, password-protected computer files) and location If the data is to be stored in a researcher's home, explain how the data will be kept secure.

Following completion of the study: again, specify the precise location of the storage place and explain who will have access to the data. Note that it is **not generally** acceptable for original data to be stored in a researcher's home. State also the date/stage at which raw data (personal participant identifiers, audiotapes, videotapes etc.) will be disposed of and the method of disposal.

19 d) Preserving data for possible future use

Where the researcher plans to maintain the data collected for possible future use in another research project, the researcher must specify:

- the nature of the data to be maintained
- when the data might be used in another project
- how that data might be used and for what purpose it might be used and
- who might be given access to the data for another project.

Note that any further use of the data is subject to a specific separate ethics approval at the time it is to be used. The intention to preserve data for future use must be included in the Information and Consent Form. If this is the case, **do not** include a statement in the Information and Consent Form giving specific names of who will see the data because this will restrict only those named individuals to seeing the data in the future.

ITEM 20: Dissemination of findings

20 a) Publications

If the researcher intends that the research will appear in any hard copy or electronic publication (e.g. journal, conference, thesis, report) state this here. Include this information on the Information and Consent Form. If the intent is to include transcripts of interviews, art works or written narratives prepared by participants in a thesis or in any publications, this should also be stated here and included on the Information and Consent Form. Researchers should provide participants with copies of the transcripts or narratives to approve prior to inclusion in the thesis or publication. Please note that it is advisable to ask participants to provide a secure address for sending such documents to avoid the risk of confidential material being accessed by unauthorised persons (e.g., where mail in a workplace is routinely opened by persons other than the participant).

The HREC appreciates that the findings of research are normally published in formats and venues capable of peer review. However, the researcher must also consider the rights of participants who are providing the research data, particularly with regard to extended written responses or art works that may give rise to questions of copyright ownership.

The researcher may wish to incorporate the following as checklist items in the informed consent form, presented as Yes/No tick boxes:

> I agree to my responses being published by NIODA in any format
>
> I agree to my responses being published by NIODA but wish to be consulted about the format this will take prior to publication and I understand I can withdraw my consent at this time or any time prior.

I do not agree to my response being published by NIODA

Researchers are to consider the Intellectual Property Policy for guidance in matters of copyright.

20 b) Availability of personal data to participants

Information Privacy legislation at Commonwealth and State levels requires an organisation provide an individual with access to personal information it holds about that individual on request, except in specified circumstances. *Victorian Privacy Legislation* is subject to the *Freedom of Information Act 1982 (Vic.)* which provides that individuals have the right to access documents held by an organisation covered by the Act, except where specified exemptions apply. Researchers are therefore advised to inform participants that personal information about the individual collected in the course of the research will generally be provided to the individual if requested except where the exceptions under the privacy legislation or the *Freedom of Information Act* apply. This should be stated in the Information and Consent Form.

ITEM 21: FURTHER Ethical issues

Carefully assess whether any of the listed ethical issues apply to the project and tick "Yes" if there is **any possibility** that the item applies. If "Yes" is ticked for any item, provide details of how the issue is relevant to the study and **justify** the need for that item.

Please make sure that all the appropriate CHECKLIST boxes are selected.

ITEM 22: Declarations

All researchers involved in the project must sign the Declarations.

2.4 Related Documents

Ethics Application

Ethics Guidelines

Annual or Final Ethics Report

Final Ethics Report for Masters Students

Ethics Application Form

Student Grievance Policy

National Statement on Ethical Conduct in Human Research

Attachment A: Information related to relevant Privacy Legislation

1. Victorian legislation[2,3]

PRIVACY AND DATA PROTECTION ACT 2014 (NO. 60 OF 2014), SCHEDULE 1, contains the Information Privacy Principles.

The IPP's prescribe how personal information is to be collected, used, disclosed and stored. Researchers must comply with the IPP's in carrying out their research. While researchers should familiarize themselves with all of the IPP's, it is important to note that IPP 2.1 and IPP 10.2 are of particular relevance to research where it is not proposed to obtain an individual's consent to the use, disclosure or collection of personal information.

IPP 2.1 (c) provides that an organisation may *use or disclose* personal information about an individual for a secondary purpose without that individual's consent if the use or disclosure is necessary for research, or the compilation or analysis of statistics, in the public interest, other than for publication in a form that identifies any individual, and:

- it is impracticable for the organisation to seek the individual's consent; and
- in the case of disclosure, the organisation reasonably believes that the recipient of the information will not disclose the information.

IPP 10.2 provides that an organisation may *collect sensitive information** about an individual without that individual's consent if:

- the collection is necessary for research, or the compilation or analysis of statistics, relevant to government funded targeted welfare or educational services; and
- there is no reasonably practicable alternative to collecting the information for that purpose; and
- it is impracticable to seek the individual's consent to the collection.

* *Sensitive information* is personal information that is information or an opinion about an individual's racial or ethnic origin, political opinions, membership of a political association, religious beliefs or affiliations, philosophical beliefs, membership of a professional or trade association or trade union, sexual preferences or practices, or criminal record.

Under the (Privacy and Data Protection Act, 'personal information' means information or an opinion (including information or an opinion forming part of a database), that is recorded in any form and whether true or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion, but does not include information of a kind to which the *Health Records Act 2001* applies.[4]

Researchers should note that in most instances, the individual's consent to the collection, use or disclosure of personal information should be obtained. Mere inconvenience is not a sufficient reason not to obtain an individual's consent.

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[2] A helpful overview of current policies can be found at https://www.cpdp.vic.gov.au/images/content/pdf/CPDP_Information_Sheet_-_Privacy_Legislation_in_Victoria.pdf

[3] The relevant State Government office is the Office of the Victorian Information Commissioner (OVIC) , Privacy and Data Protection: The Privacy and Data Protection area of OVIC functions under the Privacy and Data Protection Act 2014 (amended). The Act is designed to protect all information held by the Victorian public sector. Its mission is to safeguard Victorians' information and support information innovation.

[4] https://www.cpdp.vic.gov.au/menu-privacy/privacy-what-is#Section3

The Privacy and Data Protection Act is set out in the following link:
http://www9.austlii.edu.au/cgi-bin/viewdb/au/legis/vic/num_act/padpa201460o2014317/

The Information Privacy Principles are set out in Schedule 1 of this Act.
http://www9.austlii.edu.au/cgi-bin/viewdoc/au/legis/vic/num_act/padpa201460o2014317/sch1.html

The relevant governmental body is the Office of the Victorian Information Commissioner, Privacy and Data Protection: https://www.cpdp.vic.gov.au/

2. Health Records Act 2001 (Vic)

The *Health Records Act* establishes a regime for the responsible collection and handling of personal information that is *health information* by health service providers and others who handle health information. *Health information* is information about the health of an individual or about the provision of health services to him/her.

The Act was operational from 1 July 2002. The Act applies when health information is being handled by a Victorian public sector organisation, by a body established for a public purpose by a Victorian Act, or by an organisation that provides a health service in Victoria. The *Health Records Act* also applies to any person or body that collects, holds or uses health information within Victoria.

The Health Privacy Principles (HPP) are central to the Act, and prescribe how health information is to be collected, used, disclosed and stored. Researchers must comply with the HPP in carrying out their research. While researchers should familiarise themselves with all of the HPP, HPP 1.1 and HPP 2.2 are of particular relevance to research where it is *not* proposed to obtain the individual's consent to the collection, use or disclosure of health information.

HPP 1.1 (e) provides that an organisation may *collect* health information about an individual without that individual's consent if the collection is necessary for research, or the compilation or analysis of statistics, in the public interest, and:

- that purpose cannot be served by the collection of de-identified information; and
- it is impracticable to seek the individual's consent to the collection; and
- the information is collected in accordance with guidelines issued by the Health Services Commissioner.

HPP 2.2 (g) provides that an organisation may *use or disclose* health information about an individual for a secondary purpose without that individual's consent if the use or disclosure is necessary for research, or the compilation or analysis of statistics, in the public interest, and:

- it is impracticable to seek the individual's consent before the use or disclosure; and
- that purpose cannot be served by the use or disclosure of de-identified information; and
- the use or disclosure is in accordance with guidelines issued by the Health Services Commissioner.

Researchers should note that in most instances, the individual's consent to the collection, use or disclosure of health information should be obtained. Mere inconvenience is not a sufficient reason not to obtain an individual's consent.

The current Health Records Act (2001) is available at the link below. The 11 Health Privacy Principles are contained in Schedule 1 of the Act.

https://hcc.vic.gov.au/sites/default/files/health_records_act_2001_authorised033.pdf

3. Health Services Commissioner's Statutory Guidelines on Research

The Health Services Commissioner has issued Guidelines under the Health Records Act pursuant to HPP 1.1 (e) (iii) and HPP 2.2 (g) (iii). The Guidelines are available at:

https://www2.health.vic.gov.au/about/publications/researchandreports/39Guidelines39--Health-Records-Act-2001-Vic-Statutory-Guidelines-on-Research-issued-for-the-purposes-of-Health-Privacy-Principles-11ei-ii-amp-22giii-February-2002

Researchers who are proposing to conduct research in circumstances where either of these HPP applies must submit to the HREC the information required by those Guidelines. The HREC will consider the proposal in accordance with the procedures set out in the Guidelines. In order to approve a proposed activity, the HREC will need to be satisfied that the public interest in the research or compilation or analysis of statistics substantially outweighs the public interest in the protection of privacy.

4. Privacy Act 1988 (Commonwealth)

4.1: The Privacy Act 1988 (Privacy Act) is an Australian law which regulates the handling of personal information about individuals.

Personal information is information or an opinion about an identified individual, or an individual who is reasonably identifiable.

4.2: The Privacy Amendment (Enhancing Privacy Protection) Act 2012, which commenced on 12 March 2014, introduced many significant changes to the Privacy Act, including:

the Australian Privacy Principles, which replaced the IPPs and the NPPs, to regulate the handling of personal information by Australian and Norfolk Island Government agencies and some private sector organisations. The thirteen Australian Privacy Principles (APPs) set out standards, rights and obligations for the handling, holding, use, accessing and correction of personal information (including sensitive information).

Further information is held at the Office of the Australian Information Commissioner: https://www.oaic.gov.au/privacy-law/

4.3: Privacy Amendment (Private Sector) Act 2000 (Commonwealth)

This Act came into effect on 21 December 2001 and extends the Commonwealth Privacy Act to protect personal information held by private sector organisations by requiring them to comply with 13 Australian Privacy Principles regarding the use, collection, storage and disclosure of personal information. The APP apply to businesses (including non-profit organisations) with an annual turnover of over $3 million, and to all health service providers, irrespective of turnover. The NPP cover personal information, sensitive information and health information.

Further information is held at the Office of the Australian Information Commissioner: https://www.oaic.gov.au/privacy-law/

5. Privacy Amendment (Private Sector) Amendment Act 2000 (Commonwealth)

The Section 95 Guidelines provide a framework for the conduct of medical research using information held by Commonwealth agencies where identified personal information is proposed to be used without the consent of the individuals to whom the information relates. In these situations, a Commonwealth agency may collect or disclose personal information in identifiable form, for medical research purposes without infringing the Privacy Act if the proposed research has been approved by a Human Research Ethics Committee in accordance with the Section 95 Guidelines. To approve a proposal, the Committee must decide that the public interest in the research outweighs, to a substantial degree, the public interest in privacy.

Researchers should note that in most instances, the individual's consent to the collection, use or disclosure of personal information should be obtained. Mere inconvenience is not a sufficient reason not to obtain an individual's consent.

Guidelines under section 95 of the Privacy Act 1988 (the s95 guidelines), first released in 2000, have recently been updated to accord with the Privacy Amendment (Enhancing Privacy Protection) Act 2012 which amends the Privacy Act effective 12 March 2014. These guidelines were issued in March 2014 and re-issued, effective 11 November 2014.

Further information on the 2014 amendments to the Privacy Act 1988 is available from the Office of the Australian Information Commissioner. The Section 95 guidelines are available at:

https://www.nhmrc.gov.au/guidelines-publications/pr2

6. NHMRC Guidelines under Section 95A of the Privacy Act

Guidelines approved under Section 95A of the Privacy Act 1988 (the Guidelines) provide a framework to ensure privacy protection of health information that is collected, used or disclosed in the conduct of research and the compilation or analysis of statistics, relevant to public health or public safety, and in the conduct of health service management activities. The Guidelines form part of compliance requirements under the Australian Privacy Principles established in the amended Privacy Act 1988.

An organisation may collect, use or disclose the personal information in identifiable form, without infringing the Privacy Act if the proposed research has been approved by a HREC in accordance with the Section 95A Guidelines. To approve a proposal, the HREC must decide that the public interest in the research outweighs, to a substantial degree, the public interest in privacy.

Researchers should note that in most instances, the individual's consent to the collection, use or disclosure of health information should be obtained. Mere inconvenience is not a sufficient reason not to obtain an individual's consent. The Section 95A guidelines are available at:

https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/pr2_guidelines_under_s95a_of the_privacy_act_140311.pdf

Attachment B: Preparation of Information and Consent Form

The information to be included in the informed consent form is set out below. The format and content should not normally vary from that described here.

- NIODA letterhead must appear at the top of the page.
- Title of the project (Block Letters).
- Names, affiliations and convenient contact details of all researchers (NIODA as well as external researchers). Applicants must state the name of the course of study for which the research is being conducted and who is supervising the research.
- A description in lay language of the aims of the project and how the participant has been identified and recruited.
- A declaration of the name(s) of any companies/organisations that have provided funding or sponsorship for the project, if applicable.
- A description of the NIODA research procedures including the anticipated time commitment expected of the participant, the information or materials that will be obtained, the sources of that information, and any other requests of the participants.
- A statement of any possible/probable risks, discomforts or harms which may result from participation in the project. Include an explanation of how any such risks or harms will be minimised.
- A statement which details the use of the data. This must be explained in sufficient detail that participants will be able to give informed consent as to the actual use of the data. This statement must include:
    - procedures to be followed to ensure security and confidentiality of data if required. Please note that if participants do not require confidentiality this must be stated explicitly.
    - circumstances under which the confidentiality of the participant cannot be guaranteed, if applicable;
    - how and in what format (e.g., hard copy and/or electronic) the data will be used for reporting and publications (including publication of interview transcripts, written narratives, or art works prepared by participants);
    - that the participant may request a copy of their personal data collected in the course of the research (if applicable);
    - that participants will be provided with an opportunity to review transcript(s) of their interview(s) prior to submission of a thesis or publication of reports or papers (if applicable);
    - that participants will be provided with a copy of the research document when completed
    - when, how, and for what purpose the data might be preserved for possible future use in another project;
    - who might be given access to data preserved for possible future use in another project;
    - when and how the data will be disposed of
    - A section that enables the participants to identify their copyright of art works as data. The participants should be asked to tick yes/no boxes.
    - I agree to my responses being published by NIODA in any format.
    - My response to any experiential tasks undertaken as a result of this research is original and I am the sole author.
    - A statement of the benefits of the project to the participant (or lack thereof) and to society in general.

- A statement that explains that there are no disadvantages, penalties or adverse consequences for not participating or for withdrawing prematurely from the research, or changing a request for confidentiality/or not. This is particularly important where participants are dependent on the researchers or their professional colleagues for continuing treatment or care.
- An offer to answer any questions the participant has regarding the project, as follows:

  "Any questions regarding this project may be directed to the Researcher(s) (name(s)), NIODA on 52009883."

- A statement advising the method of complaint/query as follows:

  "If you have any complaints or queries that the researcher has not been able to answer to your satisfaction, you may contact the Chairperson of the NIODA HREC on (phone number and email contact)

- A statement that explains the participant is free to withdraw consent and to discontinue participation in the research at any time. However, the HREC acknowledges that in a limited range of cases it is appropriate to distinguish between the right of a participant to withdraw from active participation in a project and the right to demand that no data arising from their participation is used. Participants may request data to be destroyed, in instances where a participant has a right to request withdrawal of their consent and removal of data arising from their participation. It is important, however, to retain evidence of the withdrawal of consent and request to remove the participant's data. In such cases, HREC will consider the use by researchers of consent forms that include a time limit on requests for the withdrawal of data (i.e. a sunset clause), provided the time limit specified is not less than four weeks following the completion of data collection (please refer to item 3). An example of the suggested wording of sunset clauses follows:

  "You have the right to withdraw from active participation in this project at anytime and, further, to demand that data arising from your participation are not used in the research project provided that this right is exercised within four weeks of the completion of your participation in the project. ***You are asked to complete the "Withdrawal of Consent Form" or to notify the researcher by email or telephone that you wish to withdraw your consent for your data to be used in this research project.****"*

- A signed statement of agreement to participate, as follows:

  "I (the participant) have read (or, where appropriate, have had read to me) and understood the information above, and any questions I have asked have been answered to my satisfaction. I agree to participate in the project, realising that I may withdraw at any time. I agree that research data provided by me or with my permission during the project may be included in a thesis, presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used."

  Or, if a sunset clause is to be used:

  "I (the participant) have read (or, where appropriate, have had read to me) and understood the information above, and any questions I have asked have been answered to my satisfaction. I agree to participate in the project, realising that I may physically withdraw from the study at any time and may request that no data arising from my participation are used, up to four weeks following the completion of my participation in the research. I agree that research data provided by me or with my permission during the project may be included in a thesis, presented at conferences and published in journals on the condition that neither my name nor any other identifying information is used."

- Provisions for signatures of the participant (or authorised representative) and the researchers:

Name of Participant (block letters):

_____

Signature_____ Date _____

*__Name of Authorised Representative (block letters):__

_____

Signature: _____ Date _____

_____

Name of Researcher (s) (block letters):

_____

Signature: _____ Date _____

**__Name of Supervisor (s) (block letters):__

_____

Signature: _____ Date_____

*Use this signature block only in such cases where the participant is not capable of providing his/ her own informed consent. See Question 6(g) of the application form.

**To be used when the researcher is a postgraduate student.

Attachment C: WITHDRAWAL OF CONSENT FOR USE OF DATA FORM

WITHDRAWAL OF CONSENT FOR USE OF DATA

(THIS FORM MUST BE ON NIODA LETTERHEAD)

(This form is to be used by participants who wish to withdraw consent for the use of unprocessed research data.)

Project Title:

I, (the participant), wish to WITHDRAW my consent to the use of data arising from my participation. Data arising from my participation must NOT be used in this research project as described in the Information and Consent Form. I understand that data arising from my participation will be destroyed provided this request is received within four weeks of the completion of my participation in this project. I understand that this notification will be retained together with my consent form as evidence of the withdrawal of my consent to use the data I have provided specifically for this research project.

Participant's name (printed): ……

Signature: ……

Date: ……