Tool for Supervisors
Is an HDR candidate's project ready for research ethics review?
DIRECT PARTICIPANT PARTICIPATION

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Consider the matters below. Are they clearly addressed by the project design? If there is more than one possible response has justification been provided for the selected approach?

This Tool is for supervisors whose students are submitting applications to an Australian HREC. The document draws on material from Chapter 3.1 of the National Statement (2007 updated 2018). Even if the research occurs under the auspices of an Australian institution, the NS may not be the only point of reference if the body of work is being conducted elsewhere in the world.

1. PROJECT'S FOUNDATION

Thinking separately about the project's research question; objective; and selected methodology – was this suggested by previous research, the literature or a publicly recognised problem (in Australia see the ethical principle of Merit and Integrity and Element 1 of Chapter 3.1 of the National Statement) and:

Is the research question clearly stated?

Is it clear why that question is worth asking and answering?

Is it clear that the chosen methods are suitable to answer that question?

Are the lines of responsibility clear to all research team members?

Does the analysis described allow the aims to be realised?

Has the appropriate level of review been identified?

2. PARTICIPANTS

See the ethical principles of Merit and Integrity, Beneficence, Justice and Respect and Elements 2 and 3 in Chapter 3.1.

2.1. Participant cohort(s)

Is it clear who will participate in the project i.e. are the inclusions and exclusion criteria specified?

Are the participant cohorts appropriate for the aims of the study?

Is the sample size justified?

How will the cohorts be located/identified?

Is the pool over researched?

Is the identification and involvement of the potential participant pool fair?[1]

Could participating in the research project expose people to potential harm; if so is this explained?

Does the targeted participant pool include any of the following:

- Women who are pregnant and/or the human fetus (NS 4.1)
- Children and young people (NS 4.2)
- People in dependent or unequal relationships (NS4.3)
- People highly dependent on medical care who may be unable to give consent (NS 4.4)
- People with a cognitive impairment, an intellectual disability, or a mental illness (NS 4.5)
- People who may be involved in illegal activities (NS 4.6)

[1] The exclusion of potential participants because of their Indigeneity, because they live with a disability, their language competence, because they are pregnant, or because they are otherwise vulnerable, could silence an important voice or experience. It can also constitute a significant limitation that must be disclosed in research outputs.

- Aboriginal and Torres Strait Islander Peoples (NS 4.7)
- People in other countries (NS 4.8).

If so, does the application reflect how the potential vulnerabilities of those participants will be addressed?

2.2. Recruitment

How will participants be recruited?

Do the needs of the project necessitate more than one recruitment strategy?

Does the recruitment method raise any risks, conflicts of interest or privacy considerations?

Will any other party become aware of the identities of persons approached about participating, or their decision?

Are any incentives, reimbursements or thank-you gifts appropriate for all aspects of participation?

Could the recruitment strategies expose anyone to harm; if so, is this explained?

2.3. Consent

What strategy will be used to seek and gain the consent of participants?

Do the needs of the project necessitate more than one consent strategy?

Does the consent method raise any voluntarinees or privacy considerations?

Will any other party be aware of the identities of people who were asked for their consent, or their decision?

Could the consent strategies expose anyone to harm?

Has the information provided to participants encompassed the full scope of participation including purpose, methods, demands, risks and potential benefits?

Is it presented in a way appropriate for the participant cohort?

Are there any consequences of choosing not to participate?

Are these clear in the application and to the participant?

Are the benefits realistic, understated or overstated?

Is the description of risks complete, accurate, understated or overstated?

Is it clear how someone can withdraw from the research, when this can be done and what will happen if this occurs? (NS 2.2.20)

Does the nature of the potential participant pool require assessing their capacity or seeking the views of third parties?

Is it necessary to reconfirm consent, such as for use of a quote or photograph in research outputs?

Alternatively, does the duration of a project, its iterative nature, phases or other needs warrant seeking consent more than once or across the duration of a project?

Have all interests been revealed? Have conflicts of interests or duality of roles been declared and addressed, and where appropriate, formally reported to the institution?

Have funding and collaborative arrangements been revealed and described?

Are there potential intellectual property and copyright issues in the research? If so, are they explored in the consent strategy?

4.3.1. Alternatives to express consent

Will any alternatives to explicit consent (such as a waiver of the consent or an opt-out approach) be used? If so, has this been described and each item addressed per the requirements at National Statement 2.3.10).

4.3.2. Limited disclosure

Will there be some form of limited disclosure used with participants? Is this described and each item addressed per the requirements at National Statement 2.3.1), is a disclosure/withdrawal of consent mechanism included?

4.3.3. Existing relationship

Is there an existing relationship between potential participants and the researchers? This includes unequal and captive relationships. Describe and address the requirements in the national arrangements (in Australia, see National Statement Chapter 4.3).

3. DATA COLLECTION/GENERATION/ACCESS

What data or information are required to achieve the objectives of the project?

How and by whom will the data or information be generated, collected and/or accessed?

How and by whom will the data or information be used and analysed?

Will the data or information be disclosed or shared and, if so, with whom?

How will the data or information be stored and disposed of?

What are the risks associated with the collection, use and management of data or information and how can they be minimised?

What is the likelihood and severity of any harm/s that might result?

How will the collection and management of the data or information adhere to the ethical principles in Section 1 of this National Statement?

If appropriate for the project design, what arrangements are in place with regard to the Identifiability of information?

Is there a clear data management plan, consistent with institutional policy, and relevant legislation? Are aspects of data collection, storage, transfer, retention, disposal etc. considered?

4. RESULTS

4.1. Individual findings/results

Could the research generate findings or results of interest to participants?

Could the findings or results be of significance to the current or future welfare or wellbeing of participants or others?

Are potential participants in the research forewarned of this possibility?

Will the consent of participants be obtained to enable any planned or necessary disclosure of findings or results?

Who will communicate the findings or results and how?

Will the findings or results be disclosed to third parties and/or the public?

4.2. Disclosure

Are there any legal, contractual or ethical reasons for the sharing of results with third parties?

Is this a potential source of risk?

Was this anticipated by the consent strategy?

4.3. Research outputs

What is the plan for reporting, publishing or otherwise disseminating the outputs/outcomes of the research?

Will participants in the research be offered a timely and appropriate summary of the project outputs/outcomes?

How will the planned dissemination of the outputs/outcomes contribute to knowledge or practice or serve the public?

Are the results of the outcomes of the study being provided to the participant cohort? (NS 1.5)

5. AFTER THE PROJECT

Is future use of data, including data sharing, explicitly declared in the application and to participants?

Will the data or information be retained only for the minimum period required by relevant policy?

Do the data or information have cultural, historical or other significance that could warrant longer, or perpetual retention?

Are the arrangements regarding intellectual property (individual, community, organisational, commercial) and copyright related to the outputs of the research clearly understood and communicated?

Will the data or information be banked or added to a repository, such as an open or mediated access facility, for future use?

Will participants need following up after their participation has ended? If so, is it clear in what circumstances and how this will be done?