Southern Adelaide Local Health Network Human Research Ethics Committee

Reviewer checklist

This checklist is designed to guide and assist HREC members when reviewing studies on behalf of the committee. The checklist includes common issues identified by the HREC and the requirements of the *National Statement on Ethical Conduct in Human Research* (2007, updated 2018) and the *Australian Code for the Responsible Conduct of Research* (2018).

**This checklist is a guide only and is not an exhaustive list of all issues that may arise when reviewing applications.**

**By completing this reviewer checklist you are confirming that you do not have a potential, perceived, or actual conflict of interest relating to this research study. If you do have a conflict of interest relating to the study you have been asked to review, please inform the Chair and Executive Officer so that appropriate action can be taken.**

**You will find the section for your questions/comments to the Investigators at the end of the checklist.**

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| **Reviewer Name** |  |
| **Study Title** |  |
| **Study Reference Number** |  |

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| **Study Design** | **YES** | **NO** | **N/A** |
| **Do the likely benefits of the study outweigh the risks?**  (The likely benefit of the research must justify any risks of harm or discomfort to the participants. The likely benefit may be to the participants, to the wider community, or to both) (NS 1.1, 1.6, 1.7, 1.8, 3.3.1) |  |  |  |
| **Has the study been peer reviewed?**  Where prior peer review has judged that a project has research merit, the question of its research merit is no longer subject to the judgement of those ethically reviewing the research (NS 1.2). |  |  |  |
| **Has a thorough literature review been performed to justify the study?**  (NS 1.1(c), 3.1.1(c)) |  |  |  |
| **Is the design likely to meet the stated objectives and address the hypothesis?**  (NS 1.1(b), 3.1.1(d), 3.1.2, 3.1.4) |  |  |  |
| **Is there a control or comparator arm and is this appropriate? Should there be one?**  (NS 3.1.5) |  |  |  |
| **If the study includes blinding, does the methodology ensure the integrity of the blinding process? If unblinding is required, will inappropriate re-identification be avoided?**  (NS 1.1(b), 1.7) |  |  |  |
| **Is the statistical analysis plan satisfactory?**  (NS 1.1(b), 3.1.1(d), 3.1.2(b))  If appropriate, has a sample size calculation been performed to ensure statistical validity of the data collected? |  |  |  |
| **If the study is a clinical trial, has it been registered on a publicly available register?**  Clinical trials are studies that prospectively assign human participants or groups to one or more health related interventions to evaluate the effects on health outcomes.  (NS 3.1.7) |  |  |  |
| **If the study involves a genetic component, is there any possibility of incidental findings? Is the plan to handle these appropriate?**  (NS 3.3) |  |  |  |
| **Have the investigators sought feedback from consumers or community engagement groups regarding the design of the research?**  Investigators should be encouraged to consult with these groups when designing research to ensure their views and needs are being addressed. |  |  |  |
| **Study Personnel and logistics** | **YES** | **NO** | **N/A** |
| **Is the principal investigator appropriately skilled, qualified and experienced to conduct and supervise the study?**  (NS 1.1(e), 3.1.9(b), 3.2.4(b), 3.3.56, 4.8.7, 5.1.2(b), 5.7.3(b)) |  |  |  |
| **Do any of the research team have a conflict of interest? If a conflict of interest exists is it being declared and managed appropriately?**  Conflicts of interest should be declared and managed according to institutional policy and procedure. Flinders University and SALHN have separate and different procedures regarding conflicts of interest.  (NS 5.4) |  |  |  |
| **Is the site adequately resourced to conduct the study? Are appropriate facilities available to investigators and participants?**  (NS 1.1(f), 3.1.9, 3.3.57) |  |  |  |
| **Has the source and amount of funding clearly been identified and explained?**  (NS 2.2.6(h), 5.2.8) |  |  |  |
| **Recruitment** | **YES** | **NO** | **N/A** |
| **Does the research proposal clearly describe the recruitment strategy? Is this strategy appropriate?**  (NS 3.1.12, 3.1.13) |  |  |  |
| **Are the inclusion criteria adequate and appropriate?**  (NS 3.1.14, 3.1.15) |  |  |  |
| **Are advertising materials being used? Have these been provided and are they appropriate in the context of the research?**  (NS 3.1.20, 5.2.25) |  |  |  |
| **Does the recruitment strategy limit the risk of coercion and pressure to participate?**  (NS 3.1.22) |  |  |  |
| **If any vulnerable groups will be recruited, have the appropriate protections been put in place for these participants?**  Vulnerable groups include:   * Women who are pregnant and the human fetus * Children and young people * People in dependent or unequal relationships * People highly dependent on medical care * People with cognitive impairment, an intellectual disability, or a mental illness * People who may be involved in illegal activity * Aboriginal and Torres Strait Islander peoples * People in other countries   (NS 4) |  |  |  |
| **Participant Information Sheet** | **YES** | **NO** | **N/A** |
| **Is the PIS written in lay language?**  Participant information sheets should be written at the reading level of a 12 year old.  (NS 2.2.2, 2.2.3, 3.1.26) |  |  |  |
| **Is all the information outlined in section 2.2.6 of the National Statement provided to participants?**  (NS 2.2.6) |  |  |  |
| **Have the risks of participating in the study been adequately identified and explained in the PIS?**  (NS 2.2.2) |  |  |  |
| **Does the PIS adequately explain that a person’s decision not to participate will not result in any negative consequences?**  (NS 4.3.7, 2.2.9) |  |  |  |
| **If limited disclosure is involved, is this appropriate?**  (NS 2.3.1) |  |  |  |
| **Is the reimbursement and/or costs involved in participation clear in the PIS?**  (NS 2.2.10, NS 2.2.11) |  |  |  |
| **Consent** | **YES** | **NO** | **N/A** |
| **If participants lack the capacity to consent, has a pathway been included that will allow these people to participate? Is this pathway appropriate?**  (NS 1.13, 2.2.12, 4.2, 4.4, 4.5) |  |  |  |
| **Will the participants potentially be in an unequal or dependent relationship with the person consenting them? Has this been adequately addressed?**  Unequal or dependent relationships, such as those patients have with their clinician; can impact on a person’s decision to participate. Steps should be taken to minimise the impact of these relationships and the approach should be justified.  (NS 4.3) |  |  |  |
| **If a waiver of consent approach is being proposed, does this comply with the guidelines in section 2.3.10 of the National Statement?**  (NS 2.3.9, 2.3.10, 2.3.11, 2.3.12) |  |  |  |
| **If an opt-out consent approach is being proposed, does this comply with the guidelines in section 2.3.6 of the National Statement?**  (2.3.5, 2.3.6, 2.3.7, 2.3.8) |  |  |  |
| **Data Collection, Management, Storage, and Security** | **YES** | **NO** | **N/A** |
| **If the data being collected is identifiable or re-identifiable, are there adequate provisions in place to ensure privacy and confidentiality of participants?**  (NS 3.1.41, 3.1.42) |  |  |  |
| **Has a data management plan been outlined in the study documentation?**  The data management plan should outline researcher’s intention to generate, collect, access, use, analyse, disclose, store, retain, dispose, share, and re-use the data.  (NS 3.1.45, 3.1.46) |  |  |  |
| **Will the data re retained for an appropriate period?**  Research data in public health research should be retained for at least 15 years as per General Disposal Schedule 28. Research data in University research should be retained for a period of 5 years, 7 years, 15 years, or permanently depending on the nature of the research as per General Disposal Schedule 24. |  |  |  |
| **Notes for the committee** | | | |
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| **Queries to be sent back to the investigators** | | | |
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