SAC HREC Reviewer Guide

Number	Issue	SAC HREC position
1	Funding is not clear	The study funding sources and amounts should be declared in section Q1.6 of the HREA and in the participant information sheet. The requirement to disclose funding sources and amounts to participants in the participant information sheet is outlined in section 2.2.6(h) of the National Statement
2	Recruitment - contacting potential participants	Potential participants should not be "cold called" as part of a research project. Researchers should ask someone who has a pre-existing relationship with the participant to ask them if they would like to be approached regarding research. This approach will avoid potentially upsetting the person by calling them without their consent.
3	Inclusion and exclusion criteria are not clear or fair	The inclusion and exclusion criteria should be justifiable and fair (NS 3.1.15). The inclusion and exclusion criteria should be clearly outlined in the protocol. If specific groups are being excluded, such as those who can't speak English or ATSI people, strong justification should be provided as to why those people are being excluded. This justification should be in alignment with the ethical value of justice.
4	Identifiability of DNA	DNA samples cannot be described to participants as de-identified, as they are always inherently identifiable given the genomic sequence of an individual can be obtained from them, which could lead to their identification.
5	Electronic tools with no paper copies	If a study uses electronic tools, a paper option should always be provided to participants, as some participants will prefer paper to electronic devices, and they should be given that option.
6	Complex jargon in the PICF	The PICF should not contain any complex medical jargon or terminology that may be unknown to the participants. It should be written to a level where the average 12-year-old could understand it. Any complex terms or jargon that need to be used for the purpose of describing the study should be accompanied by a lay explanation.
7	Investigators are mandated notifiers	Participants should be informed if the investigators are mandated notifiers who are required by law to notify the Department for Child Protection if they suspect on reasonable grounds that a child or young person is, or may be, at risk of harm. What types of information may result in a report should be clear. More information on mandated notifiers is available here.
8	GP notification	When the study involves an intervention into a participant's healthcare, the participant's GP should be notified. The onus to notify the GP should be on the investigators, not the participant.
9	US English spelling in study documents	All documents should be written in Australian English rather than US English. All documents should also be appropriate for the Australian context and should be sensitive to Australian customs and tradition. Some documents from overseas studies will use overseas terms. These should be replaced Australian terms in participant facing materials. Examples include: • Subjects should be participants • Miles should be kilometres

		• IRB/IEC should be HREC • Images in documents should be culturally sensitive
10	Access to post-trial medications	The investigators need to be clear as to whether the study medication will be available to participants after the trial, and what the conditions of access are (i.e. participants will have to pay to access the study medication) (NS 3.1.28(c)).
11	Capacity to consent	For studies involving people with a cognitive impairment, intellectual disability, or a mental illness, the investigators need to establish whether a potential participant has the capacity to provide informed consent, or whether an appropriate third party will need to consent on behalf of them (NS 4.5).
12	Statistical analysis plan	The investigators need to outline a statistical analysis plan in the protocol. The analysis plan should be clear and should be capable of addressing the research question (NS 1.1(b)). If any doubt exists, the plan should be reviewed by a committee biostatistician.
13	Interpreters	Studies should involve people who can't speak or understand English as standard. Interpreters should be used to facilitate their inclusion. If they are excluded this should be strongly justified. Family members should not serve as interpreters to avoid potential coercion.
14	Witness signatures in consent forms	Witness signatures are generally not required and can be removed from consent forms. If the participant is unable to read or if a legally acceptable representative is unable to read, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to participants, is read and explained to the participant or the participant's legally acceptable representative, and after the participant or the participant's legally acceptable representative has orally consented to the participant's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and that informed consent was freely given by the participant or the participant's legally acceptable representative. *From ICH GCP 4.8.9 available here.*
16	Data Safety Monitoring Boards (DSMBs)/ Independent Data Monitoring Committees (IDMCs)	Clinical trials that involve a drug or device intervention should establish a DSMB or IDMC. These should be constituted according to NHMRC guidance here.
17	Ionizing radiation	When research participants are exposed to ionizing radiation (from tests such as x-rays or CT scans) **which is additional to that received as part of their normal clinical management**, the ARPANSA radiation protection series 8 code of practice applies. The code requires that an independent medical physicist must verify or assess the total effective dose and organ doses.

		The HREC must consider the estimated dose and the associated risks to participants. The code outlines radiation dose constraints for participants. The risks of the estimated dosage must be communicated to the participants in the participant information sheet. The wording used must be that outlined in annex 2 of the code of practice available here.
18	Dependent/unequal relationships	The relationship between a treating clinician and their patient is an unequal relationship as outlined in Chapter 4.3 of the National Statement. This impacts the voluntary nature of consent where the patient is asked by their treating clinician to participate in research. The SAC HREC is of the view that recruitment of patients by treating clinicians should be avoided wherever possible. A third party without the unequal relationship, such as another clinician or study team member should provide the information, answer any questions and obtain informed consent from the participant. An exception to this position is made when the study in question is a highly sophisticated clinical trial and there is a need to have a comprehensive understanding of the potential participant to gauge whether they would be suitable for the clinical trial. An example of this is commercially sponsored Oncology clinical trials. In this case the potential participant should be encouraged to speak with someone outside the study team, such as their GP, or a family member or close friend, regarding whether they should participate.
19	Counselling for distressed participants	If the research has any potential to cause distress to the participants, the investigators should ensure that counselling services will be made available to participants to manage any distress that arises as a result of the research. This counselling should be provided free of charge and should be arranged by the investigators. This should be additional to providing the phone number for support services such as Lifeline or Beyond Blue.
20	Potential for SA Health staff to feel distress	If studies involving SA Health staff have the potential to uncover distress, investigators should include resources to support staff, such as information on how to access the Employee Assistance Program (EAP).
22	Clinical trial registration	All clinical trials must be registered on a publicly available clinical trial register complying with international standards before the recruitment of the first participant (NS 3.1.7).
23	Reimbursement and costs to participants	Participants should be reimbursed for their participation in studies where reimbursement is financially possible. This should include covering costs along with reimbursement for time. If this is not financially possible, any costs of participating in the research should be clearly explained in the participant information sheet. The reimbursement offered to participants should not be disproportionate to the time involved in such a way that it encourages the participant to take risks they would not normally take (NS 2.2.10).
24	Time for participants to consider participation	Potential participants should be given adequate time to decide whether they wish to participate in a study. At least one week should generally be given for most research. If potential participants are given less than a week, strong justification should be provided as to

		why.
25	Questionnaires	All questionnaires that will be used in the study should be provided to the HREC for review. The questionnaires used in studies should be validated tools. Tools that are not validated are only acceptable if the study is aiming to validate the tool or if there is no validated tool available that will allow the aims of the study to be achieved.
26	Access to MBS/PBS data	Data linkage between MBS/PBS datasets and other datasets can be arranged through the Australian Institute of Health and Welfare (AIHW). The AIHW has its own ethics committee that approves MBS/PBS data link age projects. This is separate and additional to SAC HREC approval. The AIHW Ethics Committee expects that, where feasible, researchers will seek written consent from participants.
27	Sample size	The study protocol must demonstrate that the study sample size will be able to achieve the aims of the study. This is usually shown through a power calculation. If the committee is unsure whether the power calculation is correct, the study should be referred to a committee biostatistician (if available).
28	Consenting young people without parental/guardian consent	Where it is proposed that a child under the age of 18 participates in research, consent should be obtained from both the child (if they have the capacity to make their own decision about participating in the research) and from a parent / guardian / primary care giver / other lawfully-appointed decision-maker. The committee can require consent from both parents (and not just one parent) if the research is particularly risky. The consent obligations for research are higher than for medical treatment: it is possible that a child under the age of 18 might be able to consent to medical treatment without parental consent and yet be unable to consent to participate in research without parental consent. (NS 4.2)
30	Previous review of research	The Human Research Ethics Application (HREA) form in section Q1.12 asks the applicant whether the scientific or academic merit of the research project has been evaluated. If the answer to this question is “yes” a further question regarding what the review process was and what was the outcome is asked. There is also an option to attach evidence of the outcome of the scientific or academic review process. If this is available, it should be attached to the application.
31	Manuscript provided after Interviews	Participants who participate in an interview as part of a research project should be provided a manuscript of the interview after it has been conducted and should be allowed to make any changes to this manuscript that they feel are appropriate. Indigenous participants may prefer a verbal debrief and this should be accommodated. At the end of the interview an open-ended question should be asked that would allow a participant to express thoughts not covered by questions previously asked. The interviewer should also ensure the interview has not impacted on the participants health and wellbeing. If it has, appropriate support should be offered.
32	GCP training for investigators	It is required that all investigators undergo Good Clinical Practice (GCP) training. A free training resource is available from the SALHN Office for Research training website.
33	Waiver of consent for interventional research	The SAC HREC has received legal advice that a waiver of consent cannot be granted for a procedure done purely for research purposes that is not medical treatment. Third party consent for non-medical

		treatment research can only be given under an Advanced Care Directive or as a SACAT appointed guardian.