Scope HREC review and approval

Tips to Prevent Delays

The information has been prepared to help researchers avoid delays in the ethical review and approval by Scope's Human Research and Ethics Committee.

Determining capacity to consent

Information about determining capacity to consent is often missing, particularly as it relates to people with cognitive impairment or intellectual disability. It is not sufficient to say that capacity to consent will be determined using standard procedures. The Committee recommend providing information specifically about how capacity to consent will be determined, and who will make that determination.

Identifying and managing risk/s associated with participation (including adverse reactions and distress)

The risk associated with participating in research is often underestimated. Eliciting information about sensitive topics (e.g., violence, abuse, physical health, mental health, satisfaction with services) could lead to distress in participants. The Committee expect that researchers provide information about the risk/s associated with participation, and implement strategies to manage these (e.g., access to counselling). Details of risks should be included in any information distributed to potential participants (e.g., participant information sheets/ explanatory statements).

Management of dependent / unequal relationships

In some cases, Scope is approached by external researchers to assist with recruitment by distributing information to potential participants. Assisting with recruitment often means that a Scope employee (e.g., therapist, support worker, manager) is being asked to pass on information about the research to people who they already have a relationship with (e.g., therapist to client, manager to support worker). In these situations, there is a power relationship and the potential for coercion that needs to be acknowledged and addressed to ensure that participation is free and voluntary. Dependent / Unequal relationships are also likely to arise in research conducted by Scope researchers, which should also be addressed.

Seeking unspecified consent

Unspecified consent means consenting to data being used in *any* future research. When unspecified consent is sought, the wide ranging implications must be explained to participants and included in any information distributed to them (e.g., participant information sheets / explanatory statements).

Complexity of language

It is essential that the information (e.g., participant information sheets/ explanatory statements, consent forms, recruitment advertisements) distributed to potential participants is written in a way that will be understood. The Committee expect that researchers avoid the use of technical and academic language, especially when potential participants are children or people with cognitive impairment or intellectual disability. Instead, researchers

should use lay language (i.e., plain language). Researchers should also consider consulting with experts about writing in Easy English.

Lack of information about the research

At times, in the information provided to potential participants, there is a lack of information about the aims of the research and what participation involves. The Committee expects that the participation requirements are clearly articulated (e.g., interviews, surveys, time commitment required, examples of questions that will be asked). The Committee also expect that, in the information provided to potential participants, specific information about the aim/s of the research is included, rather than just a broad statement being made about the research.

In the project proposal section of the ethics application, researchers should provide enough background information in order to demonstrate that the research is based on current knowledge and methods, and has a clear rationale (e.g., literature review).

Attachments

The Committee sometimes find that researchers do not attach all the relevant documents referred to in their applications. For example, recruitment materials, consent forms, surveys, and observation forms. Researchers should take care to ensure that all the relevant attachments have been included.

HREC Approval Clause

Participant Information Sheets/Plain Language Statements/Explanatory Statements must include the HREC Approval Clause:

This research {insert Scope project number & title of research} has been approved by the Scope Human Research Ethics Committee (HREC Identification Number: EC00428; Organisation Identification Number: ORG0554)

Complaints Clause

Participant Information Sheets/Plain Language Statements/Explanatory Statements must include Scope's Complaints Clause:

If you have any complaints about anything to do with the project, the way it is being conducted or any questions about your rights as a research participant, please contact: Emily Garrett HREC Officer Scope Human Research Ethics Committee Scope (Aust) Ltd Level 2, 302 Burwood Road Hawthorn 3122 Email: HREC@scopeaust.org.au Telephone: 03 9843 2026 **{insert number & title of research}**