SOP 9: Working with Vulnerable Persons or Populations

The South African College of Applied Psychology Research Ethics Committee (SACAP REC)	
Title	SOP 9: Working with Vulnerable Persons or Populations
SOP No	SOP 9_SACAP REC_9.1
Date of approval	January 2022
Revision date	October 2021
Pages	7

1. COMPILATION AND AUTHORISATION

Action	Designated Person	Date	Signature
Compiled for SACAP by	Dr Malesa Kgashane	6 August 2021	
Amended for SACAP by	REC Office	26 October 2021	K. J. Young
Checked by	Academic Manager	11 November 2021	C.E. Ford
Authorised by	Academic Dean	20 January 2022	J. O. Lotter
Revised by	SACAP REC Chair	5 April 2022	D.S. De Sousa
Authorised by	Academic Dean	25 April 2022	J. O. Lotter

2. DOCUMENT HISTORY

Date	Version No	Reason for revision
July 2021	1	Development of the document
April 2022	2	Amendments to include process of determining intellectual capacity and proxy consent processes for research with people with Intellectual Disabilities (ID)

3. ABBREVIATIONS AND DEFINITIONS

Abbreviation	Definition
ID	Intellectual Disabilities
SOP	Standard Operating Procedure
MHCA	Mental Health Care Act 17 of 2002
NHA	National Health Act 61 of 2003

4. PURPOSE OF THE SOP

The purpose of this SOP is to provide guidance to the SACAP REC regarding protecting the welfare of particularly vulnerable subjects, such as:

- Adults with incapacity to provide informed consent;
- Persons in dependent relationships;
- Persons highly dependent on medical care;
- Persons with physical disabilities;
- Prisoners; and
- Collectivities.

Please Note: Research involving children is dealt with separately in the *SOP 5 for Research Involving Minors*.

5. SCOPE

The SACAP REC must ensure that it has adequate representation to consider specific kinds of research involving these vulnerable populations in a satisfactory manner. Just as in providing medical care, research studies that plan to involve potentially vulnerable persons or populations must have adequate procedures in place for assessing and ensuring each participant's capacity, understanding, and informed consent and assent is obtained and honours the principle of beneficence. Beneficence can be described as safety in participation by not exposing participants to dangerous situations and preventing them from being harmed (physical and/or emotional).

6. PROCEDURE(S)

The procedures provide for the minimum conditions for research involving vulnerable persons or populations. The SACAP REC may require additional safeguards to protect potentially vulnerable people or populations.

6.1. Research Involving Incapacitated Adults

Adults who are factually incapable of giving informed consent should participate in research only where their participation is indispensable to the research, i.e., the research cannot deliver the desired outcomes if capable adult participants were to be used instead. Furthermore, the research should investigate a problem of relevance to incapacitated adults. Where research can be undertaken with capable adults, but nevertheless proposes also to include incapacitated adults, strong justification for their inclusion must be provided.

Decision-making incapacity may result from a variety of causes and take various forms. The most important insight is that incapacity to decide is a question of fact to be determined on a case-by-case basis. Even if for other purposes, a person has been declared legally incompetent, they may retain the capacity to make decisions. It is thus vital that researchers bear this in mind, because to ignore this fact is to seriously violate the person's constitutional right to dignity as well as the ethical principle of respect (autonomy), including the right to be informed about the nature and potential consequences of the study, the right to decide whether to participate in a study as well as the right to withdraw at any time.

When recruiting participants, the crucial elements are whether the person retains the capacity to decide whether to participate and whether they are able to communicate that decision.

The first point to note, therefore, is the difference between the capacity to decide and the ability to communicate the decision.

The capacity to decide necessarily includes the capacity to understand the information that is communicated to them. The ability to communicate includes the ability to hear and to speak or otherwise signal or express one's wishes. For example, deafness should never be mistaken for incapacity to decide. Similarly, the inability to speak should not be mistaken for a lack of capacity to decide whether to participate.

Research involving incapacitated adults should be approved only if:

6.1.1. The research, including observational research, is not contrary to the best interest of the individual;

6.1.2. The research, including observational research, places the incapacitated adult at no more than minimal risk (i.e., the *'everyday risk standard'* which means the risk is commensurate with *'daily life or routine medical, dental, or psychological examinations and in social or education settings activities'* – referred to as *'negligible risk'* in some guidelines); or

6.1.3. The research involves greater than minimal risk but provides the prospect of direct benefit for the incapacitated adult. The degree of risk must be justified by the potential benefit;

6.1.4. The research, including observational research, involves greater than minimal risk, with no prospect of direct benefit to the incapacitated adult, but has a high probability of providing generalizable knowledge, i.e., the risk should be justified by the risk-to-knowledge ratio;

6.1.5. Greater than minimal risk must represent no more than a minor increase over minimal risk; The legally appropriate person (treatment proxies as stipulated in NHA s 7 or s 27(1)(a) of the Mental Health Care Act 17 of 2002) gives permission for the person to participate; and/or

6.1.6. The NHA specifies the sequence of legally appropriate treatment proxies as spouse or partner; parent; grandparent; adult child; brother or sister. The MHCA provides, in no sequence, that legally appropriate proxies are spouse; next of kin; partner; associate (defined as *'a person with a substantial or material interest in the well-being of a mental health care user or a person who is in substantial contact with the user'*); and parent or guardian.

6.2. Persons in Dependent Relationships

This class of persons includes persons in junior or subordinate positions in hierarchically structured groups. This may include relationships between older persons and their caregivers; persons with chronic conditions or disabilities and their caregivers; persons with life- threatening illnesses; patients and health care professionals; wards of state and guardians; students and teachers; employees and employers, including farm workers, members of the uniformed services and hospital staff and their respective employers. This group may be vulnerable to coercion or undue influence, or manipulation due to power relations. Particular attention should be given to ensuring that participants are adequately informed and can choose voluntarily whether to participate in research. Issues related to coercion should be adequately addressed.

6.3. Patients Highly Dependent on Medical Care

Patients who are highly dependent on medical care deserve special attention when considering research participation. The gravity of their medical condition may require invasive measures that carry an increased risk of harm. The quality of informed consent may be compromised by the effect the medical condition has on the participant's decision-making or communication abilities. A patient may be reluctant to refuse consent for fear that this may compromise their medical treatment. Adequate provision must be made for informing patients and their relatives about the research, to ensure that stress and other emotional factors do not impair their understanding. The dependency of patients and their relatives on caregivers should not unduly affect research participation decisions. In particular circumstances, The SACAP REC may approve delayed consent. Delayed informed consent involves the enrolment of patients who lack decision making capacity into a clinical trial before obtaining consent.

Note: this does not mean that informed consent is waived. The SACAP REC should ensure that a clear and full justification for the proposed delay accompanies the research proposal. The individual circumstances of the patient must be carefully considered to prevent inadvertent violation of personal or cultural values.

The SACAP REC may approve a delay in obtaining informed consent for research participation by patients highly dependent on medical care if:

6.3.1. The research is based on valid scientific hypotheses that support a reasonable possibility of more benefit than that offered by standard care; and

6.3.2. Participation is not contrary to the medical interests of the patient; and

6.3.3. The research interventions pose no more risk of harm than that inherent in the patient's condition or alternative methods of treatment; and

6.3.4. The research is based on valid scientific hypotheses that support a reasonable possibility of more benefit than that offered by standard care; and

6.3.5. As soon as reasonably possible, the participant and her relatives or legal representatives will be informed of the participant's inclusion in the research; be requested to give delayed consent; and advised of the right to withdraw from the research without any reduction in quality of care.

6.4. Persons with Physical Disabilities

Recruitment strategies for research participation in general should be sensitive to the possibility that persons with physical disabilities may wish to volunteer and therefore should ensure that there are no unintended barriers to such participation, e.g., the absence of ramps or a lift for wheelchair-bound potential participants. Research involving participants with physical disabilities should anticipate possible barriers and include measures to minimize them.

6.5. Persons with Intellectual Disabilities (ID)

Recruitment strategies for research participants with intellectual disabilities should refer to Ethics in Health Research: Principles, Processes and Structures – p. 36 Section 3.2.4 to determine the steps required in determining the degree of incapacity, obtaining proxy consent from legal guardians as well as obtaining assent from research participant as far as possible.

Determining capacity to consent should take place before obtaining and documenting consent because some individuals with ID may be incapable of giving consent. For example, individuals with mild to moderate ID will likely be able to provide consent, whereas those with more severe to profound ID may not have this capacity. Steps may therefore need to be taken to involve others who know the individual best, such as family members or caregivers, when assessing capacity to provide consent and obtaining informed consent to participate in research.

Furthermore, the researcher must consider the way research participation is communicated to persons with intellectual disabilities. This communication must accommodate the specific features of ID for each individual participant, including not only the content but also the method of communication. For example, graphics, vignettes, storybooks, symbols, simple language, and other inventive methods of information must used to obtain informed consent, especially because individuals with ID have difficulty reading and understanding lengthy sentences, which might impede their ability to express their concerns or queries regarding the research project or to give appropriate responses.

Additionally, the researcher should consider the effects of specific disabilities on the research, e.g., researchers should break instructions into component parts, as well as complement auditory instruction with written or visual instruction, and how interview questions may need to be specifically tailored to each participant depending on their cognitive and linguistic abilities. For example, it may be necessary to have someone present who is able to assist in interpreting the language and meaning of a particular response. For example, participants who have little or no verbal abilities may respond to questions using sign language. o Researchers often assume that their ethical obligations are completed once consent to participate has been obtained.

Consent should also be viewed as an ongoing process. Individuals' preferences and concerns regarding the research project may change over time, researchers should continually communicate with their participants and obtain consent throughout the duration of the research, termed process consenting. This allows participants to play a collaborative role in decisions regarding their ongoing participation throughout the research process. Process consent allows the participant the freedom to withdraw from the interview or study at any time and ensures that the participant has a say in confidentiality throughout the research process. A combination of family consent and continuous process consent is thus recommended to constantly evaluate the participants' wellbeing for the duration of the study. It is important that should a participant not wish to participate that quality of care is not affected is clearly communicated in a way that tasks into consideration the person's cognitive limitations. Also, the researcher must check that the participant has understood this, including confirming this with someone who can understand the person's cognitive limitations.

6.6. Prisoners

The chief reason to consider prisoners as a vulnerable class of persons is the potential effect of incarceration on the voluntariness of the decision to participate in research. Neither coercion (direct threat of negative sanction) nor undue influence is acceptable in the informed consent process. Researchers should pay attention to whether their intended participants are awaiting trial prisoners or convicted prisoners. Quite obviously, different ethical issues arise for the former group who remain innocent until proven guilty, notwithstanding being incarcerated. The recruitment strategy design must pay careful attention to how coercion and undue influence will be avoided. Similarly, persons administering questionnaires or conducting interviews must be conscious of environmental factors that may influence voluntariness to participants in research. The SACAP REC should include, at least on an ad hoc basis, a member with experience and knowledge of working with prisoners when deliberating on the protocol. The researchers must comply also with the requirements of the Department of Correctional Services as listed at http://www.dcs.gov.za/services/Research.aspx.

Research should be conducted amongst prisoners only if:

6.6.1. Their participation is indispensable to the research;

6.6.2. The research cannot be conducted with non-prisoners;

6.6.3. The research concerns a problem of relevance to prisoners;

6.6.4. Sound informed consent processes can be ensured;

6.6.5. Engagement with relevant role players about the proposed research has occurred; and/or

6.6.6. In the case of minor prisoners, the limitations and restrictions on independent consent must be remembered. In general terms, it is unlikely that independent consent by the minors will be justifiable.

6.7. **Collectivities (i.e. persons participating in research as groups)**.

'Collectivity' is a term used to distinguish some distinct groups from informal communities, commercial or social groups.

6.7.1. Collectivities are groups distinguished by the following:

6.7.1.1. Common beliefs, values, social structures, and other features that identify them as a separate group;

6.7.1.2. Customary collective decision-making according to tradition and beliefs;

6.7.1.3. The custom that leaders express a collective view; and

6.7.1.4. Members of the collectivity being aware of common activities and common interests.

6.7.2. Research involves a collectivity when:

6.7.2.1. Property or information private to the group as a whole is studied or used;

6.7.2.2. Permission of people occupying positions of authority, whether formal or informal, is required; and

6.7.2.3. Participation of members acknowledged as representatives is involved.

6.7.3. Research involving collectivities should include measures to ensure:

6.7.3.1. Dispute resolution mechanisms for anticipated or actual disagreements between the researcher and the collectivity;

6.7.3.2. Respectful negotiation with the collectivity or its leaders;

6.7.3.3. Permission is sought from appropriate representatives of the collectivity to approach individual participants;

6.7.3.4. Informed consent process for individual participants are in place;

6.7.3.5. Fair distribution of research-related benefits and harms among affected collaborating parties;

6.7.3.6. Agreement about ownership of data and rights of publication of research findings; and

6.7.3.7. Agreement about feedback to the collectivity about the findings.

7. REFERENCE DOCUMENTS

- Bracken-Roche, D., Bell, E., Macdonald, M., & Racine, E. (2017). The concept of 'vulnerability' in research ethics: An in-depth analysis of policies and guidelines. *Health Research Policy and Systems*, *15*(8). https://doi.org/10.1186/s12961-016-0164-6
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- Georgetown University. (n.d.). *Informed consent and limitations on decision making capacity* (Ch. 2). https://bioethicsarchive.georgetown.edu/nbac/capacity/Informed.htm