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RHODES UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

SOP 4.1 INFORMED CONSENT

Approved by:	Name	Signature	Date
Human Research Ethics Committee	Dr Janet Hayward (Chair)		29/04/2024
Endorsed by:			
VC Legal Unit	Mr Ismail Amojee		24/05/2024
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COMPILED BY Dr Janet Hayward, Chair, Rhodes University Human Research Ethics Committee

DOCUMENT HISTORY

Version 1.01 (November 2014): Rhodes University Ethical Standards Handbook (comprising Institutional Policy, Terms of Reference and Standard Operation Procedures).

Version 2.0 (April 2024): Derived from division of previous version into separate documents and revised to align with RU Research Policy (2021) and DoH Guidelines (2015; 2024).

INFORMED CONSENT

1. Purpose

The purpose of these guidelines is to define the ethical principle of informed consent, the procedure for obtaining it when conducting research with human participants, and where waiver of informed consent may be requested.

2. The Principle of Informed Consent

2.1. The principle of respect for persons underpins the requirement that a person must choose voluntarily whether to participate in research based on information that allows an informed choice to be made.

2.2. Persons over the age of 18 years, may make independent decisions, but may wish to consult with family members or others in keeping with personal preference or cultural practices. Consequently, the process should permit sufficient time for consultation between the recruitment approach and the point of decision-making. No person should be required to make an immediate decision.

2.3. Persons under the age of 18 years must have informed consent from their parents or guardians before participating in research.

2.4. Persons between the ages of 7 and 18 (unless they are legally emancipated) must sign informed assent to participate in research in addition to having parental (or substitute) informed consent.

2.5. The Rhodes University Research Ethics Committee (RU-HREC) should assess the proposed process for informed consent as well as the information that potential participants and/or their parents) will be given and the measures to facilitate understanding. Considerations for assessment include the following:

1) the choice to participate is voluntary and refusal to participate will not be penalised.
2) choosing to participate can be reversed at any time without explanation or prejudice, and any data already collected from them will be destroyed.
3) the setting is sufficiently private and minimises the possibility of undue influence.
4) the person conducting the informed consent process must do so impartially.
5) the text of the participant informed consent form must:
    - be in plain language and free of complex terminology
    - be free of jargon and unexplained acronyms
    - explain technical terminology
    - be translated into language(s) appropriate to the context
    - state that participants may contact the RU-HREC at the contact details provided if they have queries or complaints about their rights and welfare as research participants
    - state that participants may contact the researcher at the contact details provided if they have queries about the research project

2.6. All documents given to participants must be approved by the RU-HREC.

3. Information to participants

3.1 All researchers interacting with human participants will identify themselves to their participants. They will identify their association with the University, and their status as staff member, student, or research assistant.

3.2 All participants will receive the following information necessary to facilitate their giving fully informed consent:

1) the nature of the research, its purpose and usefulness,
2) a precise description of the procedures in which the participant will be asked to participate,
3) The fact that participation is voluntary and that the participant may withdraw at any stage with no consequences,
4) expected duration of participation,
5) anticipated discomforts,
6) the anticipated personal risks, including direct physical, psychological or social harm and measures to minimise risk of harm,
7) the expected benefits of the research,
8) the extent to which confidentiality is possible and methods for protection of confidentiality and anonymity which will be observed by the project supervisor and colleagues in respect of the participant's participation as well as the legal limitations to anonymity and confidentiality,
9) how the participant will receive feedback about the research,
10) that research interactions will be audio or video recorded (if applicable),
11) that signing the informed consent document will not result in the participant waiving any legal claims, rights, or remedies, and
12) that the research has been approved by RU-HREC (include identifying details, for example National Health Research Ethics Council registration number).

3.3 Where applicable, information must be provided to participants on:

1) reimbursement and/or incentive given for participation,
2) information about the sponsor,
3) potential conflicts of interests,
4) the anticipated personal benefits derived from this participation,
5) what social benefits are anticipated, and to whom they accrue,
6) the anticipated risks to a larger social group or a third party,
7) the extent to which risks in the project have been pretested, and whether the project the participant will participate in differs from pre-tested practice,
8) the possibility that the data from this research project may be stored and used for a different purpose in future without obtaining new consent from the participant,
9) where the results of the project will be available when they are published, and
10) for more than minimal risk research: insurance in the event of research related injury.

3.4 Except where the Principal Investigator justifies an alternative method, the information set out in 3.2 and 3.3 will be presented to the participant in writing, as part of the consent form.

3.5 Where the project supervisor justifies presenting the information set out in 3.2 and 3.3 to the participant verbally, the person who presents the information will refer to a printed copy of the information.

3.6 Documents must be understandable in the participant's language. In case of an interpreter being involved for this purpose, she/he must be independent and present at all discussions with participants. Where there is no significant risk for the participant, friends or family members of the participant may perform this role.

3.7 Special precautions should be taken to ensure that participants understand the information provided as part of informed consent, especially when research is conducted in cross-cultural settings, or in vulnerable communities.

4. Informed consent of participants

4.1. A person must give express consent to participate in any research as a human participant, free of coercion, constraint, or inducement, with information adequate to evaluate the anticipated risks and benefits inherent in personal participation in the project.

4.2. Research should only involve persons under a legal disability (cannot be legally bound by their own actions) where other participants are not appropriate for inclusion. Persons under a legal disability include:

1) Children (persons under 18 years of age),
2) Pregnant, lactating and/or women who have recently given birth.
3) Individuals from vulnerable communities[1]
4) Individuals participating as groups
5) Individuals in dependent relationships[2]
6) Prisoners,
7) Individuals with intellectual or mental impairment or other disabilities,
8) Individuals for whom English is not a first language, and
9) Research involving persons highly dependent on medical care.

4.3. Research must not systematically avoid inclusion of participants under a legal disability (see 4.2) if no compelling reasons for exclusion apply.

4.4. Unless the Principal Investigator has justified the use of verbal consent in the methodology/protocol, consent shall be given in writing.

[1] UNAIDS defines 'vulnerable community' as having some or all of the following characteristics: limited economic development; inadequate protection of human rights and discrimination on the basis of the health status; inadequate community/cultural experience and understanding of scientific research; limited access to health care and treatment options; limited ability of individuals in the community to provide informed consent (Department of Health Guidelines, 2015:22).

[2] Individuals in dependent relationships include persons in junior or subordinate positions in hierarchically structured groups and may include relationships between older persons and their care-givers; persons with chronic conditions or disabilities and their care-givers; persons with life-threatening illnesses; patients and health care professionals; wards of state and guardians; students and teachers (including university teachers); employees and employers, including farm workers, members of the uniformed services and hospital staff and their respective employers. Particular attention should be given to ensuring that participants are adequately informed and can choose voluntarily whether to participate in research (Department of Health Guidelines, 2015:29).

4.5. It is preferable that the information and consent forms be integrated; where this is not possible, the following elements of information must appear on the consent form:
   1) the name of the University and name of the project supervisor,
   2) a brief but explicit description of the procedures the participant personally will participate in,
   3) an explanation that the participant is free to withdraw from the project at any time, even after having given consent and the project has commenced,
   4) when the research exposes participants to more than minimal risk, the consent form shall include an acknowledgement by the participant of the risk(s) involved in the research and the provisions made for compensation of injury or a waiver of claims arising from those risks.

4.6. It is recommended that the consent form contains general words indicating that participants understand that the nature of the variables being considered may make it impossible to be informed completely of the nature and purpose of the procedures to be followed, but that they will be fully informed when their participation has been completed.

4.7. Remuneration for participation as a participant, if any, shall be based on the time required of the participant and the inconvenience caused, and shall not be sufficient to induce the participant to disregard any risks inherent in participation.

4.8. The provision of incentives (e.g. payment for participation) should not cause undue influence. It should be ensured that the participant is able to make an independent decision regarding consent. Payments to participants should be in the spirit of the National Guidelines on Payment of Trial Participants in South Africa (Available under Resources at the RU Research Ethics webpage; https://www.ru.ac.za/researchgateway/ethics/).

4.9. Provision of informed consent is understood to include consent to publish findings subject to the requirements in respect of participant confidentiality and anonymity. Even though consent may be given by a participant, the researcher must consider whether the publication will stigmatise a group or groups to which the participant belongs. Research should not exploit the vulnerability of a community but should rather reduce such vulnerability. (See section 3.8 for more details on publication of results.)

5. Waiver of informed consent

5.1. Where data originally collected for other purposes is made secondary use of as research data, and the results of such research would not place any individual, family, or community at social, psychological, legal, or economic risk of harm, the researcher may apply for waiver of informed consent.

5.2. RU-HREC may grant waiver of informed consent may be granted where:[3]

   1) Persons from whom the data was collected are anonymous or data has been anonymised by a party other than the researcher who must sign an agreement not to release the identifiers to the research team.
   2) The research could not be conducted if the waiver were not approved.

[3] DoH Guidelines, 2015: 32, 37.

6. Activities involving deception, concealment, or covert observation

6.1. As a general principle, deception of identifiable participants, concealment of the purposes of research or covert observation are not considered ethical because they are contrary to the principle of respect for persons and the obtaining of informed consent. In studies of human behaviour there may be exceptional circumstances when studies cannot be conducted without deception, concealment, or covert observation of participants. Before approving research that involves any degree of deception, concealment or covert observation, an ethics committee must be satisfied that:

1) the provision of detailed information to prospective participants about the purpose, methods and procedures of the research would compromise the scientific validity of that research,
2) the precise extent of deception, concealment or covert observation is defined,
3) there are no suitable alternative methods, not involving deception, concealment, or covert observation, by which the desired information can be obtained,
4) participants are not exposed to an increased risk of harm because of the deception, concealment, or covert observation,
5) adequate and prompt disclosure will be made, and de-briefing provided to each participant as soon as practicable after the participant's participation is completed,
6) participants will have the opportunity to withdraw data that was obtained from them during the research without their knowledge or consent, and
7) activities will not corrupt the relationship between researchers and research in general, with the community at large.

6.2. Where it is necessary to withhold or to misrepresent significant facts in informing the participant, such deception must be expressly justified in the methodology/protocol. It must demonstrate:

1) that the deception is indispensable to the effectiveness of the project,
2) that the deception must extend to all the elements as proposed,
3) that all alternative investigative methods are unsatisfactory,
4) that the deception will not invalidate the informed consent of the participant, and
5) that the participant will be fully informed of all elements of the programme which were withheld or misrepresented as soon as possible after participation in the project has been completed.

6.3. No application will be approved where deception disguises or misinforms the participant of the risks or creates a substantial risk to the participant's self-esteem and dignity.

7. Effective date of this SOP

29 April 2024 with the next revision date being 29 April 2027, or as deemed necessary by a quorate meeting of RU-HREC.