



# RHODES UNIVERSITY

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## RHODES UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

### SOP 4.3 RESEARCH INVOLVING VULNERABLE PERSONS

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

## RESEARCH INVOLVING VULNERABLE PERSONS

### 1. Purpose

The purpose of these guidelines is to outline why the definition of vulnerability requires a nuanced approach, consider the kinds of situations and circumstances that might render certain research participants more vulnerable to harm than others, and emphasise the need for researchers to recognise the agency and autonomy of research participants.

### 2. The concept of Vulnerability

- 2.1. The Nuremburg Code of 1947 assumed that all research participants are vulnerable and mandated informed consent as a measure to counter potential coercion of research participants.
- 2.2. The Belmont Report of 1979 noted that some research participants are particularly vulnerable, for example racial minorities and those who are economically disadvantaged, very sick or institutionalised, because they are more susceptible to coercion and/or exploitation, have increased risk of harm, and lack the capacity to consent to research. If extra protections could not be provided, participants from such groups should be excluded as research participants.<sup>1</sup>
- 2.3. The DoH Ethics in Health Guidelines<sup>2</sup> is guided by the Belmont Report in defining vulnerability in terms of certain groups of participants that may be more easily persuaded to agree to participate in research without being able to properly consider and/or understand the implications and recommending exclusion of such participants unless extensive justification is provided by the researcher and accepted by the Research Ethics Committee.
- 2.4. Recent scholars have criticised definitions of vulnerability that depend on the creation of stereotypes or labels to characterise certain subpopulations.<sup>3</sup> Such conceptions can lead to paternalism and discrimination, whereas assumptions should not be made about people's vulnerability based on the groups to which they belong, because this leads to the exclusion of research participants and silencing of certain voices due to their presumed vulnerability.<sup>4</sup>
- 2.5. Vulnerability should not be understood as a fixed state and does not relate to particular subpopulations.<sup>5</sup> It is better understood in terms of 'layers' and as 'relational' because each 'layer' of vulnerability occurs within a particular context and layers of vulnerability come and go as contexts change.<sup>6</sup>
- 2.6. RU-HREC should facilitate autonomous decision-making by research participants wherever possible to promote the voice, agency, and active citizenship of those typically labelled as vulnerable. Participants need to be involved in the determination of their own vulnerability rather than categorised as members of homogenous groups, and those deemed incapable of making decisions should be given greater opportunities to make informed choices and decisions.<sup>7</sup>

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<sup>1</sup> Meek et al, 2013:334.

<sup>2</sup> DoH Ethics in Health Guidelines, 2015: 22.

<sup>3</sup> Luna, 2009:129, Peter & Friedland, 2017:107-108, Meek et al, 2013:334.

<sup>4</sup> Peter & Friedland, 2017:108-9.

<sup>5</sup> Peter & Friedland, 2017:113.

<sup>6</sup> Luna, 2009: 129

<sup>7</sup> Peter & Friedland, 2017:109,113.

### **3. Situations and circumstances requiring special consideration**

The following are not clear-cut categories but examples of situations and circumstances that may expose participants to added risk of coercion or harm, especially when two or more categories intersect with one another. RU-HREC must ensure that special consideration is given when research participants belong to one or more of these groups, especially regarding informed consent. They must also ensure that research does not systematically avoid inclusion of participants in any of these classes if no compelling reasons for exclusion apply.

3.1. Childhood: Refer to SOP 4.4 RESEARCH INVOLVING MINORS.

3.2. Womanhood: Researchers must give extra attention to research that involves women who are, or may become pregnant, because of the additional health concerns during pregnancy and the need to avoid unnecessary risk to the foetus. Reasons for excluding women from research should be adequately justified both from the point of protecting the health of a foetus and from the perspective of whether such exclusion is scientifically supportable.

3.3. Unequal relationships: Persons whose proposed involvement in research arises from dependent or unequal relationships need additional attention. Such relationships involve persons who are in junior or subordinate positions in hierarchically structured groups and include relationships between older persons and their caregivers, persons with chronic conditions or disabilities and their caregivers, wards of the State and their guardians, patients and health-care professionals, school children/university students and teachers, prisoners and prison authorities, employees and employers.

3.4. Advanced age.

3.5. Extreme poverty.

3.6. Limited access to health care and treatment options.

3.7. Belonging to a minority group, being an asylum seeker or undocumented individual.

3.8. Mental or intellectual impairment or disability: Special care should be taken to respect the autonomy of persons often labelled or stereotyped as disabled, and to recognise the agency of those who contest being labelled as such and/or describe themselves as for example, 'differently abled' or 'neurodiverse'.

3.9. Acute illness or dependence on medical care: The research should not adversely affect the routine treatment of patients, nor should it disrupt routine management protocols.

3.10. Incarceration: Prisoners might be especially susceptible to coercion and research that could be conducted on a population other than prisoners should not be permitted, unless cogent motivation is presented, and the ethics committee is satisfied that the motivation

does not represent exploitative research. Researchers must follow the procedures and guidelines issued by the Department of Correctional Services.

- 3.11. Communities where the ability to provide informed consent might be limited due to inexperience and understanding of scientific research and/or where English is not a first language and/or where there are low levels of formal education and/or literacy. Care must be taken to ensure that research participants know that they are taking part in research and research should only be carried out with their consent. This requires that particular attention should be paid to the content, languages and procedures used to obtain informed consent.
- 3.12. Collectivities: These are groups that are distinguished by common beliefs, values, social structures and/or other features that identify them as a separate group. The members are aware that they share common activities and interests, and it is customary for group leaders to express the collective view. Where property or information private to the group is used as data and the research requires permission from group leaders (formal or informal), ethical clearance for research with a collectivity must be obtained. Informed consent must be acquired from both the leaders of the collectivity and individual participants.

#### **Effective date of this SOP**

15 May 2024 with the next revision date being 15 May 2027, or as deemed necessary by a quorate meeting of Rhodes University Human Research Ethics Committee.

#### **References**

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