**HREC (Medical) Risk level categories definitions (May 2019)**

In South Africa, as elsewhere, it is necessary to assess the level of risk involved in undertaking research. The risk may be to research participants or patients, to communities, to institutions, or even to the researchers themselves. This is to ensure that responsible investigators have applied their minds and, in so doing, put in place whatever measures may be required to prevent or minimize unintended or negative outcomes.

This table identifies broad categories of risk. Schools/Departments can provide specific examples of these categories that are specific to that particular discipline, or the types of data collection methods or participant groups that are most common in that discipline.

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| **Risk category** | **Definition** | **Example** | **Notes** |
| No risk | No contact with identifiable individuals, *e.g.* when study involves anonymized information | *In vitro* laboratory study using commercially-available cell lines, bacterial cultures, etcReview of anonymized information in the public domain | These studies usually qualify for an ethics waiver |
|  |  |
| Minimal risk | Where the likelihood and magnitude of possible harm are no greater than those imposed by daily life in a stable society, or are to be found in routine clinical testing | Questions about participant’s everyday lives, activities and opinions*,* without detailed identifiable information. Student opinion surveys would, for example, usually fall into this category No sensitive questions or topicsNo vulnerable participant categories; participants may be experts, officials, professionals |  |
| Low risk | Where the only foreseeable risks is that of temporary discomfort, or where there may be some sensitivity involved in terms of the questions asked  | Questions about participant’s everyday lives, activities and opinions, which may include biographical information and some potentially sensitive questions and/or topicsTaking of blood samples may cause minor discomfortQuestions about a participant’s HIV status or sexual behavior can be sensitiveNo vulnerable participant categories  |  |
| Medium risk | Where there is a possible risk of some harm for participants and/or the researcher, but where appropriate steps can be taken to mitigate or reduce risk | Sensitive topics and/or questions that may have potential for trauma and emotional distressDrug trial, pre-general release to the marketMay include vulnerable participant categories or marginalized groups. There is a clear justification to undertake the research using this participant group and/or using the proposed instruments, because likely benefit exceeds likely risks | Support/counselling services must be provided for participants, when appropriateA distress protocol should be given, when appropriate |
| High risk | Where there is a real and foreseeable risk of harm, which may lead to serious adverse consequences if not managed in a responsible manner | Clinical procedures in which a successful outcome cannot be guaranteed, but where non-intervention is likely to result in harm to the individualHighly sensitive topics, e.g. experiences of inter-partner violence, rape, mistreatment of children, etc Vulnerable or marginalized participant groups, or where multiple vulnerabilities existResearch involving deception of the participantsWhere the participants place themselves at risk of harm if they participateWhere the researcher/s may place themselves at risk of harmWhere the researcher/s may place themselves at risk of breaking the law, or may be legally required to report what they find, e.g. child abuse or neglect. In such instances, the researcher should consult a competent person or agency, as to whether referral to the Police or Social Welfare is warrantedWhere the research may reveal information that may place the participant or others at risk (e.g. victims of abuse, violence, crime), requiring intervention from state institutionsThere is a clear justification to undertake the research using this participant group and/or using the proposed instruments, despite the potential risks | Remedial interventions by external professionals can be taken should harm occurExternal support/counselling services must be provided for participants and/or for the researcherA distress protocol and debriefing strategy should be given, if appropriateResearch involving orphans under the age of 18, who have no formal Guardian, may only proceed if a court order is handed down by the High Court |

**NOTES:**

**(1) Definitions of terms**

**Discomfort** refers to a sensation of uneasiness, disturbance or mild pain.

**Risk** refers to (i) the likelihood of exposure to a particular negative consequence, and/or (ii) the magnitude of the possible consequences of exposure, and/or (iii) the possibility that research could result in harm.

**Harm** refers to damage incurred (which may include physical, psychological/emotional, social, economic or legal harm) as an outcome of an action, or through emotional distress.

**(2) Discussion of risk**

Individuals who may be at increased risk include:

• Those who are dependent/reliant on the institution/person who provides/mediates access to researchers;

• Those who are involved in illegal activities or who are criminalized by the state, e.g. drug dealers, sex workers, undocumented migrants.

NB: it is essential to consider the individual – not an aggregated group – when assessing risk.

**(3) Discussion of vulnerability**

Vulnerability can stem from: a lack of capacity or impaired ability to provide voluntary informed consent; health status; social pressures that may impact on the ability to make a free and informed decision; any inability to protect one’s interests in research. Vulnerability may be considered as dynamic and specific to a particular context, and may also arise as a result of power asymmetries between participants and researchers/institutions. There may be layers of vulnerability that function and interact within a participant’s circumstances. Being vulnerable does not necessarily imply that harm or exploitation will occur, but it does increase the risk of harm or exploitation through research.

In addition to those in vulnerable categories, vulnerability may also include individuals whose ability to provide informed consent may be reduced where:

* Their decision-making capacity is limited due to individual mental health status;
* They are physically impaired to the extent that they are largely or wholly dependent on others to function from day to day;
* Their decision-making capacity is limited due to the environment in which they live/work, e.g. prisoners/detainees, residents of drug rehabilitation centres;
* They exist in a hierarchical structure which constrains their freedom of operation, *e.g.* members of the armed forces, certain religious orders;
* They are under 18 years of age;
* They are dependent on the state to maintain a legal status, e.g. documented asylum seekers, documented refugees.

NB: it is essential to consider the individual – not an aggregated group – when assessing vulnerability.

The researcher needs to minimise the risk of harm, ensure that the consent process supports a truly informed decision, and put in place additional measures to ensure ethical involvement of vulnerable groups. Where necessary, applications should include details of steps to be taken to facilitate data collection across language barriers (e.g. interpretation or translation) and/or in cases of illiteracy.

It is important for researchers to consider the inconvenience or cost to participants taking part in their research so that appropriate travel costs or refreshments are provided. Loss of income and absence from work needs to be avoided or compensated appropriately.

Useful references:

Bracken-Roche, D., Bell, E., Macdonald, M.E. and Racine, E. (2017). The concept of ‘vulnerability’ in research ethics: an in-depth analysis of policies and guidelines. *Health Research Policy and Systems*, 15 (1), 8, doi:10.1186/s12961-016-0164-6.

Horn, L., Sleem, H. and Ndebele, P. (2014). Research vulnerability. In: M. Kruger, P. Ndebele and L. Horn (Eds.), *Research ethics in Africa: A resource for research ethics committees*. Stellenbosch: SUN Press, pp. 81-90.

**(4) Distress protocol**

 A ‘distress protocol’ is a procedure to follow in emergency situations where, for example, a participant becomes clearly distressed during an interview. Under such situations, the interview is terminated and the distress protocol is enacted. Researchers may need to consider:

1. The possible distress experienced by the participant: e.g. questions that address issues of abuse, abandonment, previous negative sexual experiences, or traumatic memories that may induce distress. A distress protocol must include the name and contact details of an appropriate provider who can provide support, at no cost to the participant. This may include counselling services or access to legal services; specific contact details of such services must be included.

2. The possible distress experienced by the researcher: this may include provisions for how the safety of the researcher will be supported, and should be discussed with supervisor and the name and contact details for counselling services provided if needed.