HREC (Non-Medical) Risk level categories definitions and study monitoring framework (June 2024)

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. Please note that any study involving minors cannot be considered by Schools irrespective of the risk level. The right hand column indicates the level of monitoring of any study granted ethics clearance.

Risk category	**Definition**	**Examples**	**Notes**	**Monitoring required**
No risk	No contact with human participants	• Document analysis or literature review • Studies based on theoretical or secondary analysis alone • Use of non-human, quantitative datasets (e.g. economic data)	These studies do not require full ethics clearance but an ethics waiver form must be completed if required by a university, faculty or external body.	Not required. Any amendments to the ethics application need to be reported, please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance. If any ethical issues arise during the research process, these also need to be reported, please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance.
		• Use of previously-collected human datasets (where previous participants gave their consent for their data to be reused – please check this against the original consent forms; and where a permission letter from the P.I. of the previous study has been obtained) • Use of anonymized and aggregated human datasets (e.g. census data)	These studies may require full ethics clearance, dependent on the type of study and faculty requirements. If full clearance is not needed, an ethics waiver form should be completed, if required by a university, faculty or external body. Applications deemed No Risk can be considered at School level.	Not required. Any amendments to the ethics application need to be reported, please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance. If any ethical issues arise during the research process, these also need to be reported, please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance.
Minimal risk	Where the likelihood and magnitude of possible harm are no greater than those imposed by daily life in a stable society, or routine educational or psychological tests	• Questions about people's everyday lives, activities and opinions rather than detailed biographical information • No sensitive questions or topics • Review of privileged information (e.g. documentation not publicly available) • Use of posts from social media	Applications deemed Minimal Risk can be considered at School level.	Annual report due by 31 December. Any amendments to the ethics application need to be reported, please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance. If any ethical issues arise during the research process and outside of the reporting time, these also need to be reported, please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance.
Low risk	Where the only foreseeable risks is that of discomfort, or where there may be some sensitivity	• Questions about people's everyday lives, activities and opinions – may include biographical information and	Applications deemed Low Risk can be considered at School level.	Annual report due by 31 December. Any amendments to the ethics application need to be reported, please contact Shaun Schoeman shaun.schoeman@wits.ac.za in

	involved in terms of the questions asked	some potentially sensitive questions and/or topics • May include some vulnerable participants and / or contexts • Use of posts from social media		the first instance. If any ethical issues arise during the research process and outside of the reporting time, these also need to be reported, please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance.
Medium risk	Where there is a likely 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 distress • May include vulnerable categories or marginalized groups, may include some types of low-level illegal activities, such as artisanal mining • Research locality itself may contain potential risks to the participants and/or researcher • There is a clear justification to undertake the research using this participant group and/or using the proposed instruments, despite the potential risks • Use of posts from social media	Applications deemed Medium Risk cannot be considered at School level and must be referred to the main committee. Support/counselling services must be provided for participants, if appropriate. A distress protocol should be given, if appropriate.	Annual report due twice yearly on 30 June **and** 31 December. If the report indicates ethical challenges, the HREC Chair may request a meeting with the applicant (and supervisor) to discuss. Any amendments to the ethics application need to be reported, please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance. If any ethical issues arise during the research process and outside of the reporting time, these also need to be reported, please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance.
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	• Highly sensitive topics, e.g. experiences of violence, rape, illegal activities • Vulnerable or marginalized groups, or where multiple vulnerabilities exist • Research involving deception of the participants • Research involving serious illegal and criminalized activities, such as violence, fraud • Where the participants place themselves at risk of harm if they participate • Where the researcher may place themselves at risk of harm • Where the researcher may place themselves at risk of breaking the law	Applications deemed High Risk cannot be considered at School level and must be referred to the main committee. Remedial interventions by external professionals can be taken should harm occur. Support/counselling services must be provided for participants and/or for the researcher. A distress protocol and debriefing strategy should be given, if appropriate	Annual report due twice yearly on 30 June **and** 31 December. If the report indicates ethical challenges, the HREC Chair may request a meeting with the applicant (and supervisor) to discuss. Any amendments to the ethics application need to be reported, please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance. If any ethical issues arise during the research process and outside of the reporting time, these also need to be reported, please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance.

		• Where the research may reveal information that may place the participant or others at risk (e.g. victims of abuse, violence), requiring intervention from government, university or other institutions • There is a clear justification to undertake the research using this participant group and/or using the proposed instruments, despite the potential risks		

NOTES:

(1) Definitions of terms

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

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.

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.

(2) Discussion of risk

Individuals that 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; an inability to protect one's interests in research. Vulnerability may be considered as dynamic and specific to a particular context, and may 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;

• 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 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, 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.

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 NGOs/law clinics;

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.

3. Guidelines on how to draw up a distress protocol are given on the ethics website.