HREC (Non-Medical) Risk level categories definitions and research study monitoring framework (June 2026)

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 legal minors (where participants are below the legal age of 18) cannot be considered by School HREC:NM Sub-Committees irrespective of the risk level. The right-hand column of this table indicates the level of monitoring of any study granted ethics clearance or waiver, and the procedures for amendments.

Risk category	**Definition**	**Examples**	**Notes**	**Monitoring required**
No Risk	No contact with human participants	• **Conceptual Work:** Purely theoretical or philosophical studies without any primary data collection. • **Literature-Based Reviews:** Secondary research focused solely on the analysis of published academic literature. • **Non-Biological Experimental Work:** Technical or laboratory experiments that do not involve humans, animals, biological tissues or remains outside of archaeological or palaeontological contexts, and that do not pose a risk to researchers when they follow correct laboratory safety procedures. • **Geospatial Data Analysis:** Geographic Information System or Remote Sensing-based work that does not involve human participants or animal subjects. • Use of **non-human, publicly available quantitative datasets** (e.g. economic data). Please note, permission letters from organisations may be required if these data are not in the public domain.	These studies are exempt and do not require an ethics waiver unless this is required by a university, faculty or external body. Disciplines and Faculties may also decide that students should undergo full ethical clearance for these studies that would otherwise be waivered.	**Monitoring is not required** for ethics waivers. The exceptions to this are (1) where Schools/Departments wish to do so, or (2) where it may be required by external professional bodies. For **amendments** to an ethics waiver: (1) If the waiver was submitted by a student on a taught programme, the amendment can be considered by the School HREC:NM Sub-Committee that handled the original application. (2) If the waiver was submitted to the University HREC:NM, the amendment application needs to be considered by that committee. If any ethical issues arise during the waivered research study, these need to be reported. Please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance.

		• Use of previously collected human datasets and where previous participants gave their consent for their data to be reused. Researchers need to check against the original consent forms. A permission letter from the P.I. of the previous study will also have to be been obtained, granting the researcher access to this secondary data. • Use of anonymized and aggregated human datasets (e.g. census data)	These studies may require full ethics clearance depending on the type of study and faculty requirements. If full clearance is not needed, an ethics waiver should be obtained, if required by a university, faculty or external body. Applications deemed No Risk submitted by students on taught programmes can be considered by School HREC:NM Sub-Committees.	**Monitoring is not required** for ethics waivers. The exceptions to this are (1) where Schools/Departments wish to do so, or (2) where it may be required by external professional bodies. For **amendments** to an ethics waiver: (1) If the waiver was submitted by a student on a taught programme, the amendment can be considered by the School HREC:NM Sub-Committee that handled the original application. (2) If the waiver was submitted to the University HREC:NM, the amendment application needs to be considered by that committee. If any ethical issues arise during the waivered research study, these need to be reported. Please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance.
Minimal Risk	Contact with human participants and/or their data, 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 that do not include sensitive topics	These studies will require full ethics clearance. Applications deemed Minimal Risk submitted by students on taught programmes can be considered by School HREC:NM Sub-Committees.	Where **monitoring is required** for applications deemed Minimal Risk: (1) For applications deemed Minimal Risk that have been granted ethics clearance by the University HREC:NM. This is done by researchers completing and submitting an Annual Report (due by 31 December of each calendar year of the project). Where **monitoring is not required** for applications deemed Minimal Risk: (2) For applications deemed Minimal Risk that have been granted ethics clearance by a School HREC:NM Sub-Committee. This is because these are limited-duration programmes. For **amendments** to applications deemed Minimal Risk: (1) If the application was submitted by a student on a taught programme, the amendment can be considered by the School HREC:NM Sub-Committee that handled the original application. (2) If the application was submitted to the University HREC:NM, the amendment application

				needs to be considered by that committee. If any ethical issues arise during the research for any study deemed Minimal Risk, these need to be reported. Please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance.
Low Risk	Contact with human participants and/or their data, where the only foreseeable risk 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 some potentially sensitive questions and/or topics • May include some vulnerable participants and/or contexts • Use of posts from social media covering sensitive topics and/or involving specific or vulnerable participants, depending on context	These studies will require full ethics clearance. Applications deemed Low Risk submitted by students on taught programmes can be considered by School HREC:NM Sub-Committees.	Where **monitoring is required** for applications deemed Low Risk: (1) For applications deemed Low Risk that have been granted ethics clearance by the University HREC:NM, researchers must complete and submit an Annual Report (due by 31 December of each calendar year of the project). Where **monitoring is not required** for applications deemed Low Risk: (2) For applications deemed Low Risk that have been granted ethics clearance by a School HREC:NM Sub-Committee. This is because these are limited-duration programmes. For **amendments** to applications deemed Low Risk: (1) If the application was submitted by a student on a taught programme, the amendment can be considered by the School HREC:NM Sub-Committee that handled the original application. (2) If the application was submitted to the University HREC:NM, the amendment application needs to be considered by that committee. If any ethical issues arise during the research for any study deemed Low Risk, these need to be reported. Please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance.
Medium Risk	Contact with human participants and/or their data, where there is a likely risk of some harm for	• 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 common but illegal activities, such as artisanal	These studies will require full ethics clearance. Applications deemed Medium Risk cannot be considered at School level and must be referred to the main University HREC: NM committee.	**Monitoring is required** for applications deemed Medium Risk that have been granted ethics clearance by the University HREC:NM. This is done by researchers completing and submitting an Annual Report due twice yearly on 30 June **and** 31 December in each calendar year of the project. If the report indicates any ethical challenges, the

	participants and/or the researcher, but where appropriate steps can be taken to mitigate or reduce risk.	mining • The research locality itself may contain potential risks to the participants and/or researcher • Use of posts from social media covering sensitive topics and/or involving specific or vulnerable participants	Support/counselling services must be provided for participants, if appropriate. A distress protocol should be given, if appropriate. There must be clear justification in the ethics application to undertake the research using this participant group and/or using the proposed instruments, despite the potential risks.	HREC:NM Chair may request a meeting with the applicant (and supervisor) to discuss. For **amendments** to applications deemed Medium Risk: The amendment application needs to be considered by the University HREC:NM. If any ethical issues arise during the research for any study deemed Medium Risk, these need to be reported immediately. Please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance.
High Risk	Contact with human participants and/or their data, where there is a real and foreseeable risk of harm which may lead to serious adverse consequences for participants and/or the researcher and/or for other individuals or communities if not managed in a responsible manner.	• Highly sensitive topics, e.g. experiences of violence, rape, dangerous illegal activities • Highly 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 as a result of exposure to emerging research data or during data collection • Where the researcher may place themselves at risk of breaking the law	These studies will require full ethics clearance. Applications deemed High Risk cannot be considered at School level and must be referred to the main University HREC: NM committee. Research may only proceed if appropriate resources for support/counselling services can be provided for all participants and/or for the researcher. A distress protocol and debriefing strategy should be provided. There must be clear justification in the ethics application to undertake the research using this participant group and/or the proposed instruments, combined with appropriate steps to mitigate or reduce that risk.	**Monitoring is required** for applications deemed High Risk that have been granted ethics clearance by the University HREC:NM. This is done by researchers completing and submitting an Annual Report due twice yearly on 30 June and 31 December in each calendar year of the project. If the report indicates any ethical challenges, the HREC:NM Chair may request a meeting with the applicant (and supervisor) to discuss. For **amendments** to applications deemed High Risk: The amendment application needs to be considered by the University HREC:NM. If any ethical issues arise during the research for any study deemed High Risk, these need to be reported immediately. Please contact Shaun Schoeman shaun.schoeman@wits.ac.za in the first instance.

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.

Relational vulnerability means that vulnerability is not a fixed trait inside a person, but rather a state created by their relationships with others or their environment.

Multi-directional vulnerability means that vulnerability during a study flows in multiple directions and can affect everyone involved, not just the participants.

Research-induced vulnerability refers to any additional risk, distress, or exposure to harm that is generated directly by the research process, methodology, or the behaviour of the researcher, rather than pre-existing participant characteristics.

(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.
- Those whose structural or socioeconomic conditions make them susceptible to exploitation due to power imbalances inherent in the research setting.

(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.

Furthermore, ethical assessments must account for **multi-directional vulnerability**. This includes evaluating the potential for secondary trauma, emotional distress, or institutional pressures faced by the researchers themselves, which can indirectly impact participant safety. It must also account for **research-induced vulnerability**.

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 (with hyperlinks):

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. https://doi.org/10.1186/s12961-016-0164-6

Grigis, A., Beretta, G., Borry, P. and Sanchini, V. 2025. Vulnerability in research ethics: A systematic review of policy guidelines and documents. *PLoS One*, 20(7), e0327086. https://doi.org/10.1371/journal.pone.0327086

Grzymała-Moszczyńska, H., Seddighi, G. and Vidūnaitė, M. 2025. Contextual vulnerability of the researcher: reflections on methodology. *International Journal of Qualitative Methods*, 24, 16094069251343139. https://doi.org/10.1177/16094069251343139

Luna, F. 2019. Identifying and evaluating layers of vulnerability – a way forward. *Developing World Bioethics*, 19, 86–95. https://doi.org/10.1111/dewb.12206

Pieper, I.J. and Thomson, C.J.H. 2020. Vulnerability in human research. *Monash Bioethics Review*, 38, 68–82. https://doi.org/10.1007/s40592-020-00110-4

Ratnam, C. and Drozdzewski, D. 2022. Research ethics with vulnerable groups: ethics in practice and procedure. *Gender, Place & Culture*, 29, 1009-1030. https://doi.org/10.1080/0966369X.2021.1994932

Traianou, A. and Hammersley, M. 2024. Interrogating the concept of vulnerability in social research ethics. *Diametros*, 80, 7–22. https://doi.org/10.33392/diam.1891

Victor, E., Luna, F., Guidry-Grimes, L. and Reiheld, A. 2022. Vulnerability in practice: Peeling back the layers, avoiding triggers, and preventing cascading effects. *Bioethics*, 36, 587–596. https://doi.org/10.1111/bioe.13023

(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.

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

Useful reference (with hyperlink):

Whitney, C. and Evered, J.A. 2022. The Qualitative Research Distress Protocol: A Participant-Centered Tool for Navigating Distress During Data Collection. *International Journal of Qualitative Methods*, 21, 1–9. https://doi.org/10.1177/16094069221110317