University of the Witwatersrand, Johannesburg

Ethics WAIVER Application Form for *Human Research Ethics Committee (HREC Non-Medical)* (SCHOOL ETHICS COMMITTEES: Revised November 2023)

Instructions

1. This form must be completed by Honours (4th year) and Masters by Coursework and Research Report students who are applying for a WAIVERED ethics clearance. Note that waivers for staff non-degree applications, PhD and research Masters students must complete the online ethics application form.
2. Completed waiver applications must be submitted to the relevant School Ethics Committee.
3. Applications may be submitted as hard or soft (electronic) copies, but the first page of the application must contain the signatures of the student and supervisor. Final revised versions must be in soft (electronic) copy as all documentation will be archived.
4. Incomplete or handwritten applications will **NOT** be considered, including where signatures are missing.

Please ensure that you have included all the relevant documents in your Ethics Application:

- Completed ***Ethics Application Form***.
- Copy of the ***Research Proposal***.

Please complete the signature page below to indicate that you agree with the conditions of application:

SIGNATURES (REQUIRED)

Declaration: We, the signatories, declare that all information on this form is correct and that we will strive to maintain the highest ethical standards in this research at all times, according to disciplinary and university expectations, recognising that ethical practice in research is always a continuing process.

I as the Principal Investigator have prepared this application. I recognise that it is my responsibility to conduct my research in an ethical manner according to Guidelines of the University of the Witwatersrand, according to any laws and/or legal frameworks that may apply, and according to the norms and expectations of my discipline. In preparing this Application for Ethics Clearance form, I have consulted the Guidelines for Human Research Ethics Clearance Application/Non-Medical (available on this website https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/) and have familiarised myself with the ethical guidelines specific to my discipline.	☐ Yes	☐ No

By signing this form, the researcher and supervisor of this project undertake to ensure that any revisions to this application that are required by the Human Research Ethics Committee (Non-Medical) and School Ethics Committees are made and approved before the project commences.

	Date	Name	Signature*
Student			
Supervisor			

*electronic signatures are permitted

1. Summary of risk categories of this research project		
1.1 Does this project involve human participants? *If YES, you need to apply for full ethics clearance through the relevant committee*	☐ Yes	☐ No
1.2 I have read and understood the risk categories table *Applicants must have read the table of risk level category definitions on the final page of this document. This table is also available on the University Ethics Committee webpage.*	☐ Yes	☐ No

1.3 The applicant must tick the box for the risk category that best applies to this project:

Risk category	Tick the appropriate box
No risk	
Minimal risk	
Low risk	
Medium risk	
High risk	

Only *No Risk* studies can be considered for a waiver

Studies falling in all other risk categories must complete ethics form and be referred to the School committee

1.4 I confirm that I understand that if my research changes to include human participants, or secondary analysis of data collected from human participants, or a different risk category other than 'no risk', it is my responsibility to immediately apply for full ethics clearance from the relevant committee ☐ Yes ☐ No

2. Researcher's personal data

Your family name:	Your first name:
Title: ☐ Mr ☐ Ms ☐ Other : _____	
School:	
Your student number:	
Your email:	
Your tel number:	
Name of supervisor(s):	
Your supervisor's Wits email:	
Your supervisor's Wits tel number:	

3. Research project

3.1 Title of research project:

3.2 Is this research for degree purposes? ☐ Yes ☐ No

3.3 If YES, for what degree?

☐ Honours ☐ Masters (research report) ☐ Other (specify) _____

3.4 Has the proposal been **approved** by the relevant School or Faculty higher degrees committee or other unit?

☐ Yes ☐ No ☐ Submitted and pending

3.5 What are the **aims and objectives** of the research? (Please be specific)

3.6 Summary or abstract of the research (100 words maximum)

Give a brief outline of the research plan such that reviewers can understand what the study is about, what data you will use (and is this in the public domain), how you will collect or get access to the data, and what analyses will be used.

3.7 Will this study reuse data that have been previously collected by other researchers? ☐ Yes ☐ No

If **YES**, did the previous participants agree on the *Consent Form* to have their data reused? *Please check the original Consent Form* ☐ Yes ☐ No

AND

If **YES**, do you have written permission to reuse the data? ☐ Yes ☐ No

If you don't, you must obtain this permission from the principal investigator

3.8 Will this study use anonymised data that is publically available?	☐ Yes	☐ No
3.9 Will this study use anonymised data that is not publically available but which comes from a specific organisation? *If YES, please supply Permission Letter from the organisation concerned granting you access to this data*	☐ Yes	☐ No
3.10 Will this study use data generated by Artificial Intelligence (AI)?	☐ Yes	☐ No
3.11 Is this application for a multi-student project (i.e. several students working on exactly the same topic under the same supervisor)? If **YES**, list the names and student numbers of additional students working on this project:	☐ Yes	☐ No

HREC (Non-Medical) Risk level categories definitions (November 2023)

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.

Risk category	Definition	Examples	Notes
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 <u>do not</u> require full ethics clearance but an ethics waiver form must be completed if required by a university, faculty or external body.
		• 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 <u>may require</u> 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.
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.
Low risk	Where the only foreseeable risks is that of discomfort, or where there may be some sensitivity involved in terms of the questions asked	• 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	Applications deemed Low Risk can be considered at School level.
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 • 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.

		• There is a clear justification to undertake the research using this participant group and/or using the proposed instruments, despite the potential risks	
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 • 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	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

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.