

ETHICS REVIEW CHECKLIST

Instructions for completion:

- Select the section applicable to you and complete the appropriate checklist.
- If you have **any yes answers** in your applicable section, you will have to apply for ethical approval.
- Should you have **only no answers**, it means you do not require ethical approval. This will be confirmed by the scientific/proposal committee reviewing your proposal.
- Attach the completed and signed list with your application to the scientific/proposal committee.

INTRODUCTION

This checklist is for the use of researchers in the Faculty of Health Sciences or other Faculties making use of either the Health Research Ethics Committee (HREC) or the Ethics Committee on Animal Care, Health and Safety in Research (AnimCare).

It also guides researchers not doing health related research but doing research with vulnerable participants or that are medium and high risk level studies.

Research with **human participants** *can never have a “no risk level”* and if it is *health or health related research*, it will *always require ethics approval from a National Health Research Ethics Council (NHREC) registered research ethics committee (REC) for research studies of both academics and students.*

The World Health organisation defines **health** “*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*”.

In this context **research** refers to “*a range of activities conducted by many disciplines that may use different methodologies and explanatory frameworks to extend knowledge through disciplines or systematic investigation*” (Ethics in Health Research: Principles, Processes and Structures. Second edition. Department of Health, 2015) Further referred to as DoH, 2015.

Health research is defined as “*research that contribute to biological, clinical, psychological or social welfare matters, including processes as regards humans; causes and effects of and responses to disease; effects of the environment; health care systems; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health and health care*” (DoH, 2015:7 1.1.3).

Health related research refers to any research conducted by disciplines other than health disciplines about topics or participants within the field of health or investigating or striving to improve the bio-psycho-social wellbeing of human participants.

Note: Although data or biological material are separate from their source, within the South African context they *symbolise that person* and should be handled with the necessary respect and consent.

A researcher in the Faculty of Health Sciences making use of **human participants** *can only make use of a NHREC-registered REC (HREC) specifically focussed on health research.*

A researcher in the Faculty of Health Sciences making use of **animals** *can only make use of a NHREC-registered REC (AnimCare) specifically focussed on health research with animals.*

Research in the Faculty of Health Sciences with a **possible negative environmental impact or posing a risk to the name of the North-West University** also needs ethical approval (e.g. using endangered plant species, controversial matters).

SECTION A: FOR RESEARCHERS IN THE FACULTY OF HEALTH SCIENCES

1. Research making use of human participants

All research with human participants (or their data or biological material) require ethics review (*all minimal to high risk level studies*).

The exceptions however that do not require ethical clearance are:

- Research that relies exclusively on publicly available information or that is accessible through legislation or regulation. This does not mean that ethical considerations are irrelevant to the research.
- Research involving observation of people in public spaces and natural environments, provided:
 - the researcher does not interact directly with individual groups;
 - the researcher does not stage any intervention;
 - the individuals or groups do not have a reasonable expectation of privacy;
 - dissemination of research findings does not identify any individual or groups.
- Quality assurance and quality improvement studies, programme evaluation activities and performance reviews *not intended for publication*.

Note: Should *publication be envisaged* for the above mentioned research and ethics approval may be requested (e.g. required by sponsor or journal), prospective ethics approval should be obtained before the research activity, because RECs may not and cannot grant retrospective ethics approval.

2. Research making use of animal research

All academics and students doing research that uses animals, biological samples of animals or previously collected data of animals for research should obtain ethical approval.

The exception however, that do not require ethical clearance but only notification to AnimCare is:

- Research on lower invertebrate animals.
- Observation studies that do not involve any direct interaction with animals or have any adverse environmental impacts.

3. Other scenarios not using human or animals for research purposes that might require ethics approval

- Systematic reviews that have a direct impact on human intervention studies.
- Laboratory work with dangerous chemicals placing the researcher/s and/or others at risk.

- Laboratory analysis involving genetic modification.
- Laboratory work using bacterial and/or infectious materials placing the researcher/s and/or others at risk.
- Risk to the researcher due to the research site etc.
- Studies with potential harm to the environment (adverse impacts).

Checklist to be used by researchers in the Faculty of Health Sciences:

Items	Yes	No
Does the study involve human participants?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study use previously collected data or biological samples of human participants?	<input type="checkbox"/>	<input type="checkbox"/>
Is the study a systematic review that has a direct impact on health interventions with humans?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve animals?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve previously collected data or biological samples of animals?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve the development of a new skill in animal techniques or preparation of an animal model?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study have a potential risk for a negative environmental impact?	<input type="checkbox"/>	<input type="checkbox"/>
Does the journal to which the publication is to be sent, require an ethics approval number?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study pose a risk to the researcher?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study pose a risk to the name of the NWU?	<input type="checkbox"/>	<input type="checkbox"/>

Note: If the answer is "Yes" to any of the above, ethics review is required.

SECTION B: FOR RESEARCHERS FROM OTHER FACULTIES MAKING USE OF HREC OR ANIMCARE

Research with **human participants** can never have a “no risk level” and will always require ethics approval from a REC for research studies of both academics and students.

Research conducted in *other Faculties than the Faculty of Health Sciences* that does **health related research** with **human participants** whether *minimal, medium or high risk level* research, require ethics approval from a NHREC-registered REC (HREC) that focuses on health research.

Note: **Health related research** refers to any research conducted by disciplines other than health disciplines about topics or participants within the field of health or investigating or striving to improve the bio-psycho-social wellbeing of human participants.

All research making use of **animals** for research has to obtain ethical approval from a NHREC-registered animal research ethics committee (AnimCare) when using animals for research (e.g. laboratory animals, farm animals, pets or wild animal).

Checklist to be used by researchers in other Faculties than the Faculty of Health Sciences doing health related research:

Items	Yes	No
Is the research health related?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve animals?	<input type="checkbox"/>	<input type="checkbox"/>
If the answer is yes to any of the first two questions, please continue:		
Does the study involve human participants e.g. Theology, Educational Sciences?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study use previously collected data or biological samples of human participants e.g. Natural Sciences?	<input type="checkbox"/>	<input type="checkbox"/>
Is the study a systematic review that has a direct impact on health related interventions with humans?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve previously collected data or biological samples of animals e.g. Natural Sciences?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve the development of a new skill in animal techniques or preparation of an animal model?	<input type="checkbox"/>	<input type="checkbox"/>
Does the journal to which the publication is to be sent, require an ethics approval number?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study pose a risk to the researcher?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study pose a risk to the name of the NWU?	<input type="checkbox"/>	<input type="checkbox"/>

NOTE: See guidance for more detail under section 1.1 to 1.3 (health research).

If the answer is “Yes” to any of the above, ethics review by the HREC/AnimCare is required.

SECTION C: FOR RESEARCHERS IN OTHER FACULTIES DOING RESEARCH WITH VULNERABLE GROUPS AND WHERE THE RISK LEVELS ARE ABOVE MINIMAL RISK BUT IS NOT HEALTH RELATED RESEARCH

Research with **human participants** can never have a “no risk level” and will always require ethics approval from a REC for research studies of both academics and students.

The NHREC registered REC, **Education, Management, Humanities and Social Sciences Research Ethics Committee (EMHS-REC)**, reviews all research with human participants that:

- Is *not health related* research and;
- Includes *vulnerable* participants (e.g. children, staff members, students, elders, prisoners, mentally disabled people, participants from low socioeconomic groups, people in dependant/power relationships) or;
- has a *medium* or *high* risk level (see section D for risk levels above minimal risk level research).

Checklist to be used by researchers in other Faculties that are required to make use of the EMHS-REC:

Items	Yes	No
Does the study involve vulnerable human participants?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve specifically children even if only observing them?	<input type="checkbox"/>	<input type="checkbox"/>
Is the study risk level greater than minimal risk (medium or high risk level) in the case of adults, as determined by the scientific/proposal and/or faculty ethics committee?	<input type="checkbox"/>	<input type="checkbox"/>
The study does not involve specifically <i>health related</i> research? (Note: If it does involve health related research it has to go through the HREC)	<input type="checkbox"/>	<input type="checkbox"/>

Note: If the answer is “Yes” to any of the above, ethics review by the EMHS-REC is required.

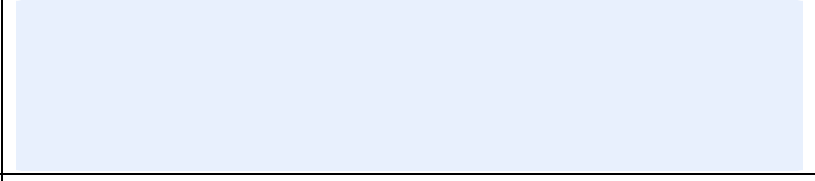
SECTION D: Checklist for risk levels above minimal risk level research

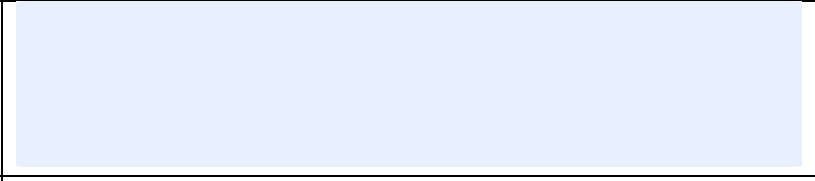
The following checklist helps you to assess whether your research is above a minimal risk level

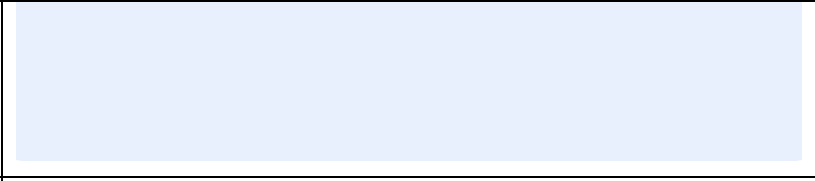
Items	Yes	No
Does the study involve vulnerable human participants where there is a diminished ability to fully safeguard their own interests in the context of the research to be conducted e.g. staff members, students, patients, aged, prisoners, mentally disabled people, participants from low socioeconomic groups, people in dependant/power relationships, ethnic and religious minorities?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve specifically children even if only observing them?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve participants in interviews with sensitive questions e.g. related to personal information, personal socio-economic information, sexual preference or activity, drug use, crime, violence etc.?	<input type="checkbox"/>	<input type="checkbox"/>
Is the research topic considered as sensitive e.g. personal in nature like finances, sexuality, illness or confidential topics etc.?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve participants in focus groups with sensitive questions e.g. related to personal information, personal socio-economic information, sexual preference or activity, drug use, crime, violence, religious activities or choices etc.?	<input type="checkbox"/>	<input type="checkbox"/>
Is there the possibility of a loss of privacy and/or confidentiality e.g. collect information with personal identifiers (names, student numbers, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve a psychological, physical, educational or socio-economic intervention?	<input type="checkbox"/>	<input type="checkbox"/>
Will the study involve potentially harmful activities e.g. sharing confidential information, biological sample collection, involved in focus groups on sensitive topics, severe physical exercises etc. ?	<input type="checkbox"/>	<input type="checkbox"/>
Will the participants be misled/deceived in any way?	<input type="checkbox"/>	<input type="checkbox"/>
Will any personal data of a human participant be used?	<input type="checkbox"/>	<input type="checkbox"/>
Could the study induce more than negligible stress or emotional reactions (e.g. trauma, embarrassment, stigma, devaluation of values and beliefs) beyond those encountered in everyday life?	<input type="checkbox"/>	<input type="checkbox"/>
Could the wider community be linked to the research and suffer harm e.g. community stigma, stigmatization due to religious choices?	<input type="checkbox"/>	<input type="checkbox"/>
Is there the possibility that the research may cause varying degrees of harm to any participant?	<input type="checkbox"/>	<input type="checkbox"/>
Does the risk of harm include several identified risks (e.g. physical, psychological, educational, social, legal, socio-economic, dignitary or community)?	<input type="checkbox"/>	<input type="checkbox"/>
Are there no precautionary measures available for some of the identified risks of harm?	<input type="checkbox"/>	<input type="checkbox"/>

Does the study have the possibility of adverse or serious adverse events (e.g. undesirable or unintended responses or occurrences from a research participant during research that is related or not related to the research), occurring during the research study?	<input type="checkbox"/>	<input type="checkbox"/>
Are there any conflicts of interest e.g. a researcher's individual interests or responsibilities have the potential to influence the carrying out of his or her role or professional obligations during the research?	<input type="checkbox"/>	<input type="checkbox"/>
Does the research investigate illegal activities e.g. involving participants who are illegal immigrants or engaged in illegal activities, studying the practice of religious leaders that demand members to drink dangerous substances or conduct dangerous actions?	<input type="checkbox"/>	<input type="checkbox"/>
Will the researcher (or research team) be placed at a real risk of harm (e.g. dangerous site, breaking the law by carrying out certain activities like research investigating gang activities and the possession of illegal firearms)?	<input type="checkbox"/>	<input type="checkbox"/>
Is there a possibility that the research may reveal information that requires mandatory action on the part of the researcher or the university that could place the participant or others at risk, e.g. research involving child victims of physical or sexual abuse, victims of domestic violence, etc.?	<input type="checkbox"/>	<input type="checkbox"/>
Is there a risk to the name of the NWU?	<input type="checkbox"/>	<input type="checkbox"/>
Is there a potential risk to the environment?	<input type="checkbox"/>	<input type="checkbox"/>
Aspects specifically related to Health Research:		
Does the research involve the collection of biological material other than human blood through a needle prick e.g. venepuncture, sputum or urine samples?	<input type="checkbox"/>	<input type="checkbox"/>
Does the research include commercially available cell line research where cells are infected or undergo genetic modification?	<input type="checkbox"/>	<input type="checkbox"/>
Is patient information in existing health systems used for research purposes?	<input type="checkbox"/>	<input type="checkbox"/>
Is laboratory test of patients in existing health systems used for research purposes?	<input type="checkbox"/>	<input type="checkbox"/>
Is it pharmaceutical drug research?	<input type="checkbox"/>	<input type="checkbox"/>
Are human biological samples collected through invasive techniques e.g. surgery?	<input type="checkbox"/>	<input type="checkbox"/>

Note: If the answer is "Yes" to any of the above, the risk level is above minimal risk.

Researcher/Student	
Name and surname	Click here to enter text.
Signature	
Date	Click here to enter a date.

Supervisor	
Name and surname	Click here to enter text.
Signature	
Date	Click here to enter a date.

Chairperson of the Scientific/Proposal committee	
Name and surname	Click here to enter text.
Signature	
Date	Click here to enter a date.

Developed by: Prof Minrie Greeff
 Head of the Faculty of Health Sciences Ethics Office
 7 April 2017

Original details: (23239522) G:\My Drive\9. Research and Postgraduate Education\9.1.5.6 Forms\HREC\9.1.5.6_Ethics_Review_Checklist_June2018.docm
 26 June 2018

File reference: 9.1.5.6