

CHECKLIST TO GUIDE RESEARCHERS AND SCIENTIFIC COMMITTEES ON RECOMMENDATIONS FOR FULL ETHICS REVIEW

Instructions for completion:

- If you have **any yes answers** in the checklist, the study will require a full ethics review.
- Should you have **only no answers**, it means the study do not require a full ethics review. The scientific committee (SC) reviewing the proposal confirms the researchers' evaluation.
- Attach this completed and signed list with your application to the scientific/proposal committee.

Checklist for full ethics review:

Items	Yes	No
Does the study involve human participants?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study use existing data set or biological samples of human participants?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve animals?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve existing data set or biological samples of animals?	<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 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.


Checklist for medium to high risk studies


The following checklist helps you to assess whether your research is above a low risk level (Note: The list is not limited to these risks only but is intended as a guide)

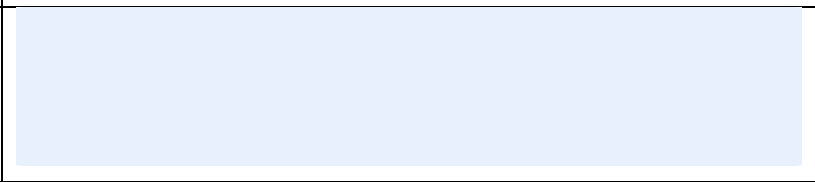
Items	Yes	No
Does the study involve vulnerable human participants where there is a diminished ability to fully safeguard their own interests in the context of the research to be conducted e.g. staff members, students, patients, aged, prisoners, mentally disabled people, participants from low socioeconomic groups, people in dependant/power relationships, ethnic and religious minorities?	<input type="checkbox"/>	<input type="checkbox"/>
Does the study involve specifically children?	<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?	<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 actions 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 could be above a low risk level.

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.

Adopted from Faculty of Health Sciences

Original details: (23239522) G:\My Drive\9. Research and Postgraduate Education\9.1.5.6 Forms\HREC\9.1.5.6_Ethics_Review_Checklist_July2019.docm
25 July 2018

File reference: 9.1.5.6