NWU-ENG-REC Reviewer feedback report[i]

Title of the study			
Ethics application no.		**Applicant's Name (Principal investigator / Supervisor)**	
Reviewer code		**Date of Review**	

1 Study information

	Element	Y / N / NA	Comments
1	Is the title appropriate to the content and aim of the research?		
2	Has the research proposal been evaluated by a scientific/research proposal committee?		

2 Study team

	Element	Y / N / NA	Comments
1	Is all relevant information and documentation included, regarding the study team?		
2	Is conflict of interest clearly stated and how it will be handled?		

3 Research including human participants (If applicable)

1	Is the selection of the study population (sample size) fair and just? • Method clear and complete • Fair distribution of burden and likelihood of benefit • No groups are deprived of an opportunity		
2	Are the inclusion and exclusion criteria clearly stated, appropriate and justified? • Rationale for the planned number reasonable • Rationale for inclusion and exclusion criteria clear and reasonable		
3	Is the process of recruitment and enrolment clear and in detail?		

4	Will the participants be appropriately reimbursement? • Time • Inconvenience • Expenses • No coercion or undue influence		
5	Is the participant's privacy and confidentiality protected? • Personal information and records protected • Identity protected		
6	Is the process of obtaining informed consent/permission clear? • Informed and voluntary • Written • Sufficient time given to consult and make an informed decision before signing • Can withdraw • Without coercion, undue influence or inappropriate incentives • Understandable and valid informed consent form • Need for translation		
7	Are all applicable permission documents included and correctly completed? ▪ Written goodwill permission ▪ Confidentiality agreements		
8	Is respect for participants clear throughout? • Dignity • Voluntary • Safety • Well-being • Interest of the participant		
9	Are the facilities where the research will be conducted appropriate and suitably resourced?		

4 Research using company data (If applicable)

	Element	Y / N / NA	Comments
1	Are all applicable permission documents included and correctly completed? ▪ Written goodwill permission ▪ Confidentiality agreements		

5 Research that will have a possible impact on the environment (If applicable)

	Element	Y / N / NA	Comments
1	Are all applicable information provided		

6 Justifiability of statistical procedure (if applicable)

	Element	Y / N / NA	Comments
1	Was a statistician included or consulted/proof of expertise? (If applicable)		

7 Risk/benefit ratio analysis

	Element	Y / N / NA	Comments
1	Has a risk-benefit ratio analyses been done? • Risks identified • Precautions mentioned • Direct and indirect benefit stated • Risk benefit ratio analyses favourable		

8 Data handling

	Element	Y / N / NA	Comments
1	Is data-collection method clearly explained and well managed? • What data is being collected? • How will data be obtained? • Why is the data being collected? • What will happen to the data? • How long will data be retained? • Will the data identify the participant? • Will it be shared with others and why?		
2	Is the process of data management and storage clear? • How will electronic data and hard copies be stored? • How will audio and video data be stored? • Who will store the data? • Who will have access? • How will the data be protected?		

	• For how long will data be stored? • How will it finally be disposed of?		

9 Dissemination of study results

	Element	Y / N / NA	Comments
1	Is it clear how results will be disseminated? • How will participants be informed? • Will it be done in an ethical manner?		

10 Additional notes/comments/recommendations

Additional notes/comments/recommendations

Recommendation of ethics risk level (A risk can be seen as "the probability of harm occurring as a result of participation in research" or "an unexpected negative consequence of unethical actions".)	
No risk: There is no possible risk that the research may lead to any undesirable effects or unexpected negative consequences as no participants are directly involved.	
Minimal, low or negligible risk: The probability, magnitude or seriousness of unexpected negative consequences, harm or discomfort anticipated in the research is negligible and no greater than that of ordinary encounter in daily life ("Daily life" as a benchmark should be that of daily experiences by the average person living in a stable society). Research in which the only foreseeable risk is one of minimal unexpected negative consequences, discomfort or inconvenience.	

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Medium Risk: Research in which there is a potential risk of unexpected negative consequences, harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Remedial interventions can be undertaken should harm occur.	
High Risk: Research in which there is a real and foreseeable risk of unexpected negative consequences, harm and discomfort, and which may lead to serious adverse consequences if not managed in a responsible manner.	

----------AND----------

The research studies should be referred to one of the following National Health Research Ethics Council (NHREC) registered committees:

NWU-EMELTEN-REC – Medium and High risk studies that involve human participants (vulnerable/non-vulnerable), but are not health-related	
NWU-HREC – Studies that are health, or health-related or involve vulnerable human participants (e.g. children, disabled people, etc.)	
NWU-HSSREC – Research conducted in Humanities and Social Sciences	
NWU-AnimCareREC – Research involving animal care, health and safety	
NWU-AnimProd-REC - Research involving animal production	

Recommendation for status of the application	
Approved	
Approved with minimal changes	
Approved with several changes	
Rejected	
Referred to another REC	

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Reviewer signature

[i] The NWU-HREC and NWU-EMELTEN-REC is acknowledged (and thanked) for the use of their templates (with the appropriate amendments applicable to the ENG-REC)