Life College of Learning

APPLICATION FOR ETHICS APPROVAL

With acknowledgement to and permission of NMMU

SECTION A: (Internal use)				
Application reference code:	.....	.....	.....	.....
	YEAR	**FACULTY**	**DEPARTMENT**	**NUMBER**
Resolution of R&S:	**Ethics approval given (for noting by the REC)** **Referred to REC for consideration**			
Resolution date:				
R&S Representative signature:				

BEFORE YOU FILL IN THIS FORM PLEASE READ THE FOLLOWING DOCUMENTS:

- "Research Ethics (Human) Application Process")
- "Code of Conduct for Researchers at NMMU"

WHO NEEDS TO FILL THIS FORM IN?

Any project in which humans are the subjects of research (hereafter called a *study*) requires completion of this form and submission for approval first to their Research and Scientific committee (R&S). The R&S will refer projects to the Research Ethics Committee (REC) where deemed necessary.

WHEN SHOULD THIS FORM BE HANDED IN?

The research proposal should first have been approved by the R&S before Ethics approval may be given. It should also have first been reviewed by the R&S for **Ethics** clearance before it is referred to the REC.

HOW TO FILL THIS FORM IN:

1) Complete Sections 1 to 8 in typescript (Tab between fields, select from pull-downs, information may be pasted from existing Word® documents), and save (filename must contain your name). Handwritten forms will not be accepted.
2) Use the "Save as" option to save the application form with a filename containing your name (e.g. "**J Smith** REC Application Form.doc").
3) Complete Sections 1 to 8 in typescript (Tab between fields, select from pull-downs, information may be pasted from existing Word® documents), and save (filename must contain your name). Handwritten forms will not be accepted.
4) Append the necessary information e.g. Research methodology, Informed consent form, Written information given to participant prior to participation, Oral information given to participant prior to participation (examples of these may be found on the Research Ethics webpage)
5) **Electronic copy:** Email all the files (including any appendices) to the R&S representative in the relevant Faculty.
6) **Hard copy, signed:** Print the document, get each page initialled on the lower right hand corner and get Sections 9 and 10 signed by the relevant parties. **Hand the signed hardcopy and attachments in** to the R&S representative in the relevant Faculty.

Please delete this instruction block before you save and print.

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1. GENERAL PARTICULARS

TITLE OF STUDY

a) Concise descriptive title of study (must contain key words that best describe the study):
Type title here

PRIMARY RESPONSIBLE PERSON (PRP)

b) Name of PRP (must be member of permanent staff. Usually the supervisor in the case of students):
Type PRP name here Type PRP office address here

c) Contact number/s of PRP: **Type PRP contact details here**

d) Affiliation of PRP: Faculty **Select Faculty Specify here, if "other"**
Department (or equivalent): **Type department name here**

PRINCIPLE INVESTIGATORS AND CO-WORKERS

e) Name and affiliation of principal investigator (PI) / researcher (may be same as PRP):
Type PI name here Gender: **Select gender**

f) Name(s) and affiliation(s) of all co-workers (e.g. co-investigator/assistant researchers/supervisor/co-supervisor/promoter/co-promoter). If names are not yet known, state the affiliations of the groups they will be drawn from, e.g. Interns/M-students, etc. and the number of persons involved:
Type names and affiliations of all co-workers here

STUDY DETAILS

g) Scope of study: **Select an item**

h) If for degree purposes: **Select an item**

i) Funding : **Select an item**
Additional information (e.g. source of funds or how combined funding is split) **Type details here or select "Not applicable"**

j) Are there any restrictions or conditions attached to publication and/or presentation of the study results? **Select an item**

If YES, elaborate (Any restrictions or conditions contained in contracts must be made available to the Committee):
Type response here or select "Not applicable"

k) Date of commencement of data collection: **Click here select a date**
Anticipated date of completion of study: **Type duration here**

l) Objectives of the study (the major objective(s) / Grand Tour questions are to be stated briefly and clearly):
Type objectives here

m) Rationale for this study: briefly (300 words or less) describe the background to this study i.e. why are you doing this particular piece of work. A few (no more than 5) key scientific references may be included:
Type rationale here

METHODOLOGY

n) Briefly state the methodology (specifically the procedure in which human subjects will be participating) (the full protocol is to be included as *Appendix 1*):
Type summarised method here

o) State the minimum and maximum number of participants involved (Minimum number should reflect the number of participants necessary to make the study viable)
Min: **Type minimum number here** Max: **Type maximum number here**

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2. RISKS AND BENEFITS OF THIS STUDY

a) Is there any risk of harm, embarrassment or offence, however slight or temporary, to the participant, third parties or to the community at large? **Select an item**
If YES, state each risk, and for each risk state i) whether the risk is reversible, ii) whether there are alternative procedures available and iii) whether there are remedial measures available.
Type response here or select "Not applicable"

b) Has the person administering the project previous experience with the particular risk factors involved? **Select an item**
If YES, please specify: **Type response here or select "Not applicable"**

c) Are any benefits expected to accrue to the participant (e.g. improved health, mental state, financial etc.)? **Select an item**
If YES, please specify the benefits: **Type response here or select "Not applicable"**

d) Will you be using equipment of any sort? **Select an item**
If YES, please specify: **Type response here or select "Not applicable"**

e) Will any article of property, personal or cultural be collected in the course of the project? **Select an item**
If YES, please specify: **Type response here or select "Not applicable"**

3. TARGET PARTICIPANT GROUP

a) If particular characteristics of any kind are required in the target group (e.g. age, cultural derivation, background, physical characteristics, disease status etc.) please specify: **Type response here or select "Not applicable"**

b) Are participants drawn from Life College of Learning (LCL) students? **Select an item**

c) If participants are drawn from specific groups of LCL students, please specify: **Type response here or select "Not applicable"**

d) Are participants drawn from a vulnerable group? **Select an item**
If YES, please specify how these participants be managed: **Not applicable**

e) If participants are drawn from an institutional population (e.g. hospital, prison, mental institution), please specify: **Type response here or select "Not applicable"**

f) If any records will be consulted for information, please specify the source of records: **Type response here or select "Not applicable"**

g) Will each individual participant know his/her records are being consulted? **Select an item**
If YES, state how these records will be obtained: **Type response here or select "Not applicable"**

h) Are all participants over 18 years of age? **Select an item**
If NO, state justification for inclusion of minors in study: **Type response here or select "Not applicable"**

4. CONSENT OF PARTICIPANTS

a) Is consent to be given in writing? **Select an item**
If YES, include the consent form with this application [Appendix 2].
If NO, state reasons why written consent is not appropriate in this study. **Type response here**

b) Are any participant(s) subject to legal restrictions preventing them from giving effective informed consent? **Select an item**
If YES, please justify: **Type response here or select "Not applicable"**

c) Do any participant(s) operate in an institutional environment, which may cast doubt on the voluntary aspect of consent? **Select an item**

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If YES, state what special precautions will be taken to obtain a legally effective informed consent: **Type response here or select "Not applicable"**

d) Will participants receive remuneration for their participation? **Select an item**
If YES, justify and state on what basis the remuneration is calculated, and how the veracity of the information can be guaranteed. **Type response here or select "Not applicable"**

e) Which gatekeeper will be approached for initial permission to gain access to the target group? (e.g. principal, nursing manager, chairperson of school governing body) **Type response here or select "Not applicable"**

f) Do you require consent of an institutional authority for this study? (e.g. Department of Education, Department of Health) **Select an item**
If YES, specify: **Type response here or select "Not applicable"**

5. INFORMATION TO PARTICIPANTS

a) What information will be offered to the participant before he/she consents to participate? (Attach written information given as [*Appendix 3*] and any oral information given as [*Appendix 4*])

b) Who will provide this information to the participant? (Give name and role)
Type name of information provider here **Type role of information provider here**

c) Will the information provided be complete and accurate? **Select an item**
If NO, describe the nature and extent of the deception involved and explain the rationale for the necessity of this deception: **Type response here or select "Not applicable"**

6. PRIVACY, ANONYMITY AND CONFIDENTIALITY OF DATA

a) Will the participant be identified by name in your research? **Select an item**
If YES, justify: **Type response here or select "Not applicable"**

b) Are provisions made to protect participant's rights to privacy and anonymity and to preserve confidentiality with respect to data? **Select an item**
If NO, justify. If YES, specify: **Type response here or select "Not applicable"**

c) If mechanical methods of observation be are to be used (e.g. one-way mirrors, recordings, videos etc.), will participant's consent to such methods be obtained? **Select an item**
If NO, justify: **Type response here or select "Not applicable"**

d) Will data collected be stored in any way? **Select an item**
If YES, please specify: (i) By whom? (ii) How many copies? (iii) For how long? (iv) For what reasons? (v) How will participant's anonymity be protected? **Type response here or select "Not applicable"**

e) Will stored data be made available for re-use? **Select an item**
If YES, how will participant's consent be obtained for such re-usage? **Type response here or select "Not applicable"**

f) Will any part of the project be conducted on private property (including shopping centres)? **Select an item**
If YES, specify and state how consent of property owner is to be obtained: **Type response here or select "Not applicable"**

g) Are there any contractual secrecy or confidentiality constraints on this data? **Select an item**
If YES, specify: **Type response here or select "Not applicable"**

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7. FEEDBACK

a) Will feedback be given to participants? **Select an item**
If YES, specify whether feedback will be written, oral or by other means and describe how this is to be given (e.g. to each individual immediately after participation, to each participant after the entire project is completed, to all participants in a group setting, etc.): **Type response here or select "Not applicable"**

b) If you are working in a school or other institutional setting, will you be providing teachers, school authorities or equivalent a copy of your results? **Select an item**
If YES, specify, if NO, motivate: **Type response here**

8. ETHICAL AND LEGAL ASPECTS

The Declaration of Helsinki (2000) or the Belmont Report will be included in the references: **Select an item**
If NO, motivate: **Type response here or select "Not applicable"**

a) I would like the REC to take note of the following additional information:
Type response here or select "None"

9. DECLARATION

If any changes are made to the above arrangements or procedures, I will bring these to the attention of the Research Ethics Committee. I have read, understood and will comply with the *Guidelines for Ethical Conduct in Research* and have taken cognisance of the availability (on-line) of the Medical Research Council Guidelines on Ethics for Research (http://www.sahealthinfo.org/ethics/).
All participants are aware of any potential health hazards or risks associated with this study.
I SELECT AN ITEM aware of potential conflict(s) of interest which should be considered by the Committee.
If affirmative, specify: **Type response here or select "Not applicable"**

SIGNATURE: **Type name here** (Primary Responsible Person)	**10 August 2017** Date
SIGNATURE: **Type name here** (Principal Investigator/Researcher)	**10 August 2017** Date

10. SCRUTINY BY RESEARCH AND ETHICS COMMITTEE (REC)

This study has been discussed, and is supported, by the Research and Ethics Committee. This is attested to by the signature below by the chairperson of the REC or an appointed representative.

NAME and CAPACITY	SIGNATURE	Date

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11. APPENDICES

In order to expedite the processing of this application, please ensure that all the required information, as specified below, is attached to your application.

APPENDIX 1: Research methodology

Attach the full protocol and methodology to this application, as "Appendix 1" and include the data collection instrument e.g. questionnaire if applicable.

APPENDIX 2: Informed consent form

If no written consent is required, motivate at 4a). The intention is that you make sure you have covered all the aspects of informed consent as applicable to your work.

APPENDIX 3: Written information given to participant prior to participation

Attach as "Appendix 3". The intention is that you make sure you have covered all the aspects of written information to be supplied to participants, as applicable to your work.

APPENDIX 4: Oral information given to participant prior to participation

If applicable, attach the required information to your application, as "Appendix 4".

APPENDIX 5, 6, 7: Institutional permissions

Attach any institutional permissions required to carry out the research e.g. Department of Education permission for research carried out in schools.