MANCOSA HUMAN RESEARCH ETHICS COMMITTEE (M-HREC)

GUIDELINES FOR COMPLETING THE RESEARCH ETHICS APPLICATION FORM

1& 2 **To be completed by the Student/Applicant and Supervisor**

3. PROJECT DESCRIPTION

Provide a brief overview outlining the background to the study, the key questions to be addressed, the participants (or subjects) and research site, including a full description of the sample frame, the research approach/methods and data collection.

3.1 Project title

The title that has been approved by the respective review committee (Doctoral Research Committee for doctoral research proposals)

3.2 Location of the study

Where will the study be conducted.

3.3 Aim and objectives of the study

As stated in the approved proposal

3.4 The rationale or justification for the study

As stated in the approved proposal

3.5 Research questions

As stated in the approved proposal

SECTION 3.6 Clearly outline the methods to be used, using the sub-headings below:

3.6 Research approach/methods

Set out the approach/methodology within which you will work, and indicate in step-by-step point form the methods you will use in this research in order to answer the critical questions.

1. Research philosophy
2. Research approach e.g. deductive or inductive

3. Method e.g. qualitative or quantitative or mixed methods or experimental
4. Study population
5. Population size
6. Sampling frame
7. Sampling method
8. Sample size
9. Inclusion criteria
10. Exclusion criteria
11. Research instrument
12. Development of the research instrument
13. Piloting and focus group (whichever is applicable or both)
14. How data will be collected (explain in detail)
15. Statistical or data analyses

NB. Omitting any of the above could result in your application being sent back to you.

3.7 **Proposed work plan**

Set out your intended plan of work for the research, indicating important target dates necessary to meet your proposed deadline.

4. **ETHICAL ISSUES** (4.1 – 4.11)

Preventing/Minimising Stress and/or Harm

4.1 Should your project include special/vulnerable participants (such as children, persons who are intellectually or mentally impaired- the application form has other examples), indicate how the autonomy of these participants will be protected and how social stigmatization and/or secondary victimisation of participants will be prevented

4.2 & 4.3 Also indicate how potential stress/ harm will be minimized in the following instances

- if participants are required to engage in activity that might diminish their self-respect or cause them to experience shame, embarrassment, or regret;
- If participants are exposed to questions which may be experienced as stressful or upsetting, or to procedures which may have harmful side effects; or
- If stimuli, tasks or procedures are used which may be experienced as stressful, noxious or unpleasant.

4.4 State the type instrument/s that will be used

4.5 **Autonomy of participants**

Select the appropriate response to confirm how the autonomy of participants be protected through the use of an informed consent form, which specifies (in language that respondents will understand): No answers required full explanations and justification.

4.6. Specify what efforts have been made or will be made to obtain informed permission for the research from appropriate authorities and gate-keepers (including caretakers or legal guardians in the case of minor children)? If you have received gatekeeper permission, attach the letter to this application.

4.7 Explain how the research data be stored and disposed of? NB: All non-clinical data must be stored for a minimum period of five years.

4.8 Briefly explain how anonymity/ confidentiality of the participants will be protected in the subsequent dissemination of your research findings – i.e., completed thesis, oral presentations, publication etc.,?

4.9 State the source/s of funding for your research (not tuition fees)

4.10 Briefly explain the impact of the funding on the study (if there is).

4.11 Declaration of conflict of interest- if yes please provide details-

It is an ethical rule that investigators should have no undisclosed conflict of interest with their study collaborators, sponsors or participants. Conflicts can arise, for example, when a commercial or other sponsor may not wish research results detrimental to their corporate image / interest to be disclosed, especially when the investigator is being remunerated by the sponsor for the research in question; when research participants are being rewarded for their participation in the research; or when an investigator has a vested interest in, or is an employee / shareholder / director in the sponsor's corporate entity. Investigators should note that the duty to disclose a conflict of interest to the ethics review committee begins at the stage of application for ethical approval and continues until the research in question is complete and the research results are submitted to the sponsor / published (if applicable).

If the investigator(s) has / have / foresees any such conflict of interest, these details must be provided in the Research Ethics Application Form. The declaration of conflict of interest form (as applicable, i.e., member, staff, supervisor, researcher) must also be completed.

GENERAL

Informed Consent is not valid unless the participant understands the information. It is the responsibility of the investigator to ensure comprehension.

A translation into the home language of the participant must be provided. A translation of the information leaflet into the home language of the participants must be provided in addition to the English version.

The consent forms should meet four criteria - be brief (but have complete basic information); be readable (and understandable) to most people; be in a format that helps people comprehend and remember the information; serve as a script for face-to-face discussions with potential participants.

To allow the participants to obtain additional information (or to report concerns) with respect to ethical aspects of this study, the contact details of the researcher and the research supervisor must be provided on the informed consent form.

Common mistakes

- Researchers do not introduce themselves, do not write in the first person;
- Full specification of the purpose of the study / its auspices not provided; No clear description of the research procedures that are to be used is given;
- No clear statement of the time that a participant will take to complete the requirements of the study;
- No explanation to the potential participant of how or why he / she has been selected;
- No clear, 'up front' statement that participation in the study is entirely voluntary; that a choice not to participate will have no negative consequences. Should the participant choose to participate, he / she may decline to answer questions and may withdraw from the study at any time;

- If the participants are from a workplace or similar institutional setting (i.e. a higher education institution) a lack of clear reassurance that they do not risk job loss or other institutional sanctions;
- The wording of the Participant Information Letter is unnecessarily technical / sophisticated;
- The specific guarantee of confidentiality / anonymity is not provided.
- Inadequate measures to protect the identity of participants (names, addresses, student numbers, etc. should not be recorded on the research instrument together with participants' answers). A coding system must be employed.
- Anonymous return of completed questionnaires is not provided for.
- The effects of coercion are not fully allowed for (e.g. lecturers asking students that they teach, and whose work they mark, to participate in a research study).
- If the participation in a research procedure is likely to awaken feelings of past trauma, not making arrangements for a helping person to be available to counsel the participant.
- If the questionnaire is not available for submission with the application (e.g. the questionnaire will be finalised only after a pilot study has taken place, the researcher gives no indication of the type of questions that he / she is likely to use).

Please see Appendix 1 below: **Instructions Pertaining to the Creation of a Required Letter of Information and Informed Consent Form**

APPENDIX 1 – Instructions for drafting a Letter of Information and Informed Consent Form

MANCOSA HUMAN RESEARCH ETHICS COMMITTEE

LETTER OF INFORMATION

[Place on a MANCOSA letterhead]
[NB: The tone and content of this information letter must be suitably pitched so as to neither patronise nor confuse the prospective participant. Translation may be required, and in this instance, two translators must be employed, where one performs the original translation from English into the language of choice, and a second translates the translated document back into English to ensure that no meaning has been lost]

Date: INSERT
Title of the Research Study: INSERT
Principal Investigator/s/researcher/s and affiliation: e.g. John Smith, DBA student, MANCOSA
Co-Investigator/s/supervisor/s: e.g., Prof AT Thabede, School of Education, MANCOSA

Dear (INSERT name of the Participant),

- My name is (INSERT Researcher name) and I am a student/staff member (select one option or remove the / if you hold both roles) at MANCOSA. You **are being invited to consider participating in a study that involves research for the purposes of earning a higher degree and/or scientific publication**. (INSERT the Name of the Approving Person, Organisation or Intra-Organisational Department) has given permission for this invitation to be sent to you.
- **The aim and purpose of this research is to** (describe in lay terms).
- **The study is expected to consist of** (how many participants in total, how many study sites, and where**). It will involve the following procedures** (briefly describe the research design – with special emphasis on the method of data collection, as well as the site or mode of collection – will it be in-person? Will it be on the organisational premises?)
- **The duration of your participation if you choose to participate in the study, is expected to be** (INSERT the total duration, include a request for follow-up data collection should this be anticipated).
- **The study is funded by** (provide details if relevant).
- INSERT: Is there any conflict of interest for the researcher, supervisor or other co-investigators? Details must be provided. A conflict of interest would involve any relationship or funding source that may compromise the honest reporting of findings; or may result in the researcher having the ability to exercise undue influence on the recruitment of participants. Please complete the relevant conflict of interest declaration form.

A. Making the Choice to Participate:

A1 Benefits:
INSERT: How will the participants benefit from taking part in the study? How will the study benefit the wider community? What will the researcher get out of this study? (e.g. The researcher will graduate with a Doctor of Business Administration qualification).

A2 Risks or Discomforts to the Participant:

INSERT: Description of foreseeable risks or discomforts to participants if applicable e.g. disclosure of sensitive information. List what measures are being taken to limit risks.

A3 Research-related Injury or Adverse Effect:
INSERT: What will happen should there be a research-related injury or adverse effect? An adverse effect could be anxiety attack following participating in an interview for research. Will there be any compensation should an adverse effect result directly from participation in this research project? Declare that any adverse reaction will be reported to the MANCOSA Human Research Ethics Committee (M-HREC).

A4 Online/Internet-based/Social Media Research Breach resulting in Adverse Effect:
The possibility of tampering from external sources when using the Internet or social media for collecting data cannot be completely eliminated. Although efforts will be made to protect the confidentiality of your responses, there is the possibility of hacking or other security breaches during online data collection or downloading of data that may be beyond my or MANCOSA's control, though reasonable care will be taken. [INSERT: Should a data breach occur, what are the anticipated or potential adverse effects that may be borne by the research participant? List these].

B. There is No Forced Participation and Withdrawal of Consent is Possible at Any Stage:
No one will compel you to participate in this study and there will be no negative consequences for you if you decide not to participate. There will also be no adverse consequences for you should you choose to withdraw from the study at any time. [INSERT: If any adverse consequences are envisaged, these should be communicated to potential participants prior to the commencement of the study].

C. Costs of the Study and Participant Compensation (research-related costs only):
INSERT: Will the participant be expected to cover any costs towards the study? e.g. transport costs to get to the venue for interviews. How will participants be compensated for out-of-pocket expenses (e.g. taxi fare) (if applicable)? Make it clear that these are research-related costs only, and not remuneration. Moreover, there shall be no additional monies exchanged. Please include an explanation of how no undue influence shall be maintained in the compensation of costs process. Undue influence refers to a process where compensation is so large as to induce a potential participant to consent to involvement against their better judgement or interests. Participants can only be compensated per the TIE approach, in terms of **t**ime, **i**nconvenience and **e**xpenses. In most human behavioural studies in the social and business sciences, expenses are conventionally the only compensation offered.

D. Protection, Data Storage and Sharing

D1 Anonymity and Confidentiality:
INSERT: Description of the extent to which anonymity or confidentiality will be maintained and how will this be maintained. Remember that the degree of anonymity and/or confidentiality is dependent upon the research design and methods. For example, data generated from focus group studies can be anonymised after the fact, but utterances in the group context can be attributed to one participant by other focus group attendees. Moreover, online survey packages automatically pin the location of respondents, resulting in less anonymity than a hard copy completion process. Consider all personal identifiers when pledging anonymity and confidentiality measures.

D2 Storage of Data and Duration:
INSERT: Insert where the hardcopy and electronic data will be stored and for how long. Emphasis should be placed on the steps taken to limit the number of storage locales, as well as who will have access to the data. Data security measures should also be detailed. Who will have access to the data while it is in storage? Describe how and when the data will be eventually disposed of.

D3 Sharing of Data and Utilisation for Future Studies or Publications:
INSERT: Declare if the data is going to be shared with another researcher or is going to be used for future studies or publications. (Note such data must be totally and completely anonymised prior to sharing or use in future studies or publications). Ideally, the participant should be contactable and give further permission for the sharing of this data. However, if it is completely anonymised, then such contact may prove impossible. Ideally, the participants should be contacted, permission to share the data should be granted, and then full anonymisation (removing any and all identifiers) should take place.

D4 Dissemination (Sharing of Research Findings):
Each participant has the right to be informed of the findings of the study. INSERT: How will the participants be made aware of the findings of the study? Merely stating that the thesis will be available in the MANCOSA library or online is not sufficient.

E. Research Ethics Approval:
The ethical components of this study have been reviewed and approved by the MANCOSA Human Research Ethics Committee (M-HREC) (Registration Number: REC-012623-060). While the scientific veracity of this project has been assured by another committee made up of disciplinary / domain experts, the scientific rigor and value of this proposed work has also been considered by M-HREC.

F. Person to Contact in the Event of Any Concerns or Queries:
Should you have any questions relating to this study, please contact the lead researcher on: (INSERT email address and cellular phone number of the student/staff member who is conducting the study). In the case of a student research project, you may also pose questions to the Supervisor who can be reached on: (INSERT email address only). Should you have any additional concerns or questions or wish lodge a complaint regarding your involvement in the research study, please contact the Deputy Chair of the MANCOSA- Human Research Ethics Committee (M-HREC), at Dr Bronwyn Dworzanowski-Venter (Bronwyn.Venter@mancosa.co.za). You may also forward queries and complaints to the MANCOSA -Human Research Ethics Committee Administrator on: mhrecadmin@mancosa.co.za

All complaints will be treated as confidential, and you will receive feedback within 7 days.

Thank you for considering this invitation. Your help would be so appreciated.

[INSERT STUDENT NAME AND SURNAME] [INSERT SUPERVISOR NAME AND SURNAME]

[Place on a MANCOSA letterhead]
[NB: The tone and content of this informed consent form must be suitably pitched so as to neither patronise nor confuse the prospective participant. Translation may be required, and in this instance, two translators must be employed, where one performs the original translation from English into the permission to edit of choice, and a second translates the translated document back into English to ensure that no meaning has been lost]

INFORMED CONSENT FORM

I, (INSERT full name of the participant), _____hereby confirm that I:

1. have been informed by the researcher, _____(INSERT name of the researcher as listed on the Letter of Information), about the nature, conduct, benefits and risks of this study;
2. have also received, read and understood the Letter of Information regarding the study;
3. have received an explanation from the researcher regarding the contents of the Letter of Information;
4. have been encouraged to ask questions about the study and all of my questions have been answered to my satisfaction;
5. have also been informed that the results of the study, including personal details required by the study will be anonymously processed and aggregated into a study report;
6. agree that the data collected during this study can be processed in a computerised system by the researcher;
7. agree that the data may be utilised or shared with another researcher for a future study or publication provided that the data is anonymised (i.e. cannot be traced to me) and the researcher will do their best to contact me for further permission if at all possible;
8. am aware and understand that I may, at any stage, without prejudice, withdraw my consent and participation in the study;
9. understand that a summary of significant new findings developed during the course of this research which may relate to my participation will be made available to me, upon request. I will make this request in writing, via email, by contacting the MHREC administrator at mhrecadmin@mancosa.co.za;
10. understand that I shall be asked to provide consent, in writing, to MANCOSA, should any requests be made for the additional sharing of the data or the pertinent academic outputs by a third party.

Additional consent, where applicable (EXCLUDE ANY THAT ARE NOT APPLICABLE)

I hereby provide consent to:

- ***audio-record my interview / focus group discussion:***
  YES / NO / NOT APPLICABLE (please circle your response)

- ***video-record my interview / focus group discussion:***
  YES / NO / NOT APPLICABLE (please circle your response)

- ***use of my photographs or images for inclusion in the research report or thesis only***:
  YES / NO / NOT APPLICABLE (please circle your response)

- ***use of my photographs or images for inclusion in a scientific publication or conference proceeding only:***
  YES / NO / NOT APPLICABLE (please circle your response)

- ***allow the researcher to share the data (that I contributed to) with another academic/s for co-publication (scientific purposes) only if it has been anonymised:***
  YES / NO / NOT APPLICABLE (please circle your response)

I declare that my participation in this study is entirely voluntary.

_____	_____	_____
Full Name of Participant/ Legal Guardian	**Date**	**Signature / Right Thumbprint**