UNISA Research Ethics Review Committee (URERC)	
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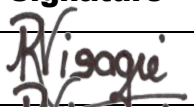
Pages	28

1. COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
Compiled by	First version compiled by Prof EL Kempen (Chairperson CAES HREC)	21/08/2018	
Revised by	Dr RG Visagie Deputy Chairperson: URERC Mrs T Coetzee Research Ethics Officer	21/09/2020	
Consulted	Dr Tladi Sebo Prof Adele da Veiga Mr Colin Pilkington Ms Eleni Flack-Davison (Compliance Manager: WITS) Prof M Labuschaigne (CLAW: Unisa; NHREC member) Research Ethics and Integrity Community of	August 2020 – July 2021	N/A

	Practice Meeting: 31 March 2021 URERC, 22 July 2021 SRIPCC, 12 August 2021		
Checked by	URERC Dr R Visagie Deputy Chairperson	19/07/2021	
Approved by URERC	URERC Prof Les Labuschagne Chairperson	22/07/2021	
Authorised by	VP: Research, Postgraduate Studies, Innovation and Commercialisation	12/08/2021	

2. DISTRIBUTION

College/department/committee	Name	Date	Signature
URERC	Dr RG Visagie	27.09.21	
Meeting: Heads of Research	Dr RG Visagie	30.09.21	 pp HM Bopape

3. HISTORY

Date	Version No.	Reason for revision
21/08/2018	1	Development of the document
July 2021	2	Revisions in response to the COVID-19 restrictions and the increased use of virtual means of data collection

4. ABBREVIATIONS/TERMS AND DEFINITIONS

Abbreviation/ term	Definition
Assent	Agreement to participate in research by a minor, someone under legal guardianship or an individual with diminished autonomy due to his/her mental state. Written assent must be obtained from children 7 years and older.

Autonomy	Person's right to make independent choices, free from undue influence from others by virtue of his/her inherent human dignity.
Electronic signatures (e-signatures)	Defined in the Electronic Communications and Transactions Act 25 of 2002[1] (ECTA) as *"data attached to, incorporated in, or logically associated with other data and which is intended by the user to serve as a signature".* It represents an electronic functional equivalent of paper-based signatures with the same legal authority if it meets legal requirements, and can include • **a typed name at the end of an email;** • **a scanned image of a handwritten signature embedded into a Word document;** • **a digital signature.** **Digital signature:** A digital signature or digital certificate is a very specific form of electronic signature that uses cryptography to establish the authenticity and validity of the signature with much greater certainty. Digital certificates are typically issued by a certificate authority (CA) which is a trusted third party. It can be created in PDF with Adobe Sign and it can also be created in MSWord. **Advanced electronic signature** A digital signature created with a digital certificate from the South African Accreditation Authority (SAAA) under section 37 of the ECTA, following a face-to-face identification process with the user. An advanced electronic signature is deemed reliable in law and is accepted as prima facie proof of validity, i.e. it is always assured to be valid and have been applied correctly to eliminate the burden of proof. In terms of section 13 of the ECTA, where the signature of a person is required by law and such law does not specify the type of signature required, an advanced electronic signature must be used. It must be noted that a written signature is still applicable. Only when an electronic signature is the preferred option would a person be obliged to use an advanced electronic signature.
Electronic informed consent	The use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive websites, biological recognition devices and card readers, to

[1] Government Gazette, Republic of South Africa, Electronic Communications and Transactions Act 25 of 2002

	convey information related to the study and to obtain and document informed consent.
ERC/REC	Ethics Review Committee or Research Ethics Review Committee – these two terms are used interchangeably in the Unisa context.
Health research	Includes any research that contributes to knowledge of • biological, clinical, psychological, or social processes in humans; • improved methods for the provision of health services; • human pathology; • the causes of disease; • effects of the environment on the human body; • development of new applications of pharmaceuticals, medicines and related substances; • the development of new applications of health technologies to improve health and healthcare.[2]
High-risk research	Research involving direct human participant involvement in which a real or foreseeable risk of harm exists which might lead to a serious adverse event if not managed responsibly.
Informed consent	The valid voluntary and informed choice of a legally capable person to participate – or refuse to participate – in a research study before data collection begins. The choice should be informed by four elements: disclosure, understanding, decision-making capacity and voluntariness.
Legal capacity	Legal subjects' ability to bear rights and duties. Capacity may be limited (e.g. because of age) or change over time, and includes a person's decision-making capacity.
Low-risk research	Research involving direct human participant involvement where the only foreseeable risk of harm is the potential for minor discomfort or inconvenience; thus research that would not pose a risk above the everyday norm.
Minor	Subject to exceptions where the law has granted a minor the capacity to act independently, a minor is a person under 18 years who lacks the maturity and legal ability to make an informed decision to participate in research.

[2] Definition according to the National Health Act 61 of 2003

Medium-risk research	Research involving direct involvement of human participants which poses a risk of harm above the everyday norm. However, steps can be taken to minimise the likelihood of the anticipated harm from occurring.
Proxy consent	The valid informed consent provided by a person with the legal right to consent on behalf of a minor, or a person with diminished autonomy, to participate in a research study, including the consent obtained from legal guardians.
Remote digital interaction	Direct, real-time digital interaction between a researcher and research participant(s) at a remote site by any means other than in person, e.g. telephonic or cloud-based video and audio software applications such as Zoom, Skype and MS Teams.
SOP	Standard Operating Procedure/s
URERC	Unisa Research Ethics Review Committee

5. PURPOSE OF THE SOP

The SOP serves as a guide to all Unisa researchers (including students), postgraduate supervisors and members of the ERCs/RECs to inform decisions concerning the appropriateness of the proposed procedure(s) on obtaining informed consent from prospective participants, including from those with diminished autonomy.

It also aims to give effect to the

- Health Research Ethics Guidelines of the Department of Health [3] concerning standards and guidance on obtaining prior, voluntary informed consent from various groups of participants, including those that are potentially vulnerable;
- Unisa Policy on Research Ethics.

6. SCOPE OF THE SOP

The scope of the SOP includes all Unisa researchers (including students), postgraduate supervisors and members of the ERCs/RECs and applies to all forms of research involving

[3] Department of Health, Republic of South Africa, 2015. "Ethics in Health Research: Principles, Processes and Structures"

human participants. Furthermore, it should be interpreted within relevant legislation, including but not limited to the National Health Act 61 of 2003, the Protection of Personal Information Act 4 of 2013 and the Electronic Communications and Transactions Act 25 of 2002.

7. REGULATORY STIPULATIONS

The stipulations below apply to the SOP following the Unisa Policy on Research Ethics (Part 2, Guidelines for research involving human participants and Part 4, Guidelines for community engagement), relevant national legislation and international guidelines:

7.1 Personal information should be collected and processed in accordance with the Protection of Personal Information Act 4 of 2013.

7.2 The participation of individuals should be based on their voluntarily informed consent obtained prior to the research.

7.3 Researchers should uphold the principle of autonomy and recognise that treating consent as a once-off event captured in a written format may be undesirable.

7.4 Researchers should respect a participant's right, at any stage, to refuse to participate in aspects of the research or to decide to withdraw their previously given consent without demanding reasons or imposing penalties.

7.5 Informed consent in community-engaged/-based research may require the involvement of community leaders that act as gatekeepers to gain access to community members identified as prospective research participants (see Part 4, Policy on Research Ethics, Guidelines for Community Engaged Research).

7.6 Participants should preferably give their consent in writing and submit the original signed document for secure storage by the researcher for a minimum period of 15 years. They, in turn, should be given written information containing adequate details of the research, including any possible or adverse consequences to their health.

7.7 If participants refuse or are unable to provide their consent in writing, consent may be recorded verbally on condition that verbal consent can be linked to the individual providing such verbal consent. For example, where a participant is illiterate, consent should be obtained in the presence of a literate witness who should verify and sign a document stating that informed consent had been given.

7.8 Electronic signatures are permitted for remotely conducted **low- to medium-risk non-health research** if all reasonable steps are taken to protect the identity of the participants and there is agreement between the researcher(s) and participant(s)

on a signing method that complies with the Electronic Communications and Transaction Act of 2002 (ECTA).

7.9 The signature requirement is met under section 13(3)(a) and (b) of the ECTA if the electronic signature method used

- identifies the person;
- indicates the person's approval of the information communicated;
- is reliable and appropriate for the purposes for which the information was communicated, having regard to the circumstances.

7.10 An advanced electronic signature is required for, but not limited to, **health and various forms of high-risk research** conducted remotely. If an advanced electronic signature is used, participants will not be required to mail/courier the original signed consent form to the researcher; if any other form of e-signature is used for health and high-risk research, participants will be obliged to mail/courier the original written signed consent form for record-keeping by the researcher.

7.11 Consent for participation in research is informed if human participants or their legally authorised representatives receive the following information:

(a) the purpose of the research;
(b) the methods and procedures, including possible randomisation;
(c) alternatives to participation in the research;
(d) the potential harm and risks of harm posed by the research;
(e) the expected benefits of the research;
(f) the freedom to choose to participate or not, or to withdraw from the research without penalty or reason;
(g) the extent to which confidentiality and privacy will be maintained;
(h) details of the contact person in the event of a query or research-related injury;
(i) reimbursement and/or incentives given for participation;
(j) information about the sponsor;
(k) any potential conflict of interests;
(I) information about approval from the health research ethics committee or the Medicines Control Council, where relevant;
(m) insurance in the event of research-related injury, for more than minimal risk research; and
(n) the availability of beneficial products or interventions post-research.

7.12 If research is conducted in a foreign country, the relevant standards for informed consent set out in the Health Research Ethics Guidelines of the Department of Health, and the Unisa Policy on Research Ethics will take precedence and apply.

7.13 Should personal information be exported to other jurisdictions, a standard applies that requires the recipient of the information in the foreign country to provide an adequate level of protection to participants in accordance with applicable privacy laws or similar provisions as those contained in the Protection of Personal Information Act (POPIA) (section 72(1)).

7.14 In the event of restrictions on movement during national or global disasters, obtaining informed consent should comply with disaster emergency laws, rules and guidelines of the country where the research is conducted. No research activities should be undertaken if they impede emergency responses. Special care must be taken to ensure the safety of researchers, fieldworkers and research participants. Research designs need to have clear risk assessment protocols and mitigation strategies to protect against the risk of infection, associated health risks and mental health impacts on research participants and researchers.

7.15 Remote, digital and telephonic interaction with research participants could be employed, taking special care to respect and ensure confidentiality and privacy.

7.16 A video or audio recording of the interaction should be possible for potential auditing purposes as a minimum requirement. The consent process needs to be well documented and evidence of the verbal or audio signing needs to be stored in a safe place.

7.17 Where informed consent documents are amended, ethics approval needs to be obtained from the relevant ERC/REC for the amended informed consent documentation.

7.18 In special cases, it is possible to request a waiver of consent. Only ERCs/RECs may approve a waiver of consent with suitable justification from the researcher.

7.19 Studies that use any form of deception of participants, concealment or covert observation need justification. The consent of the participants will have to be obtained retrospectively and a referral system for participants is required, where applicable.

8. Procedure

8.1 Access and complete the latest participant information sheet standardised for Unisa researchers **(Appendix A)**.

8.2 Insert the information as indicated on the template of this sheet.

8.3 Provide information relevant to each question or prompt stipulated on this sheet in as much detail as possible.

8.4 Ensure that the consent to participate in this study is attached to the participant information sheet for the respondent or participant to complete and sign.

8.5 Ensure that the respondent or participant has received a copy of the participant information sheet and consent form for participating well before the study commencing or allowing enough time for the respondent or participant to study the document.

8.6 If the respondent or participant cannot read, the researcher should ensure that an impartial witness is present when explaining the content of the documentation to the respondent or participant. The witness is required to attest that the researcher has accurately described the information and that the respondent or participant has understood the information presented to him/her and that consent thereafter was freely given. The witness *may* be a family member or friend or colleague who should not be involved in the study's design, data gathering or reporting.

8.7 If the respondent or participant cannot speak English, an interpreter fluent in English and the language understood by the respondent or participant must be involved to explain the contents of the participant information sheet to the respondent or participant.

8.8 The interpreter may be a family member, friend or colleague who is not involved in the design, data gathering or reporting of the study.

8.9 Read the participant information sheet and consent form to participate together with the participant during a face-to-face data gathering activity, such as focus groups or interviews. The details of the document must be explained to the participant for him/her to make an informed decision on how he/she would like to participate in the study and consider if this is what he/she wants to do.

8.10 Invite questions from the participant regarding the information communicated to him/her.

8.11 Provide enough time for the participant to discuss or consider the information given to him/her.

8.12 Verify the information provided to the participant by checking whether he/she

- is legally competent to provide informed consent;
- understands the information given by the researcher;
- does not feel pressured to decide to participate or not;
- understands that there is a voluntary choice to participate;
- understands that he/she may withdraw at any time;
- can make and communicate an informed choice.

8.13 If the participant requires clarification on whether any remuneration for participating in the study will be paid, apply the guidelines provided in the Unisa Policy on Research Ethics.

8.14 Completed consent forms must be stored on a password-protected computer and backup files or hard copies should also be stored securely.

8.15 Individual and collective autonomy should be balanced in community-engaged research through an informed consent process comprising community consultation, gatekeeper or community leader consent, followed by individual informed consent.

8.16 Consent obtained from the gatekeeper or community leader should not substitute obtaining separate informed consent from the participants.

8.17 Prospective participants should be allowed to discuss their decision with their families or peers.

8.18 Alternative ways of recording consent might be sought if participants in community-engaged research are willing to participate in a research study, but they do not want to sign a consent form, including the use of digital recordings or signing a register (see Part 4, Policy on Research Ethics, Guidelines for Community Engaged Research).

8.19 In cases where the participants refuse or are afraid to sign a consent form or to be recorded, the researcher must keep a written record that participants have been informed, and have understood and accepted participation in research but that they decline to sign. In these instances, the researcher must involve an impartial witness to confirm the participant's agreement to participate by co-signing the written record.

8.20 When obtaining written informed consent for low- to medium-risk non-health research via videoconferencing software, ask the participant to visibly display the signed consent form as evidence before collecting data. This measure is applicable if the participant cannot return a hard copy of the signed consent form before data collection commences. The researcher can follow the same procedure to sign the consent form.

8.21 When it is not possible to use an advanced digital signature for obtaining remote consent for health and high-risk research, the following guidelines should be applied:

- The researcher must email/courier two original copies of the informed consent form for each participant with a request to contact the researcher when the documentation is received.

- Once each participant has a copy of the consent form before him/her, the researcher must review the information sheet and consent document with each participant either by phone or videoconference, asking questions to gauge comprehension and allowing enough time for prospective participants to ask questions and raise concerns.
- If assent is required, the researcher must involve both the parent and/or legal guardian and minor.
- The researcher should document the entire informed consent/assent process followed for each person.
- After questions are answered, and the researcher feels confident each participant/legal guardian/parent understands the study, each person is requested to sign and date the consent form and return the original signed document.
- Whenever possible, the signed consent/assent should be returned to the researcher before a research procedure takes place.
- A consent/assent could be returned by emailing it back as a scanned PDF (where the person prints, signs and scans in) or an electronically signed document, or a signed original copy may be returned by mail.[4]
- Participants should be instructed to retain one signed copy of the consent/assent form for their own records.

[4] The role of a signature is as follows: it identifies the person assenting to or attesting the document; attributes the document to a specific person; indicates assent (a contract party) or attestation (by a witness); and authenticates the originality of the document. Electronic signatures must perform all the functions and provide at least as much legal certainty as the traditional wet signature. Section 13 of the ECTA makes a distinction between two situations: firstly, when signature is required by law (in that case, an advanced electronic signature is required as noted in s13(1) and s37), and secondly, when parties require it for an electronic transaction. Regarding the latter: the kind of data message that sufficiently identifies the person and indicates his/her approval should be adequate (Eiselen in Van der Merwe 2016:178). Therefore, a name typed at the bottom of an email is said to have constituted an electronic signature, as decided in *Spring Forest Trading* in 2015). In short, s 13 strives for functional equivalence to electronic signatures by requiring that they be adequate to link the message to a specific person (the author of the signature, thus ensuring identification and attribution) and to indicate reliably that person's approval of the document or text (thus establishing assent and authentication (ibid).
South Africa makes use of advanced electronic signatures and, as noted above, these need an authentication certificate or a third party to administer the process. Criteria need to be met before an accreditation authority can accredit an electronic signature service or product (sections 37 and 38 of ECTA). Other jurisdictions use the term "digital signatures", which are another form of electronic signatures where parties to a transaction have keys (private key and public key). In this case messages are transformed into unintelligible form and back into the original form when opened by the person who has a corresponding key. The signature should be sufficient if the requirements noted above are met.

- Once received, the researcher should sign the signature line with a current date. The researcher's signature is not to be back-dated to coincide with the date of the participant's signature.
- The researcher includes a note in the research report that consent was obtained over the phone or by videoconferencing and describes the process.
- All attempts need to be made to receive the signed version. If the signed copy is not returned, the legitimacy of the informed consent process is compromised.

8.22 If a web-based survey is undertaken, access and complete the latest Unisa template document, which is also a cover letter to an online anonymous web-based survey **(Appendix B)**. This is important to ensure that the respondent is presented with all relevant information before he/she begins the survey.

8.23 A respondent agrees to participate voluntarily in an online web-based survey by clicking on a button or typing in a response indicating he/she has read the consent information and agrees to participate.

8.24 Once the button is selected, the respondent or participant will gain access to the survey.

Normally full completion and submission constitute participation.

8.25 Protecting the confidentiality of downloaded data entails the following:

(a) IP addresses should be deleted from the downloaded data file and all responses should then be deleted from the online survey. The data file that is used for data analysis should be free of any identifiers, including IP addresses or other electronic identifiers.

(b) The data file should be stored on a password-protected computer and backup data files should also be stored securely, making use of Unisa-supported cloud-based storage space.

8.26 Proxy consent should be obtained from the legal guardians/parents of minors (participants under 18) or individuals with diminished autonomy, complemented by obtaining assent from these individuals.

8.27 Informed consent documentation should be embedded in online surveys.

8.28 Ensure that mechanisms are implemented to prevent respondents younger than 18 years from participating in surveys designed for adult participants.

8.29 Documented proxy or parental consent can be obtained as follows:

- A traditional hard copy of the proxy/parental consent form may be sent or provided to the person who will review and possibly sign it if agreeing that

the prospective minor or individual with diminished autonomy can participate **(see Appendix C for a sample assent form).**

- The proxy/parental and assent forms will be returned to the researcher and the participant may participate in the study.
- In the case of online surveys, the proxy/parent can be provided with a link for the minor participant to complete the online survey.
- Proxy/parental consent may be obtained using valid electronic signatures and emailed to the researcher, after which the researcher can email the link to the proxy/parent for the online survey.
- A copy of a signed consent document may be scanned and emailed back to the researcher, after which the researcher can email the link to the proxy/parent for the online survey.

Resources

- Anon https://sspcdn.blob.core.windows.net/files/Documents/SEP/ISEF/Resources/Online-Survey-Consent-Procedures.pdf (27.01.2020). Guidelines for Online Survey Procedures. https://sspcdn.blob.core.windows.net/files/Documents/SEP/ISEF/Resources/Online-Survey-Consent-Procedures.pdf
- Kornetsky, S. (2015). Boston Children's Hospital. Obtaining informed consent/assent remotely: process and documentation. www.childrenshospital.org
- Electronic Communications and Transaction Act 2002 (ECTA)
- Unisa Policy on Research Ethics of 2016
- International Development Research Centre (IDRC). 2020. Research ethics practices during COVID-19.https://www.idrc.ca/en/research-ethics-practices-during-covid-19
- Advanced electronic signature https://dommisseattorneys.co.za/blog/understanding-electronic-signatures-in-south-africa/#:~:text=For%20most%20purposes%2C%20standard%20electronic,when%20signing%20a%20document%20electronically.&text=In%20South%20Africa%2C%20an%20advanced,are%20excluded%20entirely%20by%20ECTA
- Solutions https://www.lawtrust.co.za/solutions/advanced-electronic-signatures

- https://support.microsoft.com/en-us/office/obtain-a-digital-certificate-and-create-a-digital-signature-e3d9d813-3305-4164-a820-2e063d86e512
- Spring Forest Trading 599 CC v Wilberry (Pty) Ltd t/a Ecowash & Another 2015 (2) SA 118 (SCA).

APPENDIX A: Human participant information sheet and consent template

Non-Unisa researchers: Do not use the Unisa logo

Unisa researchers: Use the Unisa logo

Both Unisa and non-Unisa researchers: Align the template with the specific requirements of your research and remove the prompts offered in italics.

PARTICIPANT INFORMATION SHEET

Ethics clearance reference number:
Research permission reference number (if applicable):

<date>

Title:<Exactly as it appears on your research ethics application >

Dear Prospective Participant

My name is <insert student researcher's name> and I am doing research with <insert supervisor's name>, a <insert supervisor's position, e.g. lecturer/senior lecturer/professor> in the Department of <insert department name> towards a/an <insert degree title, e.g. Grad Dip, BSc (Honours), MA, etc.> at the University of South Africa. We have funding from <insert name of funding body if applicable> for <insert why you have funding>. We are inviting you to participate in a study entitled <add title exactly as it appears on your ERC/REC application form>.

WHAT IS THE PURPOSE OF THE STUDY?

I am conducting this research to find out …
OR
This study is expected to collect important information that could … *[you may link this section to the benefits and/or outcomes of the study]*

WHY AM I BEING INVITED TO PARTICIPATE?

Indicate why you chose this person/group to participate in the study. Describe how (from whom) you obtained the participants' contact details and why you chose the particular person/group of participants (the Protection of Personal Information Act 4 of 2013 necessitates the disclosure of how access was gained to the personal information of prospective participants). Indicate the approximate number of participants. This is useful information to assist the participant in making an informed choice whether to participate in the proposed study – potential breaches of confidentiality increase with a small sample size.

WHAT IS THE NATURE OF MY PARTICIPATION IN THIS STUDY?

Describe the participant's actual role in the study with reference to the procedures that will be employed, i.e. the study involves <audio/video taping, questionnaires, surveys, focus groups, semi-structured interviews, etc.>. Indicate what types of questions will be asked or show the questions on this document. Describe the expected duration of participation and the time needed to complete specific research activities such as questionnaires, focus groups or interviews. Describe the time allocated to conduct interviews/focus groups (be realistic in your approximation).

CAN I WITHDRAW FROM THIS STUDY EVEN AFTER HAVING AGREED TO PARTICIPATE?

State that participation is voluntary and that there is no penalty or loss of benefit for non-participation.

Participating in this study is voluntary and you are under no obligation to consent to participation. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a written consent form. You are free to withdraw at any time and without giving a reason. *Do not mislead your potential participants by stating that they can withdraw from a research project at any time if the project involves the submission of non-identifiable material such as questionnaires. Explain clearly to them that it will not be possible to withdraw once they have submitted the questionnaire. Please note that this will depend on the nature of the questionnaire. Some questionnaires may clearly indicate the identity of the participant, but the researcher may have agreed to anonymise personal data. Thus, it may be possible to withdraw the data provided.*

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THIS STUDY?

Describe the presence or absence of possible benefits for the participant, the participants as a group, the scientific community and/or society. This section can be integrated in the section that describes the purpose, but it is critical information to assist with voluntary informed consent.

ARE THERE ANY NEGATIVE CONSEQUENCES FOR ME IF I PARTICIPATE IN THE RESEARCH PROJECT? *Describe any potential level of inconvenience and/or discomfort to the participant. List all possible or reasonably foreseeable risks of harm or side effects to the potential participants (outlining likely incidence and severity). Include any risk that may come from others identifying the person's participation in the research. Describe the measures that will be taken if injury or harm attributable to the study occurs. Add a description for arrangement for indemnity and/or insurance coverage for participants if applicable. Might a notifiable activity occur (abuse of minors), is this clearly explained.*

WILL THE INFORMATION THAT I CONVEY TO THE RESEARCHER AND MY IDENTITY BE KEPT CONFIDENTIAL? *If personal, identifiable information will be collected, specify why it is needed, what information is being collected,what will happen to it and how it will be de-identified? Explain the extent, if necessary, to which confidentiality of information will be maintained and indicate that the participant will be informed if personal information has been accessed by an unauthorised person or party).* You have the right to insist that your name will not be recorded anywhere and that no one, apart from the researcher and identified members of the research team, will know about your involvement in this research *[this measure refers to confidentiality] OR* your name will not be recorded anywhere and no one will be able to connect you to the answers you give *[this measure refers to anonymity]*. Your answers will be given a code number, or a pseudonym and you will be referred to in this way in the data, any publications, or other research reporting methods such as conference proceedings *[this measure refers to confidentiality].*

If relevant, identify who will have access to the <u>personal</u> or <u>de-identified</u> data (transcriber/ external coder/collaborators/any other third person) and how these individuals will maintain confidentiality (e.g. by signing a confidentiality agreement. Please note that confidentiality agreements should be submitted to the Research Ethics Review Committee for consideration). Your answers may be reviewed by people responsible for making sure that the research is conducted properly, including the transcriber, external coder and members of the Research Ethics Review Committee. Otherwise, records that identify you will be available only to people working on the study, unless you give permission for other people to see the records.

Create a sentence to inform participants or to request permission for the use of the de-identified data for research-related purposes, such as a research report, journal articles, data sharing and/or conference proceedings. Also indicate how privacy will be protected in any publication of the information, e.g. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report. *Please keep in mind that it is sometimes impossible to make an absolute guarantee of confidentiality or anonymity, e.g. when focus groups are used as a data collection method.*

Include a description of what a focus group is and state: While I will make every effort to ensure that you will not be connected to the information that you share during the focus group, I cannot guarantee that other participants in the focus group will treat information confidentially. I will, however, encourage all participants to do so. For this reason, I advise you not to disclose personally sensitive information in the focus group.

HOW WILL THE RESEARCHER(S) PROTECT THE SECURITY OF DATA?

Hard copies of your answers will be stored by the researcher for a minimum period of five years in a locked cupboard/filing cabinet *[Where? Indicate the location and provide a reasonable time for storing the data. The Unisa Library can be contacted for storing raw data on the Unisa repository. If you plan to share the data or to use if for longitudinal research, it may not be appropriate to store it for 5 years only]* for future research or academic purposes; electronic information will be stored on a password-protected computer. Future use of the stored data will be subject to further research ethics review and approval if applicable (such as using the data for a purpose unrelated to the initial aim and objectives of the study). *Indicate how information will be destroyed if necessary, e.g.* hard copies will be shredded, and/or electronic copies will be permanently deleted from the hard drive of the computer through the use of a relevant software program. *Specify whether personal, identifiable information will be sent outside South Africa, why and the level or protection that will be offered due to the cross border flow.*

WILL I RECEIVE PAYMENT OR ANY INCENTIVES FOR PARTICIPATING IN THIS STUDY?

Describe any payment or reward offered, financial or otherwise. Any costs incurred by the participant should be explained and justified in accordance with the principle of fair procedures (justice).

HAS THE STUDY RECEIVED ETHICS APPROVAL?

This study has received written approval from the Research Ethics Review Committee of the <identify the relevant ERC>, Unisa. A copy of the approval letter can be obtained from the researcher if you so wish.

HOW WILL I BE INFORMED OF THE FINDINGS/RESULTS OF THE RESEARCH?

If you would like to be informed of the final research findings, please contact <insert researcher's name> on <insert telephone number> or email <insert email address> or website <insert URL>. The findings are accessible for <insert time frame>. Please do not use home telephone numbers. Departmental and/or cellphone numbers are acceptable.
Should you require any further information or want to contact the researcher about any aspect of this study, please contact <insert principal researcher's contact details here, including email and internal phone number>.

Should you have concerns about the way in which the research has been conducted, you may contact <insert supervisor's contact details here, including email and internal phone number>. Contact the research ethics chairperson of the <insert name of the committee, the name of the research ethics chairperson and contact details here, including email and internal phone number> if you have any ethical concerns.

Thank you for taking time to read this information sheet and for participating in this study.
<insert signature>
<type your name>

CONSENT TO PARTICIPATE IN THIS STUDY

I, _____ (participant's name), confirm that the person asking my consent to take part in this research has told me about the nature, procedure, potential benefits and anticipated inconvenience of participation.

I have read (or had explained to me) and understood the study as explained in the information sheet.

I have had sufficient opportunity to ask questions and am prepared to participate in the study.

I understand that my participation is voluntary and that I am free to withdraw at any time without penalty (if applicable).

I am aware that the findings of this study will be processed into a research report, journal publications and/or conference proceedings, but that my participation will be kept confidential unless otherwise specified.

I agree to the recording of the <insert specific data collection method>.

I have received a signed copy of the informed consent agreement.

Participant's name & surname…… (please print)

Participant's signature……..Date……

Researcher's name & surname……(please print)

Researcher's signature……..Date……

TEMPLATE PERMISSION LETTER

(change as required & print on organisation's letterhead)

Request for permission to conduct research at <insert name of organisation or institution>

"<insert the title of your research exactly as it appears on your CEMS REC application form>"

<insert date>

<insert contact person's name>

<insert contact person's building No. or room No.>

<insert contact person's department>

<insert contact person's telephone number and email address>

Dear <insert contact person's title and name>
I, <insert student researcher or staff researcher's name> am doing research with <insert supervisor's name>, a <insert supervisor's position, e.g. lecturer/senior lecturer/professor> in the Department of <insert department name> towards a/n <insert degree title, e.g. Grad Dip, BSc (Honours), MA> at the University of South Africa. We have funding from <insert name of funding body if applicable> for <insert why you have funding>. We are inviting you to participate in a study entitled <add title exactly as it appears on your CEMS REC Application Form>.

The aim of the study is to… Your company has been selected because…

The study will entail… *[Describe the nature and procedures briefly with specific mentioning whether access is required to participants personal information. Include: why personal information is needed, what personal information will be collected, where and how it will be stored, who will have access to it, what will happen to it, how long will it be retained, whether it will be de-identified, how it will be de-identified or will it remain in an identifiable form, whether it will be sent outside South Africa, why and the level of protection offered to the institution/ gatekeeper and participants due to cross-border flow]*.

The benefits of this study are…
Potential risks are…

The feedback procedure will entail…

Yours sincerely

<insert signature of researcher>

<insert name of the above signatory>

<insert above signatory's position>

APPENDIX B: Cover letter for an anonymous survey

Non-Unisa researchers – please do not use the Unisa logo

TEMPLATE DOCUMENT

(change as required & adhere to Unisa brand guidelines for cover page to online survey)

Ethical clearance number:

Research permission number:

COVER LETTER TO AN ONLINE ANONYMOUS WEB-BASED SURVEY

Dear Prospective Participant

You are invited to participate in a survey conducted by <insert principal researcher's name> under the supervision of <insert supervisor's name>, a <insert supervisor's position, e.g. lecturer/senior lecturer/professor> in the Department of <insert department name> towards a/n <insert degree title, e.g. Grad Dip, BSc (Honours), MA> at the University of South Africa.

The survey you have received has been designed to study the <project description in non-scientific language>. You were selected to participate in this survey because <state reason for selecting the participant>. *[State any exclusion criteria, e.g. you will not be eligible to complete the survey if you are younger than 18 years.]* By completing this survey, you agree that the information you provide may be used for research purposes, including dissemination through peer-reviewed publications and conference proceedings.

It is anticipated that the information we gain from this survey will help us to <state anticipated outcomes of the project>. You are, however, under no obligation to complete the survey and you can withdraw from the study prior to submitting the survey. The survey is developed to be anonymous, meaning that we will have no way of connecting the information that you provide to you personally *[please note that this is only relevant to anonymous surveys]*. Consequently, you will not be able to withdraw from the study once you have clicked the send button based

on the anonymous nature of the survey *[or state:]* Any identifying information that is obtained in connection with this survey will remain confidential and will be disclosed only with your permission or as required by law. If you choose to participate in this survey, it will take no more than <insert anticipated minutes> of your time. You will not benefit from your participation as an individual, but it is envisioned that the findings of this study will <indicate anticipated benefits of the study>. We do not foresee that you will experience any negative consequences by completing the survey *OR* We foresee the following consequences in completing the survey *[describe the risks, discomforts or inconveniences expected, followed by measures to mitigate any negative consequences].* The researcher(s) undertake(s) to keep any information provided herein confidential, not to let it out of my/our possession and to report on the findings from the perspective of the participating group and not from the perspective of an individual.

The records will be kept for a minimum period of five years for audit purposes, after which they will be permanently destroyed *OR* hard copies will be shredded and electronic versions will be permanently deleted from the hard drive of the computer *[adapt according to the nature of the study; de-identified research data could be stored indefinitely to allow for data sharing or future use of the data for studies with similar aims and objectives].* You will not be reimbursed or receive any incentives for your participation in the survey.

The research was reviewed and approved by the <identify the Ethics Review Committee>. The primary researcher, <Name>, can be contacted during office hours at <insert contact details here>. The study leader, <Name>, can be contacted during office hours at <insert contact details here>. Should you have any questions regarding the ethical aspects of the study, you can contact the chairperson of the <identify the Ethics Research Committee>, <insert contact details of the ERC here>. Alternatively, you can report any serious unethical behaviour on the University's toll-free hotline 0800 86 96 93.

APPENDIX C: Sample assent form[5]

Instructions

- This form can be used to obtain assent from children aged 7 to 13 years.
- Use simple, child-friendly language appropriate for a child aged 7 to 13 years.
- Add the Unisa logo at the top.
- You may amend the template, but the document must adhere to the requirements for obtaining assent from minors.
- Please note that the gray, shaded areas should be filled in with text.
- Please delete sections **and** this instruction page before submitting to the REC/ERC.
- A copy of the completed assent form should be given to the family/guardians, along with the signed parental permission form.

Research Assent Form

Title of the research study:

Principal researcher's name:

Researcher's contact details:

What is a research study?

We can learn new things thanks to research studies. We can put fresh ideas to the test or learn more about children and the issues that affect them. We begin by posing a question. Then we try to figure out what the answer is. We invite you to join this study because *[provide a reason in simple language].*

You could ask <me/us> questions that you have at any time.

Important things to know…

- You decide if you want to take part.
- You can say 'No' or you can say 'Yes'.
- No one will be upset if you say 'No'.
- If you say 'Yes', you can always say 'No' later.
- You can say 'No' at any time.
- We will still take good care of you no matter what you decide.

[5] Adapted from the Seattle Children's Hospital Research Foundation Assent Form: https://www.seattlechildrens.org/research/resources/institutional-review-board/forms-and-policies/assent-consent-forms/

Why are we doing this research?

We are doing this research to find out more about .

What would happen if I join this research?

Include only the appropriate list items from below. If necessary, create new list items in age-appropriate terms—only list procedures/items for which assent is required.

If you decide to be in the research, we will ask you to do the following:

- Blood draws: You may need a needle poke so we can test some of your blood. We will try to get blood with only one poke.
- Questions: We will ask you to read questions on a piece of paper. Then you will mark your answers on the paper.
- Talking: A person on the research team will ask you questions. Then you will say your answers out loud.
- Medical records: We will look at your past doctor visits and use information about your care.

Could bad things happen if I join this research?

Some of the tests might make you uncomfortable or the questions might be hard to answer. We will try to make sure that no bad things happen.

You have the right to say "No" to whatever we ask you to do for the study at any moment, and we will stop.

Could the research help me?

Include the most appropriate statement for your study:

We think being in this research may help you because .

OR

This research will not help you. We do hope to learn something from this research though. And we hope that someday it will help other kids who have like you do.

What else should I know about this research?

If you don't want to be in the study, you don't have to be.

It's also fine to say yes and then change your mind. You can opt out of the study at any time. Please tell the researchers if you wish to stop.

Include the most appropriate statement for your study:
You will not be paid to be in the study.
OR
To thank you for being in the study, we would give you . It would help if you talked to your parents about how you would like to use this.

You can ask questions any time. You can talk to <List research team member's name> . Ask us any questions you have. Take the time you need to make your choice.

Is there anything else?

If you want to be in the study after we talk, please write your name below. We will write our name too. This shows we talked about the study and that you want to join.

Do you understand this research study and do you want to join in it?

YES		NO

Has the researcher answered all your questions?

YES		NO

Do you understand that you can STOP being in the study at any time?

YES		NO

Name of participant _____
(To be written by child/adolescent)

Printed name of researcher

_____

Signature of researcher

_____

_____ _____

Date ***Time***

Interpreter information *(if applicable)*

_____

Printed name of interpreter during initial presentation of study
Date

_____

Printed name of interpreter when translated form is presented
Date

Copies to:
Parents/Guardians