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Research Ethics Guidelines: Da Vinci Institute

Why must Da Vinci students and staff apply for Ethical Clearance?
Ethics clearance is necessary for legal and moral reasons. The Constitution protects bodily and psychological integrity. The National Health Act requires that all research involving human participants undergo ethics review.

Ethical clearance is thus to ensure that South Africa's people are fairly and respectfully treated by researchers and that all research conducted in the country stands up to ethical scrutiny. South Africa's research ethics systems and infrastructure are regularly updated and strengthened. This assists with the ensuring that research is conducted in accordance with the highest ethical norms and standards.

Da Vinci strives to ensure that an ethical and scientific intellectual culture prevails among its employees and students. It protects the rights and interests of participants, the researchers and the institution.

The core ethical principles – respect, scientific merit and integrity, distributive justice and beneficence – apply to all forms of research that involve living persons and the use of animals, thereby placing their safety, welfare and other interests as paramount.

To obtain more information read the following document:
Ethics in Health Research: Principles, Processes and Structures. Second Edition. Department of Health. Republic of South Africa. 2015.

Important information to keep in mind when you complete the ethics application form

- The application form and supporting documents will enter a **pre-approval phase** where the application will be reviewed for technical quality and to ensure that all sections are complete. If not, **it will be returned to the applicant.**
- Decisions reached by the Research Ethics Committee (REC) could be:
    - Approved
    - Referred back – requires modification, information or clarification
    - Disapproved with reasons.
- Complete all sections of the application form in full.
- Indicate "not applicable" or NONE when you are sure that the section does not apply to your application.
- The application should be a single document only. Separate documents cannot be accepted. All additional documents should be attached as appendices.
- Applications may only be submitted by the student once the supervisor and if applicable, the co-supervisor, have signed it and made sure that it is correct.
- Only apply for ethics clearance after the literature review has been completed and the research design is being finalised.
- All relevant supporting documents (letters requesting permission to conduct the study, consent forms AND the research instruments like interview questions, questionnaires and observations protocols) must be appended.
- Sign and date the ethics declaration (Section 4 of the application form). A signature is required (not a computer signature using a different font).
- It is the supervisor's responsibility to ensure that the application is complete and meets the requirement before it is submitted to the REC.

Risk Assessment tool

The application form has a section where the researcher needs to indicate the risk category of the research. Use the table explaining the risk categories, the definitions and the examples to guide you to make an informed decision when you indicate the risk category of your research in the application form (Section 2.4).

RISK ASSESSMENT TOOL

The checklists below have been designed to guide researchers to assess the potential risk of the proposed research. There are four risk categories, but due to the type of research which is conducted in the Da Vinci Institute most of the research will fall in Categories 2, 3 and 4 as research involves human participants.

The categories are displayed in the table below:

Category 1: Negligible risk	No apparent risk to participants. No human participants directly involved. Analysis of statistics, literature study or market research surveys. All research directly involving human participants has an inherent measure of risk and cannot be marked as risk category 1	
Category 2: Low risk	Human participants involved. Foreseeable risk of inconvenience. Non-vulnerable adult participants and non-sensitive information involved.	
Category 3: Medium risk	Potential risk of harm or discomfort. Sensitive research topic. Personal information gathered and analysed. Participants directly involved. Participants are children under the age of 18 or vulnerable adults.	
Category 4: High risk	Real and foreseeable risk of harm or discomfort. Highly sensitive topics. Participants are vulnerable children under the age of 18. Deception of research participants.	

If any items on the ethical risk checklist in Tables **2 and 3** are ticked **"YES",** the research may be likely to involve **medium risk** to the participant. The applicant needs to indicate how participants will benefit from the research and describe the steps that will be undertaken to mitigate the risk.

High risk: If a number of items on the ethical risk checklist in Tables **1, 2 and 3** are ticked **"YES"**, the research may be likely to involve significant risk to the participants, researcher(s), institutions or Da Vinci Institute. The applicant needs to indicate how participants will benefit from the research and describe the steps that will be undertaken to mitigate the risk.

Table 1	**Does your research include the direct involvement of any of the following groups of participants/research objects?**	**YES**	**NO**
Place x in box [if yes, provide details in the space allowed for comments]			
a) Children or young people under the age of 18			
b) Persons with a cognitive disability or mental impairment of any kind			
c) Prisoners or people on parole			
d) Children who are in custody of the State			
e) Persons highly dependent on medical care			
f) Military personnel			
g) Communities that may be considered as vulnerable			
h) Persons unable to give consent themselves			

i) People aged 65 and older		
j) Persons not usually considered to be vulnerable but would be considered vulnerable in the context of this research project		
k) Non-English speaking participants		
l) Women considered to be vulnerable (pregnancy, victimisation, etc.)		
m) People living in poverty		
n) People with little or no education		
o) Environmental related research		
p) Other. Please describe.		
Comments:		

Table 2	**Does your research involve any of the following types of activity?**	**YES**	**NO**
Place x in box [if yes, provide details in the space allowed for comments]			
a) Collection, use or disclosure of information WITHOUT the consent of the individual or institution whose information it is, with the exception of aggregated data or data from official databases such as StatsSA, SARS, etc.			
b) Causing discomfiture to participants beyond normal levels of inconvenience			
c) Deception of participants, concealment or covert observation			
d) Examining potentially sensitive or contentious issues			
e) Seeking disclosure of information which may be prejudicial to participants			
f) Using intrusive techniques, e.g. audio-visual recordings of participants which may be of a sensitive nature			
g) Study of or participation in illegal activities that could place individuals and/or groups at risk of criminal or civil liability or be damaging to their financial standing, employability, professional or personal relationships			
h) Innovative therapy or intervention			
i) Personal and social information collected directly from participants			

j) Identifiable information to be collected about people from available records (e.g. medical records, staff records, student records, etc.)		
k)*Psychology inventories / scales / tests		
l) Activities which may place the researcher(s) at risk		
Comments:		

**Please add details on copyright issues related to standardised psychometric tests and registration at the HPSCA of test administrator if test administration is in South Africa or of an equivalent board if administration is outside South Africa.*

Table 3	**DO ANY OF THE FOLLOWING APPLY TO YOUR RESEARCH PROJECT?**	YES	NO
Place x in box [if yes, provide details in the space allowed for comments]			
a) Reimbursement or incentives to any participants			
b) The participants will incur financial costs by participating in the study			
c) At least one of the researchers has a financial or other involvement in the research (apart from their research role) or may receive a reward			
d) Any other potential conflict of interest for any of the researchers (real or perceived financial or personal considerations that may compromise a researcher's professional judgement in carrying out or reporting research, such as conducting research with colleagues, peers or students)			
e) Research is done on the premises of Da Vinci or any of its units			
f) Research will make use of some of Da Vinci's facilities			
g) Research will be funded by Da Vinci			
Comments:			

Example of a request letter to conduct research at a Company/Institution (Example 1)

Use this example to gain permission from: The CEO of the company; the Head of the Department; or whoever the gatekeeper is at your place of work.

Example on page (6).

Example of an Information letter that will also serve as a consent form (Example 2)

Use this example to inform your participants about the research and to obtain consent from them.

Remember to also add a consent return slip and if you are going to use focus group discussions you also need to add a confidentiality agreement.

Letter must be written on a Da Vinci Letterhead

Example on the next page (7)

Example of consent/assent return slip on page (11) **(Example 3)**

Example of a confidentiality agreement on page (12) **(Example 4)**

Example of a cover letter for a questionnaire (13) **(Example 5)**

Example of a cover letter for an online anonymous web-based survey (14) **(Example 6)**

Example of a request letter to conduct research at a Company/Institution (Example 1)

Request for permission to conduct research at _____ (insert name of organisation or institution)

Title of the title of your research (**exactly** as it appears on your Research Ethic application form)

Date

Name of the person to who you address the request
Department of the person
Contact details of the person (telephone and email address)

Dear _____ (insert contact person's title and name),

I, _____ (insert researcher's name) am doing research under supervision of _____ (insert supervisor's name), a _____ (insert supervisor's position, e.g. lecturer/senior lecturer/professor, etc.) towards a _____ (insert degree title, e.g. M/D) at the Da Vinci Institute. We are inviting you to participate in a study entitled _____ (add title **exactly** as it appears on your Ethics Application Form).

The aim of the study is to_____

Your company/institution/department (select one) has been selected because_____

The study will entail _____ (describe the nature and procedures briefly)

The benefits of this study are _____ (indicate realistic benefits)

Potential risks are_____ (if no risk is involved also state it)

Participation is voluntary and information of participants will be kept confidential.

There will be no reimbursement or any incentives for participation in the research.

Feedback procedure will entail _____ (indicate how you will give feedback to participants)

Yours sincerely

_____ (insert signature of researcher)

_____ (insert name of the above signatory)

_____ (insert above signatory's position)

Example of an Information letter that will also serve as a consent form (Example 2)

Date
Title: _____ (**exactly** as it appears on your research ethics application)

Dear prospective participant
My name is _____ (insert student researcher name) and I am doing research under the supervision of _____ (insert supervisor's name), a _____ (insert supervisor's position, e.g. lecturer/senior lecturer/professor, etc.) towards a _____ (insert degree title, e.g. M /D) at the Da Vinci Institute. We are inviting you to participate in a study entitled _____ (add title exactly as it appears on your research ethics application Form).

What is the purpose of the study?
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 are you being invited to participate?
You are invited because_____ (indicate here why you as the researcher chose this particular person/group as participants?)
I obtained your contact details from _____ (Describe how you obtained the participants' contact details. *The Protection of Personal Information Act, no 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 to make 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 your participation in this study?
Describe the participant's actual role in the study.

The study involves _____ *(audio/video taping / questionnaires / surveys / focus groups /semi-structured interviews, etc.)*. Indicate what sort of questions will be asked or show a few examples the questions in this document. Describe the expected duration of participation and the time needed to complete specific research activities like questionnaires, focus groups or interviews *(be realistic in your approximation)*.

Can you withdraw from this study even after having agreed to participate?
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 (adult)/ assent (participant younger than 18 years old) 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 anonymize personal data. Thus someone could ask for withdrawing the questionnaire).*

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 participating 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].

Will the information that the participant convey to the researcher and his/her identity be kept confidential?

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 data *[transcriber/external coder]* 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 research is done 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 that their anonymous data may be used for other purposes, such as a research report, journal articles 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 every effort will be made by the researcher 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 shall, 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 period of five years in a locked cupboard/filing cabinet *[where? Indicate the location]* 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. 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 programme)*.

Will the participant 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 adherence 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 Da Vinci Institute. A copy of the approval letter can be obtained from the researcher if you so wish.

How will the participant 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 fax number) or website_____ (insert URL). The findings are accessible for _____ (insert time frame).

Should you require any further information or want to contact the researcher about any aspect of this study, please contact _____ (insert principle researcher's contact details here, including email, internal phone number and fax 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, internal phone number and fax number).

Thank you for taking time to read this information sheet and for participating in this study.
Thank you.

_____
(insert signature)

_____
(type your name)

Example of a consent/assent return slip to participate in a study (Example 3)

I, _____ (participant 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 Name & Surname (please print)

_____

_____ _____
Participant Signature Date

Researcher's Name & Surname (please print)

_____

_____ _____
Researcher's signature Date

Example of focus group consent/assent and confidentiality agreement (Example 4)

I_____ grant consent/assent that the information I share during the focus group may be used by _____ (name of researcher) for research purposes. I am aware that the group discussions will be digitally recorded and grant consent/assent for these recordings, provided that my privacy will be protected. I undertake not to divulge any information that is shared in the group discussions to any person outside the group in order to maintain confidentiality.

Participant 's Name (Please print): _____

Participant Signature: _____

Researcher's Name: (Please print): _____

Researcher's Signature: _____

Date: _____

If you are and adult who gives permission, you **consent** then delete assent

If you are a learner who gives permission, you **assent** and then delete consent

Example of a cover letter for a questionnaire (Example 5)

Title of questionnaire:

Dear participant

This questionnaire forms part of my _____ (doctoral/master's) research entitled: _____ (add title **exactly** as it appears on your CEDU REC Application Form) for the degree _____ (M / D) at the Da Vinci Institute. You have been selected by a_____ *sampling* strategy from the population of _____. Hence, I invite you to take part in this survey.
The aim of this study is to investigate _____. The findings of the study may benefit _____.
You are kindly requested to complete this survey questionnaire, comprising _____ (indicate how many) sections as honestly and frankly as possible and according to your personal views and experience. No foreseeable risks are associated with the completion of the questionnaire which is for research purposes only. The questionnaire will take approximately _____ (indicate how many) minutes to complete.
You are not required to indicate your name or organisation and your anonymity will be ensured; however, indication of your age, gender, occupation position etcetera will contribute to a more comprehensive analysis. All information obtained from this questionnaire will be used for research purposes only and will remain confidential. Your participation in this survey is voluntary and you have the right to omit any question if so desire, or to withdraw from answering this survey without penalty at any stage. After the completion of the study, an electronic summary of the findings of the research will be made available to you on request.
Permission to undertake this survey has been granted by the _____ (indicate the institution) and the Ethics Committee of the Da Vinci Institute. If you have any research-related enquiries, they can be addressed directly to me or my supervisor. My contact details are: _____ (insert telephone number) e-mail: _____ insert email address or fax number) and my supervisor can be reached at _____ (insert telephone number) and (e-mail) _____.

By completing the questionnaire, you imply that you have agreed to participate in this research. Please return the completed questionnaire to_____ before _____

Cover letter to an online anonymous web-based survey (Example 6)

Dear prospective participant,

You are invited to participate in a survey conducted by_____ (insert researcher name) under the supervision of_____ (insert supervisor's name) a _____ (insert supervisor's position, e.g. lecturer/senior lecturer/professor, etc.) towards a _____(insert degree title, e.g. M / D) at the Da Vinci Institute .

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). 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 up no more than _____ (insert anticipated minutes) of your time. You will not benefit from your participation as an individual, however, it is envisioned that the findings of this study may _____ (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 undertakes to keep any information provided herein confidential, not to let it out of 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 five years for audit purposes where after it will be permanently destroyed. 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). You will not be reimbursed or receive any incentives for your participation in the survey.

The research was reviewed and approved by the Research Ethics Committee of the Da Vinci Institute. The researcher, <Name>, can be contacted during office hours at <insert contact details here>. The supervisor, <Name>, can be contacted during office hours at <insert contact details here>.

You are making a decision whether or not to participate by continuing to the next page. You are free to withdraw from the study at any time prior to clicking the send button.

References:

Ethics in Health Research: Principles, Processes and Structures. Second Edition. Department of Health. Republic of South Africa. 2015.