**Faculty of Theology**

# INFORMED CONSENT DOCUMENTATION[1]
## FOR……

**TITLE OF THE RESEARCH STUDY:**

**ETHICS REFERENCE NUMBERS:**

**PRINCIPAL INVESTIGATOR:**

**POST GRADUATE STUDENT:**

**ADDRESS:**

**CONTACT NUMBER:**

You are being invited to take part in a **research study** that forms part of my/our…….. Please take some time to read the information presented here, which will explain the details of this study. Please ask the researcher or person explaining the research to you any questions about any part of this study that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research is about and how you might be involved. Also, your participation is **entirely voluntary** and you are free to say no to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part now.

This study has been approved by the **Research Ethics Committee of the Faculty of Theology (REC-FT)of the North-West University (NWU……)** and will be conducted according to the ethical guidelines and principles of Ethics in Health Research: Principles, Processes and Structures (DoH, 2015) and other international ethical guidelines applicable to this study. It might be necessary for the research ethics committee members or other relevant people to inspect the research records.

**What is this research study all about?**

- *We plan to ……:*
- *This study will be conducted .....and will be done by experienced health researchers trained in ..... X participants will be included in this study.*

[1] [1] The Faculty of Health Sciences Ethics Office of the North-West University is acknowledge for the use of their document with minor adjustment for the use in the Faculty of Theology at the North-West University.



**Commented [MG1]:** Add for whom and what. Be specific who your participant will be and what they will be doing so that this informed consent form will be identifiable e.g. young pregnant women being interviewed

**Commented [MG2]:** Type in the title of your study

**Commented [MG3]:** Type in your ethics allocated number

**Commented [MG4]:** Type in the name of the researcher or the study-leader

**Commented [N5]:** Type in the student's name if applicable

**Commented [MG6]:** Type in the address of the primary investigator

**Commented [MG7]:** Contact number of the primary investigator

**Commented [MG8]:** Say what studies or what research study is being undertaken. If Masters or Doctoral study do not write "my" but "a" Masters or Doctoral study as you have indicated both the study leader and the student

**Commented [MG9]:** Type your ethics approval number in

**Commented [N10]:** Describe the objectives of your research in simple language. Please do not use the scientific language of your proposal.

**Commented [MG11]:** Where? When? E.g. in Potchefstroom in a private venue of your choice.

**Commented [MG12]:** Say what the experience is in e.g. interviewing? It is important that the participant see that the researchers are experienced.

**Commented [MG13]:** Replace with your planned number of participants

**Why have you been invited to participate?**

- *You have been invited to be part of this research because you are ……..*
- *You will unfortunately not be able to take part in this research if …….*

**What will be expected of you?**

- *You will be expected to*

**Will you gain anything from taking part in this research?**

- *The gains for you if you take part in this study will be……../There will be no direct gains for you in the study.*
- *The other gains of the study is for ……..*

**Are there risks involved in you taking part in this research and what will be done to prevent them?**

- *The risks to you in this study are……. but will be limited by……..*
- *There are more gains for you in joining this study than there are risks.*

**How will we protect your confidentiality and who will see your findings?**

- *Anonymity of your findings will be protected by..... Your privacy will be respected by …… Your results will be kept confidential by …….. Only the researchers and.....will be able to look at your findings. Findings will be kept safe by locking hard copies in locked cupboards in the researcher's office and for electronic data it will be password protected. (As soon as data has been transcribed it will be deleted from the recorders.) Data will be stored for ..... years.*

**What will happen with the findings or samples?**

- *The findings of this study will only be used for this study/will be used in future……..*

**How will you know about the results of this research?**

- We will give you the results of this research when ……. by……..
- You will be informed of any new relevant findings by……

**Will you be paid to take part in this study and are there any costs for you?**

This study is funded by……
Yes, you will be paid an amount of …. when you…. /No you will not be paid to take part in the study because …..
Travel expenses will be paid for those participants who have to travel to the site...../You had no travel expenses and do not to be refunded for traveling.
Refreshments/a meal will be served when.....
There will thus be no costs involved for you, if you do take part in this study.

**Is there anything else that you should know or do?**

- You can contact ..... at ..... if you have any further questions or have any problems.
- You can also contact the Research Ethics Committee of the Faculty of Theology (REC-FT) via Mrs Tienie Buys at Tienie.Buys@nwu.ac.za if you have any



**Commented [MG14]:** Tell them why you have selected them to be part of the study. State the inclusion criteria in simple language

**Commented [N15]:** State your exclusion criteria in simple language

**Commented [MG16]:** Give a detail description of *what* will be expected of the participant, *how long, how often, when* etc. e.g an interview of 30 minutes with 6 questions once in two weeks' time/in June or with the possibility of a follow up interview. If your participant will be expected to be involved in several activities, they all have to be mentioned here in detail with the what is expected of them for each activity/procedure etc.

**Commented [N17]:** Give the direct benefit to the participant here or tell him/her that there is no direct gain for them

**Commented [N18]:** Tell them who else will gain and what these people will gain e.g. their community at large about….or researchers by gaining new knowledge about ….. etc.

**Commented [N19]:** It is important to note here that it is here you will add the section of bodily harm and insurance should it be applicable to the study.

**Commented [MG20]:** State each risk and immediately follow up with what precautionary measures will be taken by you to limit the risk. You could even bring in a table with the risk in the one column and the precautionary measure in the other column

**Commented [N21]:** Adjust this line if the risks are more to the participant in a medium of high risk study

**Commented [MG22]:** Explain how this will be ensured in this study and what will be done to protect it. Mention if it is only partial and what will be done from your side

**Commented [N23]:** Describe how you will ensure privacy while obtaining their information

**Commented [N24]:** Describe how you will ensure confidentiality once you have obtained the information and when you disseminate it

**Commented [MG25]:** Say who will have access to the data. If an agreement of confidentiality is signed with someone mention it

**Commented [MG26]:** Only add this if you have recorded data

**Commented [MG27]:** Put in the time you will store it

**Commented [128]:** Indicate whether this data/samples will only be used for this study or will it be used again for further studies or collaborative studies. If you are going to use it again indicate *for what* and *related to what*. Ensure them that for any furthers studies it will ...

**Commented [N29]:** Tell the participant when you will share the findings with them and how you will share it ...

**Commented [N30]:** Tell them how you will do this

**Commented [N31]:** Adjust this section as it is applicable to your study. Please take the TIE principle into ...

**Commented [N32]:** Mention if this study is funded or not. If funded by whom.

**Commented [MG33]:** Researchers details

**Commented [WU34]:** Where can the person contact the researcher

concerns that were not answered about the research or if you have complaints about the research.

- You will receive a copy of this information and consent form for your own purposes.

## Declaration by participant

By signing below, I ……..…… agree to take part in the research study titled:……

I declare that:

- I have read this information/it was explained to me by a trusted person in a language with which I am fluent and comfortable.
- The research was clearly explained to me.
- I have had a chance to ask questions to both the person getting the consent from me, as well as the researcher and all my questions have been answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be handled in a negative way if I do so.
- I may be asked to leave the study before it has finished, if the researcher feels it is in the best interest, or if I do not follow the study plan, as agreed to.

Signed at (*place*) .....…..……. on (*date*) ……..…….. 20....

..... .....

**Signature of participant** **Signature of witness**

**Commented [N35]:** Name and surname of participant

**Commented [MG36]:** Add tile of the study

**Commented [WU37]:** Witnesses are only added in the case of illiterate participants who then bring along a trusted person to sign on their behalf. The participant can draw a cross or make a finger print.

## Declaration by person obtaining consent

I *(name)* …… declare that:

- I clearly and in detail explained the information in this document to

  ……..

- I did/did not use an interpreter.
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I gave him/her time to discuss it with others if he/she wished to do so.

Signed at (*place*) .....…..…….. on (*date*) ……..…….. 20....

.....
**Signature of person obtaining consent**

## Declaration by researcher

I *(name)* …… declare that:

- I explained the information in this document to …….. **or** I had it explained by …… who I trained for this purpose.
- I did/did not use an interpreter
- I encouraged him/her to ask questions and took adequate time to answer them or I was available should he/she want to ask any further questions.
- The informed consent was obtained by an independent person.
- I am satisfied that he/she adequately understands all aspects of the research, as described above.
- I am satisfied that he/she had time to discuss it with others if he/she wished to do so.

Signed at (*place*) ..... on (*date*) …….. 20....

.....
**Signature of researcher**

**Commented [N38]:** Please adjust this sentence according to your process followed

**Commented [N39]:** Please adjust this sentence according to your process followed