

Informed Consent Form

PARTICIPANT INFORMATION LEAFLET

TITLE OF THE RESEARCH PROJECT: Towards the Development of an Ethical Framework related to Research on Human Tissue

PRINCIPAL INVESTIGATOR: Miss Seonaid Singh

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My name is Seonaid Singh and I am a PhD student at the University of KwaZulu-Natal. I would like to invite you to participate in a research project that aims to aid in the development of an ethical framework for research on human tissue that will assist stakeholders in undertaking research in the utmost ethical manner. This study will explore the views of REC members regarding ethical issues experienced, evaluate the regulations governing ‘informed consent’ with regards to human tissue research and human fetal tissue research, review existing guidelines on human tissue biobanks in South Africa and assess the impact of the COVID-19 pandemic on human tissue research.

Please take some time to read the information presented here, which will explain the details of this project and contact me if you require further explanation or clarification of any aspect of the study. Also, your participation is entirely voluntary and you are free to decline 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.

This study has been approved by the Biomedical Research Ethics Committee (BREXXXXXX) and will be conducted according to accepted and applicable National and International ethical guidelines and principles, including those of the international Declaration of Helsinki 2013.

What is this research study all about?

The purpose of this component of my study is to evaluate the issue of ‘informed consent’ in human fetal tissue research. This study will help in understanding perspectives of women with children on the aspect of informed consent in human fetal tissue research. Your participating involves taking part in a questionnaire. You will be asked some open-ended and closed-ended questions which will help us to explore these ethical issues. Some questions may be personal or sensitive, but you are free not to answer any specific question. Anonymity will be ensured.

Why have you been invited to participate?

You have been invited to participate because as a mother we would like your feedback and opinions on the aspect of 'informed consent' in human fetal tissue research. Your comments will help us in differentiating between 'informed consent' in human tissue and human fetal tissue research.

What will your responsibilities be?

Your responsibilities will be to voluntarily give your opinions and responses to some open-ended questions asked in the form of a questionnaire.

Will you benefit from taking part in this research?

There are no direct benefits that you will receive from participation in this study. However, your participation in the study has potential to contribute scientific knowledge to the research being conducted.

Are there in risks involved in your taking part in this research?

Presently, there are no foreseeable risks in your participation. All data will be completely anonymized and your name will not be recorded anywhere nor revealed in subsequent publications.

If you do not agree to take part, what alternatives do you have?

Please note that participation is voluntary and completely based on your willingness. You are not being forced to take part in this study. The choice of whether to participate or not, is yours alone. If you choose not to take part, you will not be affected in any way whatsoever. If you agree to participate, you may stop participating in the research at any time. You are guaranteed that there will be no penalties or any action taken against you and you will not be prejudiced in any way should you decide to withdraw from the study. If you chose not to take part or chose to withdraw from this study, your welfare will not be affected in any way.

If you are willing to participate in this study please sign the attached Declaration of Consent and hand it to the investigator.

Declaration by participant

By signing below, I agree to take part in a research study entitled **Towards the Development of an Ethical Framework related to Research on Human Tissue.**

I declare that:

- I have read the attached information leaflet and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately 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 penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (place) On (date) 2023.

Signature of participant

CONSENT FOR TAPE RECORDING

I hereby agree to the tape-recording of my participation in the study.

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Signature of participant
Date:.....