

Participant Information Leaflet

Please Read Carefully Before Completing the Questionnaire

Study Title: Evaluation of the opinion of women on prenatal screening tests for fetal trisomy

Principal Investigator: Dr Keelin O'Donoghue

Sites of Investigation: Cork University Maternity Hospital

Thank you very much for taking the time to read this leaflet. Please take the time to read the following information carefully and discuss it with others if you wish.

You are being asked to participate in a research study entitled “**Evaluation of the opinion of women on prenatal screening tests for fetal trisomy**”. In order to decide whether or not you want to be a part of this research study, you should understand enough about it to make an informed judgement.

This information leaflet gives detailed information about the research study. Once you understand the study, you will be asked to complete a questionnaire if you wish to participate.

Why is this study needed?

In Ireland, 2-3% of pregnant women receive a prenatal diagnosis of a fetal anomaly in their pregnancy. Many countries have implemented screening programmes to look for fetal anomalies, such as Down Syndrome. Ireland currently does not have such a programme. This study will help us to understand what women would want out of a screening programme as well as the level of awareness around fetal anomalies. We believe that your opinions as a woman who is currently pregnant will help providers determine what resources are needed based on what women would like to see in a screening programme.

What is my role?

As part of this study you will be asked to complete one questionnaire on your awareness and views about antenatal screening for fetal anomalies, like Down Syndrome. The questionnaire should take 10-15 minutes to complete and can be completed while you wait for your appointment at the antenatal clinic.

Important things you need to know:

If you take part in the study, withdraw from the study, or do not participate in the study there will be no change to your care or your baby's care.

How we will use your personal data?

During this study, no identifiable information (name, date of birth, address, etc) will be collected. All questionnaires will be anonymous. The information collected in the questionnaire will be held securely at Cork University Maternity Hospital (CUMH) and all electronic data will be password protected and stored securely on University College Cork (UCC) servers.

Will this be confidential?

All the information collected on the questionnaire will be completely anonymous as no identifiable information will be collected. The information shared on the questionnaire will be held securely at Cork University Maternity Hospital (CUMH) and all electronic data will be password protected and stored securely on University College Cork (UCC) servers. The information and data provided to this study will only be accessed by the research team and will only be reported at an anonymous level.

Data processing and storage:

The study is being conducted by University College Cork, based in Cork University Maternity Hospital (CUMH). This means that University College Cork (UCC) is the Data Controller for this research project and that UCC owns the data collected as part of the study. The data will be stored on UCC servers.

Hard copies of questionnaires will be stored in CUMH in the Obstetrics and Gynaecology Department and destroyed once uploaded into electronic format. All data will be stored on password protected devices only accessible to the research team without any identifiable information in accordance with both UCC and CUMH data protection policies.

Is this study approved by an Ethics Committee?

Yes, ethical approval for this study was granted to us from the Cork Research Ethics Committee of the Cork Teaching Hospitals. If you have any concerns about this study and wish to contact someone independent, you may contact the Clinical Research Ethics Committee at 021-4901901.

Do I have to sign anything?

No, if you agree to participate, we ask you to please complete the provided questionnaire. Please be aware that even though you may complete the questionnaire, you can still withdraw from the study at any time.

Contact Information:

Please, contact us if you have any questions or if you would like more information about the study. You can contact Kristin Kelly via email at kristin.kelly@umail.ucc.ie.

If you have any complaints in connection with our processing of your personal data, you can contact UCC's Data Protection Officer (DPO): DPO, Information Compliance Section, Office of Corporate & Legal Affairs, University College Cork, Western Road, Cork E: foi@ucc.ie Tel: +353 21 4903949