CONSENT FORM

Study Number: 15/NS/0123
Participant ID Number:
Title of Study: Normal development of the human fetus and the influences and mechanisms by which that development occurs and is perturbed.
Short title: S**cottish Advanced Fetal Research Study**
Name of CI: Prof Paul A. Fowler

		Please INITIAL
1	I confirm that I have read and understood the information sheet dated …….. (Version ……) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities if appropriate or from the NHS Board/Trust (but NOT the researchers themselves), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4	I understand that the information from the study is confidential and anonymised. My family doctor (GP) will NOT be informed that I have taken part in it.	
5	I agree to give samples for this study and that tissue may be used in future ethically approved studies both within and outside the UK.	
6	I understand that once my samples have been fully anonymised and processed in the laboratory I will not be able to withdraw them from the study.	
7	I agree to the storage of my samples in the NHS Grampian Biorepository and for their use in ethically reviewed and approved future studies both within and outside the UK.	
8	I agree to DNA analysis of my samples.	
9	I agree to take part in the above study.	

BLOCK CAPITALS

Name of Patient	Date	Signature
Name of Individual taking consent	Date	Signature

UNIVERSITY OF ABERDEEN

Scottish Advanced Fetal Research Study

PATIENT INFORMATION LEAFLET

We invite you to take part in a research study. This study is funded by the Medical Research Council, the Society for Endocrinology and NHS Grampian. This study aims to investigate how the fetus develops.

Before you decide it is important for you to understand why the research is being done and what it will involve. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?
This study is designed to allow us to discover how fetal development is controlled. We wish to carry out laboratory studies with fetal tissues and cells. This study will help us to determine which chemicals, drugs, medicines or other lifestyle factors may be dangerous to us and need to be properly regulated.

Why have I been chosen?
We are inviting you to take part in this study because you have been admitted for a termination of pregnancy. Participating in this study will not affect your treatment in any way.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to sign a consent form at the ward where you are undergoing the termination of pregnancy. A decision not to take part or to withdraw from the study, after you have consented, will not affect the standard of care you receive.

What will happen to me if I take part?
We will take multiple specimens and fluid samples from the placenta and fetus. These will be used to carry out our research study on fetal development. Only samples required for our research will be kept in the laboratory. The nurse will also fill in a short form to record your age, height, weight, when you had your last period, whether you have had a previous pregnancy/termination and lifestyle and medication. These are data you have already provided at the Sexual & Reproductive Health clinic.

Any information that can identify you, such as your name, your address or your hospital number, will NOT be provided to us by the nurses. You will be identified by a unique study number (allocated by the nurses) that is NOT linked with your hospital number. You will have no direct involvement with the research.

What happens to the samples?
The samples will only be used for scientific research, including DNA analysis, both in this study and future ethically approved studies. Your samples will be identified with a unique study number and NOT with your details.

Once we have collected the samples that we require, your fetus will be sensitively handled by the NHS Grampian ARI Mortuary, according to current legislation, in exactly the same way as would have happened if you had not consented to take part to the study. We will never have a record of your name and address, so the results will be totally confidential. Once the samples have been fully anonymised and processed in the laboratory, you will not be able to withdraw from the study, because we may start analysing your samples as soon as they arrive in the laboratory.

The unused samples will be kept in the NHS Grampian Biorepository, along with the signed consent form, and may be used for ethically reviewed and approved future studies.

What are the disadvantages of taking part?
There are no health risks associated with taking part to this study, as your standard clinical care will not be affected.

What are the benefits of taking part?
There will be no direct benefit to you personally. We aim to provide information that may lead to a better understanding of how the fetus develops and that, in the long term, may help us identifying babies who need additional healthcare to live a healthy life.

What if something goes wrong?
The research does not involve any change to your standard clinical treatment, and therefore you cannot be harmed by taking part in this research project. If you wish to complain, or have concerns over any aspect of the way you have been approached or treated during the course of this study, the standard National Health complaint mechanisms are available to you.

Will my taking part in the study be kept confidential?
- All information, collected about you during the course of the research, will be kept strictly confidential. Your personal identifying details will not be entered into our research records. No information about you will leave the hospital.
- Should you wish to take part in the study, we will NOT inform your GP of your participation.

What will happen to the results of this research study?
The results of this study will be published in medical and scientific journals. You will not be identifiable in any report or publication.

Who is organising and funding the research?
- This research is organised by the Institute of Medical Sciences at the University of Aberdeen.
- Funding is provided by the UK Medical Research Council and other funders, including research charities.
- The doctors involved in this research will not be additionally paid for consenting and looking after you.

Who has reviewed this study?
The North of Scotland Research Ethics Committee (2) has reviewed this study.

Contact details for further information:

ABERDEEN	GLASGOW
Prof Paul Fowler Tel 01224 437582	Dr Michelle Bellingham Tel 0141 330 5728

Thank you for considering taking part in this study

You will be given a copy of this information sheet and a signed consent form to keep.