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INVESTIGATE-I: Patient Interview Study

Thank you for your interest in our interview study exploring the experiences of women invited to take part in the INVESTIGATE-I study, but who chose not to do so.

Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read this information carefully and discuss it with others if you wish. 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 want to take part.

WHAT IS THE PURPOSE OF THE STUDY?

The main aim of the study is to find out how women who were invited to take part in the INVESTIGATE-I study, but who chose not to do so, felt about that and how they made their decision. We are going to use the information from the interviews to help us decide whether to go ahead with a larger study. If we do go ahead, the information from the interviews will help us to improve the content of the information we give to women and the way in which we recruit women into the study.

WHY HAVE I BEEN CHOSEN?

We are asking you to take part in this interview study because you were invited to participate in the INVESTIGATE-I study itself. We are keen to talk to some women who chose not to take part following their invitation.

DO I HAVE TO TAKE PART?

No, it is up to you to decide whether or not to take part. If you decide to take part you are still free to change your mind at any time and you do not have to give a reason. If you decide not to take part, or decide to withdraw from the study at any time, your care will not be affected in any way.

WHAT WILL HAPPEN TO ME IF I DECIDE TO TAKE PART?

If you return the Interview Reply Slip enclosed, our interviewer Janet Willars will get in touch with you by letter, phone or email; whichever you have said you prefer. She will talk to you about the project and answer any questions you may have. You can then decide whether or not you want to take part.

If you agree to take part Janet will arrange to interview you at a time that suits you. This will take about 30 minutes to an hour. You can choose to be interviewed in your home or we can arrange an alternative location if you prefer.

We want to make sure we talk to a range of women in different circumstances, so in the unlikely event that we have already interviewed enough women like you, Natalie Armstrong, who is leading this part of the study, will contact you and let you know.

In the interview you will have the opportunity to discuss how you felt about being asked to join the INVESTIGATE-I study and how you made your decision about whether or not to take part. The interview will be audio recorded so that we have an accurate copy of what was said. If there are any questions you would prefer not to answer, then you don't have to and you are free to change your mind at any time. We will not put your name on the recording.

Our interviewer is not involved directly with the INVESTIGATE-I study. She will only have the contact details on the Interview Reply Slip (enclosed) that you send back to us if you are interested in taking part. She will at no time have access to any of your medical information.

The recordings from the interview will be typed up on a computer. Your name will not appear on the transcript. We will not tell anyone involved in the INVESTIGATE-I study which woman said what. The INVESTIGATE-I study team will only see a summary of the results.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

We do not expect any significant risks or benefits to you from taking part. It is possible you may become upset if discussing aspects of your treatment that you found distressing at the time. Please be assured that you do not have to answer any questions that you are uncomfortable with, and you can cease to participate at any time. At the end of the interview we will check that you are still happy for us to use the information you have provided. The results from the study may help us improve the experience of joining a similar study in future, and will help to ensure that taxpayers' money used to fund public research is used as effectively as possible.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

All information which is collected about you during the course of the research will be kept strictly confidential. All the information that leaves the study centre will have your name and address removed so that you cannot be recognised from it.

WHAT WILL HAPPEN TO THE RESULTS OF THIS STUDY?

We aim to use the results of the study to try to understand what it was like to be asked to join and take part in the INVESTIGATE-I study and how we can improve the experience for women joining similar research in future.

We will produce a report of our findings and may also publish the results in journals and present them at conferences. You will not be identified in any report or publication. It may be quite a while before we present information in this way, but if you want to know

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the results of this interview study, tell us and we will send you a summary as soon as they are ready.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

The main INVESTIGATE-I study is being organised by a team of doctors and researchers in Newcastle, Leicester, Sheffield and Swansea. Mr Paul Hilton is primarily responsible for the study; he is a Consultant Gynaecologist in Newcastle where he works closely on the study with colleagues in the Clinical Trials Unit.

The interview study is being led by Dr Natalie Armstrong; she is a social scientist at the University of Leicester and carries out research exploring people's experience of taking part in health-related research.

The INVESTIGATE-I study is funded entirely by the National Institute for Health Research (NIHR); this is an organisation set up to establish the NHS as an internationally recognised centre of research excellence by conducting leading research focused on the needs of patients and the public.

Thank you for reading this information. Our interviewer will be in touch with you shortly, if you return the Interview Reply Slip.