You are being asked to take part in a study that is designed to look at ways of improving the smear test. Although the present NHS Screening Programme is very effective against preventing cervical cancers, research has shown that by doing an additional test on the sample it would be even more successful. This new test would look for infection in the cervix caused by the **H**uman **p**apillomavirus or (HPV). Up to 70% of women have this infection in their cervix at some time in their life but in most cases this clears itself up. However it has been shown that if this virus infection persists, it can be associated with abnormal changes later on. Human papillomavirus testing may identify abnormal cells not detected by the smear test, or it may indicate the need for another smear sooner than the normal 3-5 year interval for smears. A study is needed to see whether HPV testing would improve screening. The trial is to be carried out in Greater Manchester and we need to recruit 28,000 women over 2 years. Smears in this trial will be taken in the normal way then transported in a special liquid. Liquid Based Cytology is simply a different technique of processing slides to be examined at the laboratory.

What will I have to do if I take part?

You make your appointment for a smear test at your GP's surgery or Family Planning Clinic. You will be asked to sign a **consent form** to say that you understand the trial, wish to participate and allow us to use the information collected. Each woman who agrees to take part will be allocated their own unique study number. The smear and HPV test will then be taken.

In order to see how effective the HPV test is we need to compare a group of women in whom the HPV result is known with a group of women in whom the HPV result is not known. One quarter of the women who take part will not be told of their HPV result. However you will still receive a letter from the Health Authority and the trial office regarding your smear result. All abnormal smears will be treated in the same way as they are now.

All information given will be treated confidentially

Do I have to take part?

Taking part is voluntary. If you decide not to participate you will still have your smear taken in exactly the same way. If you do enter the trial but wish to withdraw at any time then you are entirely free to do so. This will not affect your treatment.

What happens if I am allocated to the group where the HPV result is revealed?

You will be told both your HPV and smear test result. If your smear is abnormal, you will be managed under the current guidelines, the same as if you were not participating in the study. If the smear is normal, but the HPV result is positive we will repeat the HPV test 12 months later (in many cases the infection clears up itself). If it is still abnormal, you could choose between a repeat HPV test or a colposcopy (examination of the cervix). If the HPV test is still positive after 24 months we would wish to do a colposcopy.

What happens if I am allocated to the group where the HPV test is not being revealed?

Your management will be exactly how it is under the current system. You will be notified of your smear result and informed of any follow up where required.

Are there any benefits in participating in this study?

By taking part in this trial you will be assisting in providing evidence as to whether or not HPV testing picks up more abnormalities than the

smear test alone. The implementation of testing for HPV might mean that in the future those women with normal smears and negative HPV results would need only attend for a smear say every 10 years. Before any changes to the programme can be made studies such as this one need to be carried out.

Most women are anxious at the time of having a smear test. This usually resolves when the smear is reported as normal. We are looking to see if the new HPV test effects levels of anxiety and to do this some women will be asked to complete a questionnaire. **This will be posted to you approximately 2 weeks after your result letter. Once completed you should return it in the accompanying pre-paid envelope. Your compliance in this is entirely voluntary. It will not effect your participation in the trial if you decide not to complete the questionnaire. All information will be treated confidentially.**

What do I do now?

Go along for your smear appointment as normal, taking your consent form with you. You can then inform the doctor or nurse that you wish to participate. They can also answer any questions that you may have.

For further information about the trial please contact:

Paula Wheeler Trial Co-Ordinator

0161 000 0000

Trial nurses on: **0161 000 0000**

The University of Manchester

MANCHESTER 1824

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Patient Information Leaflet

We are inviting you to take part in a new study of cervical smear testing. Please read this leaflet for details.

CERVICAL SCREENING PROGRAMME NHS