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**Study Title: Lichen sclerosus diagnosis: which are the most important clinical diagnostic features?**

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**Faculty of Medicine & Health Sciences Research Ethics Ref: FMHS 39-0722**

This study is investigating which are the most important criteria to diagnose vulval lichen sclerosus.

Vulval lichen sclerosus (LS) is a skin disorder that affects the female genital area. Despite being quite common, there is lack of knowledge about LS amongst medical professionals and patients. It is often misdiagnosed and delays in diagnosis mean that treatment is not always started in a timely manner. These delays can lead to complications such as scarring and an increase in risk of cancer in the vulval area. We want to improve the recognition and diagnosis of LS amongst non-experts and patients by developing a simple diagnostic tool which is easily accessible.

We are inviting health professionals who treat LS and patient support group leads to take part in this project by providing their opinion on which are the most important diagnostic features for vulval LS. Please read through this information before agreeing to participate. You can ask any questions before deciding by contacting the researchers (details below). Taking part is entirely voluntary.

**What will I be asked to do?**

After clicking the next button at the end of this information page you will be presented with a consent page. You will then be asked to provide some basic demographic information (i.e. age, sex, race) and to answer some questions about yourself. You will then be presented with a 'long list' of diagnostic criteria and the survey will ask you to rate the importance of each criterion. The survey will have up to three rounds which will be sent out over a 3-month period. It is important that all of the rounds are completed, so that we can reliably use the data. Each round will last less than 10 minutes.

We would like you to answer all questions as honestly and completely as possible however if there is a question you are not able to answer, then there is an 'unable to answer' option. You can withdraw at any point during the questionnaire for any reason, before submitting your answers by clicking the Exit button/closing the browser. The data will only be uploaded on completion of the questionnaire by clicking the SUBMIT button on the final page. At this point it will not be possible to withdraw your answers.

**What are the disadvantages of taking part?**

It is possible that you may find the issues raised in the survey are upsetting or make you feel uncomfortable. Please take time to think carefully about whether it might be an upsetting or sensitive topic for you at the moment.

**What are the advantages of taking part?**

Your contribution together with others will help the researchers to understand more about the diagnostic features that are most important for vulval LS.



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### **Who will know I have taken part in the study?**

Your answers will be kept anonymous but members of the research team will know that you have taken part as it is necessary to track responses so that 3 rounds of the survey can be completed.

### **What will happen to your data?**

To ensure your privacy any details will be stored separately on a password protected database sitting on a restricted access computer system and would only be accessed by the research team. Data will be used for research purposes only and stored on a secure dedicated web server. Access will be restricted to the research team. Designated individuals of the University of Nottingham may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines. This data will be retained for at least 7 years or for longer if required. For further information about how the university processes personal data please see:

<https://www.nottingham.ac.uk/utilities/privacy.aspx/>

### **Who will have access to your data?**

The University of Nottingham is the data controller (legally responsible for data security) and the Supervisor of this study (named above) is the data custodian (manages access to the data) and as such will determine how your data is used in the study. Your research and personal data will be used for the purposes of the research only. Research is a task that we perform in the public interest.

Responsible members of the University of Nottingham may be given access to data for monitoring and/or audit of the study to ensure it is being carried out correctly.

### **What will happen after the survey?**

The survey will yield a 'short list' of diagnostic criteria for vulval LS. The short listed criteria will then be used in a multi-centre study to assess statistically which criteria and how many criteria are needed to adequately diagnose LS.

The results may be used in academic publications and presentations.

We would like your permission to use anonymised data in future studies, and to share our research data (e.g. in online databases) with other researchers in other Universities and organisations both inside and outside the European Union. This would be used for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified).

If you have any questions or concerns about this project, please contact:

Dr Rosalind Simpson (E-mail [Rosalind.simpson@nottingham.ac.uk](mailto:Rosalind.simpson@nottingham.ac.uk))

If you remain unhappy and wish to complain formally, you should then contact the FMHS Research Ethics Committee Administrator E-mail: [FMHS-ResearchEthics@nottingham.ac.uk](mailto:FMHS-ResearchEthics@nottingham.ac.uk)