

You previously took part in a clinical trial regarding melanoma. We are carrying out further research into melanoma and would like to inform you of this research, and give you the opportunity to contact us if you do not want us to use your samples or data for the study.

If you decide not to take part your clinical care will not be affected. You can decide to opt out of this study at any time.

Aims of our study

Within each cell in our body there are packets of information called genes which influence everything about us, including characteristics such as eye colour and how tall we are. We already know that there are genes which can increase the risk of certain cancers, including melanoma, and genes that influence how we respond to treatments, for example interferon.

Our aim is to identify genetic differences that will help us identify patients who will obtain a benefit from interferon treatment and those who will develop side effects. In the long-term this will help us choose the best treatment options for each patient individually. This research has only recently become possible because of scientific advances. It was not possible when you took part in the interferon clinical trial.

Why is this relevant to you?

You have previously been involved in a study in which you were either given interferon or no further treatment, after your operation to remove your melanoma and maybe also local lymph nodes. In this study we are using stored samples of your melanoma, any skin samples and any lymph nodes that were removed. Tissue samples like this are routinely stored in the hospital pathology laboratory for many years in case they are needed. From these samples we will identify genetic changes.

What will happen to my tissue samples?

With the help of the team who originally recruited you to the interferon trial, we will find your tissue samples that were removed, and transfer them to Leeds for analysis.

At your local hospital, the samples will be labelled in such a way that the laboratory researchers working on your sample will never have the name of the person the samples have come from.

From the sample we will extract genetic material and analyse the genes inherited from your parents and genetic changes in the melanoma cells. We will then identify any changes and see if they are linked to whether you have suffered a relapse or not, or if you received benefit or developed side effects from interferon treatment or not.

When the study ends remaining tissue will be returned to your local hospital. We will keep the small pieces of tissue and the genetic material we have removed. These samples will be kept for up to 20 years and may be used for ethically approved melanoma research in the future. These samples may be transferred to other researchers across the world, however they will be labelled with study number only and no other information identifying the samples as being removed from you.

What information do you need and what will happen to my information?

We will need information about your original melanoma, whether you have suffered a relapse and how you responded to your interferon treatment if you received it. This information has already been obtained for the purposes of the original interferon trial, so this information will be sent to us in Leeds. Again, this information will be labelled in such a way so researchers will not be able to tell whom the information relates to. We plan to keep this information for 20 years and it may be used again for the purposes of ethically

approved research. This may involve transfer to other researchers in the world and in this case your information will be labelled by study number only.

What do you need to do?

The information we require has already been obtained for the purposes of the original clinical trial and the samples are in your local hospital pathology departments so we do not need any further information or samples from yourself, and we will not need to contact you in the future.

Are there any risks involved?

The information we obtain about you and your melanoma will be kept strictly confidential as will any genetic information we obtain during the study.

What are the benefits for you?

Involvement in this study will not give you any benefits in the short term. In the long term, this study may help us identify genetic changes that will help predict benefit from interferon treatment. This may be beneficial to you in the future if you need further treatment and will be essential to patients who are diagnosed with melanoma in the future. However, overall the research is unlikely to benefit you directly.

Will you be informed of any results?

We are unable to provide individualized results from this study. This is because the true meaning of these results is unlikely to be clear for a long time. However, we expect to make the general study findings available as a plain English summary on the GenoMEL website (www.genomel.org).

This information sheet and the study protocol are available on the GenoMEL website (www.genomel.org).

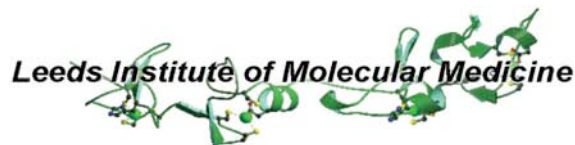
If you do NOT want to be involved or have further questions

If you would not like us to use your clinical information or tissue samples, you will need to inform us.

Please contact:

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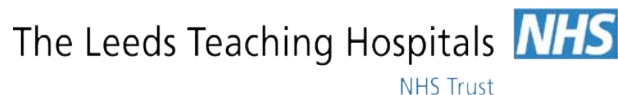
Please take time to read this information carefully and discuss it with your friends, relatives and GP if you wish.



The Leeds Institute of Molecular Medicine (LIMM) is part of the University of Leeds and dedicated to research into defining the molecules involved in human diseases and in research to convert these studies into therapies. This research will take place in the Section of Epidemiology and Biostatistics based at St. James's Hospital in Leeds. The focus of this group is on the contribution of genes to the incidence of disease in the general population and the joint effects of genes and environment. Particular research interests of this group involve the study of melanoma.



Cancer research UK is the UK's leading charity dedicated to cancer research. Our research group receives funding from this charity to continue cancer related research.



Leeds Teaching Hospitals NHS Trust is the largest trust in the UK and St. James's Hospital is the largest teaching hospital in Europe. St. James's is the regional centre for cancer care and this research will take place on the St. James's Hospital site in the Leeds Institute of Molecular Medicine.



Study Information Leaflet

Predicting Benefit From Interferon: Personalised Therapy for Melanoma



This leaflet is for people who took part in interferon trials (EORTC 18952, and 18991, Aim High)