**INFORMATION SHEET FOR CONSULTEES**

**UK Histiocytosis Registry**

This information sheet has been given to you as you have been identified as a possible consultee for someone who is eligible to donate samples to the UK Histiocytosis Registry. The attached Participant Information Sheet provides a detailed description of the study.

**Why is this person eligible to take part?**

This person has been identified as someone who could support medical research by giving a samples and medical information to the UK Histiocytosis Registry. Even very small samples are of great value for scientists trying to find out the cause of diseases or to identify new treatments. These samples may involve people with an illness or disability, and we may want to involve those people and invite those people to participate.

**What is a Consultee?**

Some people will have the ability, also called the “capacity”, to make their own decision whether to participate in the research or not. Other people, possibly those most affected by the illness, may not have that capacity. They may not be able to understand enough of the research to be able to take in the information and to weigh this up. They may not be able to make their own decision to give their consent to take part. This could be due to the illness causing confusion or because sedative drugs have been given to treat the illness. Sometimes in they may be unable to communicate a decision, for example when they are on a ventilator (breathing machine).

The Mental Capacity Act 2005 allows people to take part in research, even though they cannot give valid consent of their own. Instead of asking them for consent, the researcher must ask a Consultee who knows the person very well. The consultee is permitted to make a decision as to whether the person would have wished to take part in the research.

**Who can be a Personal Consultee?**

A Personal Consultee is any person who has a close relationship with the person and knows them well enough to be concerned about their welfare, for example:

• A family member, unpaid carer or friend

• A person acting under a Lasting Power of Attorney

• A court appointed deputy

**Who can be a Nominated Consultee?**

In circumstances where a Personal Consultee cannot be identified or a Personal Consultee is unable to attend the hospital, then a registered Medical Practitioner can act as a Nominated Consultee.

**Why have I been asked?**

You have been asked to act as a Personal Consultee because we think you might be willing and able to do this because of your close relationship.

If you have been approached as a Nominated Consultee, you are a registered Medical Practitioner who can advise on behalf of the patient and you are NOT a member of the research team.

**If I agree to be a Consultee, what do I have to do?**

We ask you to give your opinion on the past and present wishes and feelings of the person you are representing in relation to participation in the UK Histiocytosis Registry. Please read the information provided in the Participant Information Sheet. We would ask you to remember back to when the person you are representing had capacity and was able to express their own views. Did they express any specific or general views about involvement in clinical research?

You are not being asked about your own views about their participation in this study, clinical research or research in general. Please set aside any personal views you may have about the research and consider only the views and interests of the person you are representing. Please also consider the broad aims of the research together with the risks, benefits and practical considerations for the person you are representing.

If you advise that the proposed participant would want to be involved, we will include that person’s samples in the UK Histiocytosis Registry. If the proposed participant shows any sign at any time that they are not happy to be involved, you can change your advice at any time without giving a reason. Their samples and medical information will be removed from the Registry. If the person regains capacity we will also re-consent them and make sure that they wish to continue participating. If they are not happy to be involved then we will also remove their samples and medical information from the Registry. It will not be possible to withdraw any findings from research work already undertaken before they withdrew their permission.

**What will happen if I advise against participation in the study?**

We will abide by your advice and the samples will not be taken for research and will be disposed of. A decision not to take part, or to withdraw at any time, will not affect the person’s current or future medical care.

**Where can I get more information and guidance on being a Personal Consultee?**

More information is available from:

Department for Constitutional Affairs (2007). Mental Capacity Act 2005 Code of Practice

<https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/497253/Mental-capacity-act-code-of-practice.pdf>

Department of Health (2008). Guidance on nominating a consultee for research involving adults who lack capacity to consent

[http://webarchive.nationalarchives.gov.uk/20130123193236/http:/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\_083131](http://webarchive.nationalarchives.gov.uk/20130123193236/http%3A/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083131)

**Further information**

You can discuss any issues raised in this leaflet with the member of staff who will be taking consent for samples to be stored for research. For more information see the UK Histiocytosis Registry website ([www.ukhr.org](file:///Users/MC2020/Documents/Ethics/Histiocytosis%20Registry%20Ethics/Amendment%201%20Jan%202022/Consultee%20consent%20final%20version/www.ukhr.org)) or contact the registry project manager by e-mail (sarah.pagan@nhs.net).

**What do I do if there is a problem?**

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated by members of staff, NHS and Newcastle University complaints mechanisms are available to you. Please ask the research staff if you would like more information on this.

If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202

Alternatively, if you wish to make a formal complaint you can contact the Patient Relations Department through any of the details below:

Telephone: 0191 223 1382 or 0191 223 1454

Email nuth.patient.relations@nhs.net

# UKHR contact for further information

If you have questions regarding the UKHR, you can contact Dr Matthew Collin, Professor of Haematology, Institute of Cellular Medicine, Newcastle University; Tel (0191) 2139382; email matthewcolllin@nhs.net or sarahpagan@nhs.net. Further information about the UKHR can be found on our website: [www.UKHR.org.uk](http://www.UKHR.org.uk)

If you would like to find out more about histiocytosis, the following websites may be useful for you. However, we are not responsible for the contents of these websites: The Histiocytosis Association ([www.Histio.org](http://www.Histio.org)); Histio UK ([www.histiouk.org](http://www.histiouk.org)).

**Thank you for reading this leaflet, it is yours to keep; you will also be given a copy of the signed consent form that you may wish to keep.**