SWEET

Participant Information Sheet

Title: Supporting Women with adhErence to hormonE Therapy following breast cancer

We are carrying out a research study for women who are taking hormone therapy after surgery for breast cancer and we would like to invite you to take part. Joining the study is entirely up to you.

Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team can go through the information with you, to help you decide whether or not you would like to take part and answer any questions you may have.

Please take time to read the following information carefully. You may wish to speak to others before deciding whether to take part.

Part 1 tells you the purpose of this study and what will happen if you take part.
Part 2 gives you more detailed information about how the study will be carried out.

PART 1:

1. What is the purpose of the study?

Many women like you are prescribed hormone therapy following diagnosis and hospital treatment for breast cancer. Hormone therapy significantly reduces the chances of breast cancer returning. Usually, women are recommended to take hormone therapy, in the form of a daily tablet, for several years. However, we know that some women either do not take this medication everyday as prescribed or sometimes stop taking it all together (known as "poor adherence"); this can increase their risk of breast cancer returning.

We have developed a support package (called HT&Me) which aims to encourage and support women to take their hormone therapy as prescribed, and hopefully reduce the risk of breast cancer returning.

The purpose of the study is to investigate whether the HT&Me support package can improve hormone therapy adherence, and quality-of-life when compared to the standard NHS follow-up care offered in your hospital right now.

2. Why have I been invited?

You have been invited to take part this study because you have been treated for a hormone sensitive breast cancer. Treatment for this includes taking hormone therapy (sometimes called endocrine therapy or hormone blocking therapy) every day to reduce risk of your cancer coming back. This research study will offer 1460 women prescribed hormone therapy after breast cancer, across up to 80 UK NHS hospitals, the opportunity to take part.

This study is for all women prescribed hormone therapy after breast cancer surgery. Even if you have started well on hormone therapy, and do not have any problems or questions, we would still like you to take part.

3. Do I have to take part?

No. Taking part in this study is entirely voluntary and only done with permission from you (consent). Your routine NHS care will not be affected if you do not wish to take part. If you do not wish to take part, you do not have to give a reason why.

If you do decide to take part, you can change your mind at any time by letting your research team know, you do not have to give a reason for withdrawing from the study and your routine NHS care will not be affected if you do decide to withdraw. More information can be found in section 16.

4. What will happen to me if I take part?

If you decide to take part, we will ask you to complete and sign a consent form. If you are not attending the hospital for an appointment, we can do this over the phone. We will collect some details about you such as your date of birth, ethnic group, contact details (including name, address, email address and telephone number), [NHS number or insert devolved nation equivalent] and medical history (see section 20 for full details). We will also ask you to complete a questionnaire booklet about your quality-of-life and the health services you access. This will take around 30 minutes in total.

Once this information is collected, you will then be randomly allocated into one of the following two groups by a process called randomisation. This is done by a computer so neither you, nor the research team can choose which group you are randomised to. There is an equal chance of being selected for each group, like tossing a coin. We will tell you which group you have been randomised to.

- **Group A: You will receive the HT&Me Support Package in addition to routine NHS care**
- **Group B: You will receive routine NHS care**

If you are randomised to Group A you will receive access to the HT&Me Support Package which involves:

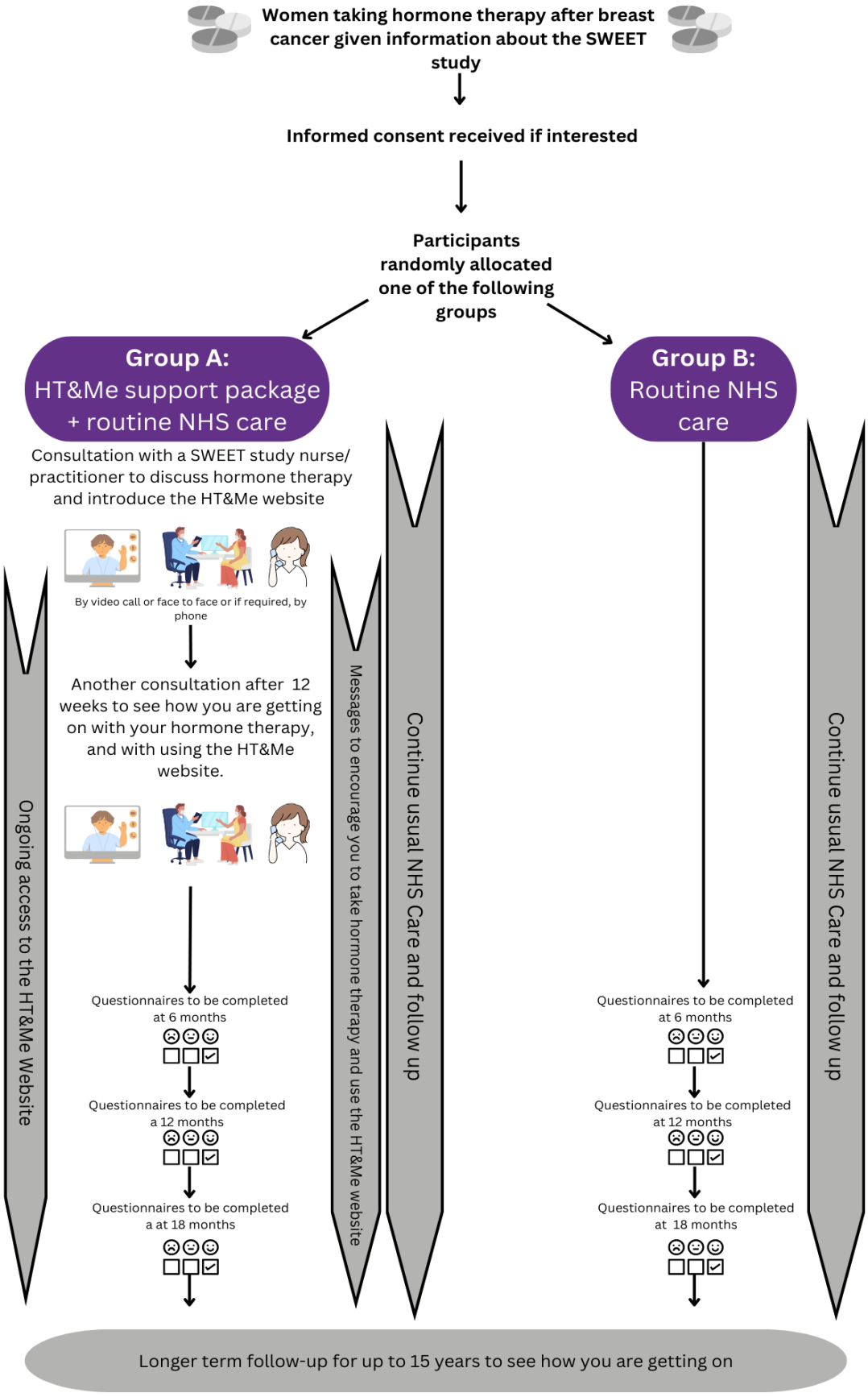
- A consultation of around 30 minutes with a HT&Me study nurse/practitioner (either based at your local hospital site, or via the charity Breast Cancer Now) to discuss hormone therapy, answer any questions you might have and introduce the HT&Me website. This appointment may be delivered in person, by video call or if required by telephone call, appointments with a Breast Cancer Now nurse will always be completed over video call.
- Access to the HT&Me website which contains short videos, information, tips & tools to support you to take your hormone therapy every day (e.g. you can set reminders to take your hormone therapy or order repeat prescriptions), get tips for managing side-effects, and information about how to get further support, if you need it.
- After 12 weeks, you will have a follow up consultation with the HT&Me study nurse/practitioner (based at your site, or via Breast Cancer Now) to see how you are getting on with your hormone therapy and the HT&Me website. For a few women, we might record their consultations; this is simply to check what information they have been given and that the consultations are going as planned. We may also ask you to provide feedback of the appointments via text message.
- You will also be sent some messages by email or text, to remind you about the importance of taking your hormone therapy and that the website may be a useful resource for you.
- You will also have your usual NHS care, including any follow-up for your breast cancer.

If you are randomised to Group B you will continue with your usual NHS care (including any follow-up for your breast cancer) and hormone therapy as prescribed. You will not receive any additional or other care.

For both groups, we would also like to follow you up at 6 months, 12 months and 18 months to see how you are getting on with your hormone therapy, how often you are taking it and to complete some health-related quality of life questionnaires. We would also like to ask you about your use of health services. As part of checking how you are getting on with taking your hormone therapy, we would also like to collect information about your prescriptions, including how often you request and collect breast cancer prescriptions and what other medications you are taking. This information will be collected from [insert dataset name according to devolved nation] held by [data controller according to devolved nation (e.g. NHS England or equivalent)] or your GP. To get this information we will need to provide them with some details about you and your breast cancer diagnosis.

You may also be contacted for up to 15 years after you enter the study to see if you would be happy to tell us how you are, for the purpose of providing longer term information. As part of this follow-up, we may also want to collect information about any breast cancer treatment related prescriptions you are taking, again through [insert data controller according to devolved nation (e.g. NHS England or equivalent)] or your GP.

We may also ask you to take part in an interview (either by telephone or video call) with an experienced researcher to talk about your experience of the trial. It is your choice if you would like to take part in an interview, not everyone will be asked to take part, and this will only be with a small number of participants. The image below may help you understand what is involved:


Women taking hormone therapy after breast cancer given information about the SWEET study
Informed consent received if interested
Participants randomly allocated one of the following groups
Group A: HT&Me support package + routine NHS care
Group B: Routine NHS care
Consultation with a SWEET study nurse/ practitioner to discuss hormone therapy and introduce the HT&Me website
By video call or face to face or if required, by phone
Another consultation after 12 weeks to see how you are getting on with your hormone therapy, and with using the HT&Me website.
Questionnaires to be completed at 6 months
Questionnaires to be completed a 12 months
Questionnaires to be completed a at 18 months
Questionnaires to be completed at 6 months
Questionnaires to be completed at 12 months
Questionnaires to be completed at 18 months
Ongoing access to the HT&Me Website
Messages to encourage you to take hormone therapy and use the HT&Me website
Continue usual NHS Care and follow up
Continue usual NHS Care and follow up
Longer term follow-up for up to 15 years to see how you are getting on

5. What do I need to take part?

To be able to access the HT&Me website you will need to have access to a smart phone, tablet (e.g. iPad), or computer that can connect to the internet, and a working email address. If you are not sure whether you have the right type of device, please speak to your research team. We may be able to loan you a device (e.g. a tablet) if you do not have access to one.

6. What are the possible benefits of taking part?

We do not know whether the HT&Me support package will be effective in helping women to continue taking their hormone therapy as prescribed or in improving quality-of-life, however women in Group A, who receive the intervention will receive more information and support whilst taking their hormone therapy and they may find this helpful.

You may not directly benefit from taking part in this research, but your participation will help guide support for women with breast cancer taking hormone therapy in the future.

7. What are the possible disadvantages and risks of taking part?

Although there is no physical risk to you from taking part in the study, we appreciate that being asked questions about your cancer may be upsetting. If you want to talk to someone at any time during the study, contact details of helpful organisations are provided at the end of this information sheet.

8. What happens when the research study stops?

Once the research study stops you will continue with any standard hospital treatment and follow-up. We will share the updates and results about the research in different ways (see section 17)

9. Who is organising and funding the research?

This research is managed by The Warwick Clinical Trials Unit (WCTU) at the University of Warwick (UoW). The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) is the sponsor for the study. The research team is based at Newcastle University, Oxford Brookes University, University College London and Oxford University. This study is funded by The National Institute for Health Research (NIHR) (project reference **NIHR200098**). NIHR would like you to know that any views expressed here are not necessarily those of the NIHR or the Department of Health and Social Care.

10. What if there is a problem?

If you have any concerns about any part of this study, you can talk to the team involved who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the [NHS complaints procedure or insert equivalent for devolved nations].

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

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

Telephone: 0191 223 1382 or 0191 223 1454

Email: nuth.patient.relations@nhs.net

Address: Patient Relations Department

The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH)
The Freeman Hospital
Newcastle upon Tyne
NE7 7DN

This study is covered by NHS indemnity insurance. In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against The Newcastle upon Tyne Hospitals NHS Foundation Trust but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you (if appropriate).

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter: nuth.dpo@nhs.net

If you are not satisfied with our response or believe we are processing your personal data or data access from [NHS England or insert equivalent for devolved nations] in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO is the UK's independent authority which was set up with the aims of upholding public interest rights, promoting public body openness and protecting data privacy for individuals. The ICO can be contacted via: https://ico.org.uk/concerns/.

11. Will my taking part be kept confidential?

All information collected about you for this study will be subject to the current UK General Data Protection Regulation (UK GDPR) and will be kept strictly confidential. The only reason we would break confidentiality would be in an emergency where your health, or someone else's health, was in danger and when we may need to let your GP, clinical team or someone else know so they can help you. **More information about how your information is kept secure can be found in section 21.**

All data requested, transferred, received, processed, and stored as part of this research will be completed under strict controls to protect your identifiable information. All organisations have Data Protection Officers (DPO) that are responsible for ensuring that there are sufficient safeguards in place.

12. Involvement of your General Practitioner (GP)

We will inform your GP that you are talking part in this research study, and we may approach them to access your prescribing data.

13. What are my choices about how my information is used?

Your rights to access, change or move your information are limited as we need to manage your information in specific ways in order for the research to be reliable and accurate.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

To safeguard your rights, we will use the minimum amount of personally identifiable information possible. If you wish to find out more about how we use your information, you can read the privacy statement on the NuTH and University of Warwick websites.

https://www.newcastle-hospitals.nhs.uk/help/privacy/privacy-notice-for-patients/

warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice

Part 2:

14. Contact details for further information

If you have any further questions, please contact your research team:

Principal Investigator:……..Tel:.....

Research Nurse/ Trial Coordinator:……
Tel:……

15. What if relevant new information becomes available?

Sometimes during a research study, new information becomes available. If so, a researcher will contact you to discuss your involvement in the study. If you decide to withdraw from the study, you should discuss your care with your doctor. If you continue in the study, you may be asked to sign an updated consent form if appropriate.

16. What will happen if I don't want to carry on with the study?

If you decide that you do not want to carry on with the study, we will only use the information that you have already given us to that point.

If we are unable to contact you to complete the study follow-up (for example if you have changed address), we may try to continue collect this information remotely using your hospital or GP records unless you tell us you would like to withdraw from the study.

If you wish to withdraw consent at any time, please contact your research team.

In the unlikely event that during the study, you are no longer able to make the decision to continue in the trial (for example if you lost capacity to make decisions), you would be withdrawn from the study, but we would keep information about you that we already have.

17. What will happen to the results of the study?

We provide updates on the progress of the trial on our website https://warwick.ac.uk/fac/sci/med/research/ctu/trials/sweet/. We will post newsletters, the latest version of this document, information sources, patient advisory groups etc on the website.

At the end of the study, we will publish the findings in medical journals that are freely accessible and at relevant conferences. You will not be identified in any reports or publications. Once all participants have been followed up and the results have been analysed, we will make a copy of the study results available via an end of study information sheet and will add this to the study website. If you have asked for a copy of the results, this will be posted out to you by your hospital site.

18. Who has reviewed the study?

Any research that involves the NHS and patients is subject to review by an independent group of people called a Research Ethics Committee. This committee is there to protect your interests. This study has been reviewed and given favourable opinion by South Central - Hampshire B Research Ethics

Committee (23/SC/0254). This study will be run in accordance with the UK Policy Framework for Health and Social Care Research. Women who have lived experience of breast cancer and hormone therapy have also reviewed this study, helped to design the HT&Me support package, and been involved in the study design.

19. What should I do if I have any questions after taking part in the study?

If you have questions about the study, please contact the research team at your hospital (i.e. the people who approached you about the study). If you would like more information, advice or support about living with breast cancer you could contact the following charities:

[For example, or insert equivalent for devolved nations]:

Breast Cancer Now (website: https://breastcancernow.org/)

Macmillan Cancer Support (website: https://www.macmillan.org.uk/)

Maggies Cancer Support Centres (website: http://www.maggies.org)

Should you be experiencing any difficult emotions or feelings and wish to speak to someone, please contact Mind for advice (website: https://www.mind.org.uk/).

20. Will my taking part be kept confidential?

The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) are the sponsor for the study, based in the United Kingdom. The study will be managed by Warwick Clinical Trials Unit at the University of Warwick (UoW).

How will we use information about you?

We will need to use information from you, your medical records, your GP and national databases for this research project. This information will include:

- Name
- Your [NHS number or insert devolved nation equivalent],
- Date of birth
- Contact details (including telephone number and email address)
- Relevant health information

NHS hospitals, NuTH and UoW will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

With your consent, some of your contact information will be shared with third parties only for the purpose of the study. If you agree to take part your name, telephone number and email address will be shared with a third-party text and email messaging service so that we can contact you about the trial. Personal identifiable data shared with or stored by third parties will be securely deleted when it is no longer needed and the trial has ended.

Where will information about me be stored, and who will it be shared with?

By taking part in the study, you will be agreeing to allow research staff from UoW to look at the study records, including your medical records. The only people at the UoW and NuTH who will have access to information that identifies you (such as your name and contact details) will be SWEET staff working

on the study, people who host the secure database where your information will be stored, or people who will audit the data collection process. Staff members working on the study from Oxford Brookes University (OBU) and University College London (UCL) may also be provided with information that identifies you for the purpose of contacting you for interviews where you have consented to this. It may also be necessary to allow authorised personnel from government regulatory authorities or the Sponsor to have access to your medical and research records. This is to ensure the study is being conducted to the highest possible standards. People who do not need to know who you are will not be able to see your name or contact details; your data will have a code number instead. Information collected about you and provided to the SWEET study team will be securely stored at the Trial Office at the Warwick Clinical Trials Unit, on paper and electronically. With your permission, the SWEET Trials Office would like to hold a record of your personal details. This is required so we can provide you access to the HT&Me website (if applicable), send you questionnaires electronically (if requested) and link your record to [NHS England or insert devolved nation equivalent] and/or your GP.

Personal identifiable information (including your name, date of birth and [NHS number or insert devolved nation equivalent]) will be shared securely with [NHS England or insert devolved nation equivalent]and your GP. This allows them to provide the linked information about your prescribed medicines. Data from [NHS England or insert devolved nation equivalent] or GPs will be kept separate from personal information supplied at the start of the study.

We may also need to share this information (and information about your treatment) with Breast Cancer Now (BCN) (for sites where the remote appointments are delivered by Breast Cancer Now), this will enable a trained member of the BCN team to contact you. Breast Cancer Now are a registered charity with professional expertise in breast cancer care. Breast Cancer Now may be working in close partnership with your hospital to help deliver this study to more women, your research team will let you know if this is the case. Staff from Breast Cancer Now working on the study have signed an agreement to safeguard and protect the information they have access to about you.

When you join the SWEET study, you will be given a unique study number; we will only use this number and your initials in any communication about you. We will not use your name. The people who analyse the information will not be able to identify you and will not have access to your name or contact details.

Interview data and appointments will be recorded using encrypted audio devices or a communication platform such as Microsoft Teams or Zoom. Recordings will be downloaded as soon as possible and stored on a secure, encrypted study area on the university servers. Once downloaded, the original recording will be deleted from its original source. Recordings will be transcribed (typed out) so we can analyse them. Sometimes we may need to use a third-party (external company) to help with this. As interviews and appointments may contain personal information about you (such as your name, or information about your health), we will only use a trusted and approved company who will sign a confidentiality agreement to protect the information they have been given.

Information about you will be kept for up to 10 years after the end of study and will be stored securely (archived). Where this information does not need to include your personal details, these will be removed before archiving.

What information does the HT&Me website collect?

The HT&Me website requires your name, email address and contact number to create an account. You will be able to set a secure password so no one else can access your account. Throughout the study, the HT&Me website will automatically collect information about how women are using it. The information collected on your use of the website ("analytics") will be anonymous and will be stored securely on a "cloud" (secure online storage service) which is hosted within the UK. Any personal or identifiable information (including your name and contact details), that the website records will be securely stored online within a two-layer encrypted folder and stored securely on the cloud hosted in the UK.

21. Who is the data controller?

Both NuTH and UoW will act as joint data controllers for the study, this means that they are responsible for looking after your data and using it properly. Under the General Data Protection Regulation (GDPR), the 'Data Controller' is responsible for what happens to data which is collected.

22. Taking part in future research

If you agree to take part, we may use information collected for future research. Any future research will only proceed if approved by a Research Ethics Committee where necessary. You may be contacted about opportunities to take part in future research studies in this area (if you have consented to this), you will be provided with full information regarding each study and you are free to decide if you wish to participate or not. From time to time, we may also be asked to share study information with researchers running other studies. This is so that researchers can perform analysis on all the collected data to answer other important questions about adherence to hormone therapy. Any such request is carefully considered by the study researchers and will only be granted if the necessary procedures and ethical approvals are in place. This information will be anonymised or coded (pseudonymised) and will not identify you in any way. The information will only be used for the purpose of health research and cannot be used to affect your care. It will not be used to make decisions about future services available to you, such as insurance. You will not be identified in any report, presentation or publication arising from this or any other study.

23. What is the lawful basis for processing your data?

The lawful basis for carrying out this research study under UK GDPR is 'Task in the Public Interest' as research cited as part of the University's duties. Also, as we are collecting special categories of personal data, this study also has a second lawful basis (Scientific Research).

24. Where can I find out more about how my information will be used?

You can find out more about how we will use your information:

- At www.hra.nhs.uk/information-about-patients/
- By asking one of the research team
- By contacting the Data Controller at nuth.dpo@nhs.net

Thank you for taking the time to read this information sheet and consider taking part in this study.