

RAPID-RT: experiences of an opt-out approach to health data sharing

Participant Information Sheet for Interviews with Patients

We invite you to take part in a research study.

Joining the study is entirely up to you. Before you decide whether to take part, we would like you to understand why the research is being done and what it will involve for you.

We appreciate that this is a difficult time for you and that you have a lot of information to process. Please take time to read this information sheet carefully. Discuss it with friends and relatives if you wish.

Ask us if there is anything that is not clear or if you would like more information.

You can contact the research team at any stage by emailing the-christie.rapidrt.patients@nhs.net

Important things that you need to know

We want to ensure that patients and clinicians are comfortable with how studies use information routinely collected as part of patient care to improve treatments, so that the studies can be as inclusive as possible.

If you choose to take part, you can stop taking part in the study at any time.

If you choose not to take part this will not impact the standard of care you are receiving now or in the future.

In this part of the research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it.

We will make sure no-one can work out who you are from the reports we write. The full information sheet will tell you more about this.

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If you have any questions about this study, please talk to the doctors who organise it: Professor Corinne Favier-Finn via her secretary on 0161 446 8200

1 Why are we doing this study?

This research is part of the RAPID-RT study, which is designed to develop a new method to help us work out whether changes made to radiotherapy treatments in the clinic are improving patient care. This study is using anonymised data collected from the medical records of patients with stage I to III lung cancer who are receiving radiotherapy for their cancer.

The method the RAPID-RT develop has the potential to greatly improve outcomes for patients receiving radiotherapy and many other treatments. These improvements can only be made if patients and clinicians are comfortable with how patients' data is used in such studies. Patients have told us that they think it is ok for anonymised data to be used in these types of studies unless patients specifically opt out. The aim of this research is to ask patients and clinicians with experience of the RAPID-RT study whether they have found this to be acceptable.

This research is being conducted by researchers from the University of Manchester, in partnership with The Christie. The University of Manchester team is led by Dr Sarah Devaney, and the interviews will be conducted by Dr Catherine Bowden.

All patients over the age of 18 receiving radiotherapy to treat stage I-III lung cancer at the Christie NHS Foundation Trust are eligible to take part in this research.

2 Why have I been invited to take part?

You have been invited to take part in this research because you are contributing your data to the RAPID-RT study, or you have opted out of doing so. This means that you have experience of being eligible for inclusion in this study on an opt-out basis. We hope to learn from your experience so that we can design future studies that are as inclusive as possible.

3 What will happen if I take part?

If you agree to take part, we will ask you to sign a consent form for this study. We will then ask you to provide contact details, some details about yourself (year of birth, gender, postcode, ethnicity) and ask you to let us know whether you chose to include your data in the RAPID-RT study or opt-out. We will use this information to make sure that the views and experiences collected reflect a diverse population.

Using your contact details you may be invited to a one-to-one interview with one of our researchers, to talk through your experience of deciding whether your data may be used in the RAPID-RT study, and, if you chose to opt out, how you found that process. If you want to, you can bring someone who has been supporting you through your treatment, such as a friend, relative or carer, to the interview and they can support you and give their views too if they wish. If you would like to bring a supporter and they are happy to attend, please let us know and we will provide an Information Sheet for Supporters for you to give to them. We will also ask them to sign a consent form before they take part in the interview.

There are no right or wrong answers: we are simply interested in what you have to say and what you think. Unfortunately, it is likely that we will not be able to interview everyone who consents to take part. If we are unable to schedule a convenient time around your radiotherapy appointments or we are unable to accommodate your interview we will let you know using your contact details. Following this, we have no basis to keep your personal information and will permanently delete this data.

If you are interviewed, the interview would last no more than 1 hour, and take place on Microsoft Teams (online videoconferencing platform), or in person at The Christie (your choice). The interview can be arranged to coincide with when you attend the Christie for treatment or for another date and time that is convenient for you.

We will audio-record face-to-face discussions (voice only) so that we can fully consider and review all that is said. Interviews conducted online (via Microsoft Teams) will automatically be video recorded and will capture your voice, head and shoulders as you appear in the Microsoft Teams format (you can turn your camera off if you do not wish to be videoed). The video file will be deleted and will not form part of the study. A University of Manchester-approved transcription service using a secure file transfer system will type up transcripts of the audio recordings of the discussions before we analyse them in our research. All transcripts will be checked for accuracy by the research team, after which the audio files will be deleted. Transcripts will only be labelled with your study ID (a unique code) rather than your name.

If you would like to receive a copy of the transcript, you can indicate this on the consent form and a copy will be provided. If at that stage you have any comments on the transcript or would like to clarify anything that was said, you can let the research team know by emailing them at the-christie.rapidrt.patients@nhs.net.

If you take part in an interview you will be invited to take part in a second interview 6 months later to see if your views have changed. You do not have to take part in a second interview if you do not wish to.

4 What are the possible benefits of taking part?

By taking part you will be helping us to design future studies that are acceptable to patients and clinicians so that they can be used to improve treatments for future patients.

5 Will I be compensated for taking part?

Yes, we are offering a £20 Love2Shop voucher to all interviewees in recognition of your time. If you take part in a second interview you will be offered another £20 Love2Shop voucher.

6 What are the possible disadvantage and risks of taking part?

The risks are limited to those associated with using the data you provide in the course of the interviews. Names and identifying details will be removed from the interview data by the research team and replaced with a participant number to minimise the risk of you being identified from the data.

7 What happens if I do not want to take part or change my mind?

- It is up to you to decide whether or not to take part.
- If you do want to take part and you have already provided written consent, please contact the team at the-christie.rapidrt.patients@nhs.net and we will ensure you are not contacted again.
- If you do decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. We will include any views from interviews that you we have already completed in our analyses unless you specifically ask us to remove this. However, it will not be possible to remove your data from the project once it has been anonymised, as we will not be able to identify your specific data. This does not affect your data protection rights.
- If you decide not to take part you do not need to do anything further.

8 What if there is a problem?

If you have a concern about any aspect of this study, you should speak with any of the research staff or the Chief Investigator, Professor Corinne Faivre-Finn via her secretary on 0161 446 8200.

If you remain unhappy and wish to complain formally, the normal NHS complaints mechanism will be available to you. Details can be obtained from the Patient Advice and Liaison Service at your hospital.

9 How will we use information about you?

We will need to use information from you for this research project.

If you agree to take part in this research, your details will be securely stored at The Christie. This will include specifically:

- Your name
- Your contact details (telephone number or email address)
- Your year of birth, gender, postcode (optional), and ethnicity (if you agree to provide these)
- A record of your consent

If you consent to taking part in an interview, your name, contact details, year of birth, gender, postcode, ethnicity and opt-out status, will be shared with the research team at the University of Manchester who may contact you to arrange an interview. This is to ensure we collect a range of views from different backgrounds. It is likely that we will not be able to interview everyone who consents to take part. Data collected from anyone who is not interviewed will be destroyed immediately after patients have been informed of this outcome and will not form part of the final data set.

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 (Study ID) instead. We will keep all information about you safe and secure and this study ID will never be linked to your hospital notes.

If you take part in an interview on Microsoft Teams, your participation in this research will be recorded and your personal data will be processed by Microsoft. You can find details of how your data would be processed at <https://learn.microsoft.com/en-us/microsoftteams/teams-privacy>

The recordings will be removed from Microsoft Teams and stored on University of Manchester managed file storage as soon as possible after the interview.

If you participate in an interview and wish to receive the Love2Shop voucher as a thank you for your time, your full name and email address will be shared with our Finance department who will send the payment to you. Your full name and email address will be securely retained by Finance for a period of up to 7 years for audit purposes only and then destroyed. It will not be used by them for any other purpose. Alternatively, if you receive a physical voucher only your name will be shared.

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.

If you indicate that you are happy to be contacted about taking part in future research activities as part of this study, we will store your name and email address so that we may contact you. Only the research team will be able to access this information and it will be deleted at the end of the study.

What are your choices about how your information is used?

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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

- At www.hra.nhs.uk/information-about-patients
- By visiting <https://documents.manchester.ac.uk/display.aspx?DocID=37095>
- Our leaflet available from: <http://www.hra.nhs.uk/patientdataandresearch>
- The Christie's Data Protection Officer - the-christie.dpo@nhs.net
- By asking one of the research team

10 What will happen to the results of the study?

At the end of the study, the results will be analysed and published in academic journals and/or presented at conferences. This may include direct quotations from the interviews. However all data will be fully anonymised and

no personal details such as name or address will ever be included in any publications or presentations to protect patient confidentiality.

If you would like to obtain a copy of the published results, please let the research team know on the consent form.

11 Additional information

Who has organised this study?

The Christie NHS Foundation Trust is legally responsible for the study.

Who is funding the study?

The National Institute for Health Research is funding this study.

Who has reviewed this study?

All research in the NHS is reviewed and approved by an independent group of people, called a Research Ethics Committee. It has also been reviewed by Research and Development department at The Christie. This is to make sure that your safety and rights are respected throughout the study. This study has been approved by the North West - Haydock Research Ethics Committee, 22/NW/0390.

Further information about cancer, including how to find support:

Cancer Research UK www.cancerresearchuk.org

Macmillan Cancer Support

www.macmillan.org.uk

Thank you for considering entry into this study. Should you decide to take part in the study, you will be given a copy of the information sheet and a signed consent form to keep.