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

Participant Information Sheet for Interviews with Patients – information for supporters

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

You have been invited to take part as a supporter of a patient who has been invited to take part in an interview to find out how comfortable patients are with studies that use information routinely collected as part of patient care to improve future treatments.

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 involvement of the person you support or their cancer treatment.

In this research study we will use information from your participation in the interview. 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 Faivre-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.

The method that RAPID-RT will 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 person you support have been invited to take place in two interviews to find out their experience of being part of the RAPID-RT study and 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.

2 Why have I been invited to take part?

You have been invited to take part in this research because you are a supporter of a patient that is either contributing data on their cancer treatment to the RAPID-RT study, or they have opted out of doing so. We hope to learn from their experience so that we can design future studies that are as inclusive as possible. From speaking to other patients we know the importance that some patients place on being able to discuss their cancer pathway and involvement in research with friends, families and carers so that they are able to make the best decisions. The person you support thinks that you might be able to support them in the interviews they have agreed to take part in. You can also provide your views on them being part of this research if you wish.

3 What will happen if I take part?

The person you support has agreed to take part in two interviews, one during their radiotherapy treatment and one in about 6 months. If both of you agree, we would like you to come with them to one or both of these interviews and offer support during the interview and answer any questions from your view point if you would like. If you attend the interview, we will ask you to sign a consent form for this study.

There are no right or wrong answers to any of the questions. 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 at a date and time that is convenient.

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 the study ID (a unique code) and never labelled with your name.

If you would like to receive a copy of the transcript, you can indicate this on the consent form and provide an email address 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.

The person you support will also be invited to take part in a second interview 6 months later to see if their views have changed. If they wish, you are welcome to attend and participant in the second interview. We will take separate consent at this stage.

4 What are the possible benefits of taking part?

By taking part you will be helping us to ensure that future studies we design are acceptable to patients, their supporters 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 the 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. Your participation choices will not affect the participation of the person you support.
- 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.

This will include specifically:

- Your name (as part of the consent form)
- Your email address (if you provide this information to receive a copy of the transcript of the interview or study results or so that we may contact you about taking part in future research as part of this study)

All information about you will be kept safe and secure by the research team at the University of Manchester.

People who do not need to know who you are will not be able to see your name or contact details. Your data will be labelled with the same code number (Study ID) that we give to label the information we collect on the person you support.

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 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.

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.

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 names will ever be included in any publications or presentations to protect 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.