

# **RAPID-RT: when should a change to radiotherapy be measured using rapid-learning?**

## **Focus Group Participant Information Sheet (PIS)**

You are being invited to take part in a research study. The aim of this research is to ask patients, their supporters, and the public, when they think it is acceptable to use patients' data to measure a change that has been made to radiotherapy treatment.

Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information.

Thank you for taking the time to read this.

### **About the research**

#### **➤ Who will conduct the research?**

This research is being conducted by researchers from The University of Manchester, in partnership with The Christie Hospital. The University of Manchester team is led by Professor Sarah Devaney, and the focus groups will be conducted by Dr Catherine Bowden (The University of Manchester) and Hannah Turner-Uaandja from Vocal (a not-for-profit organisation that helps people have a voice in health research in Greater Manchester).

#### **➤ What is the purpose of the research?**

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 that RAPID-RT develops has the potential to monitor the effect of treatments on patient outcomes in real-time allowing treatments to be rapidly optimised 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.

The aim of this research is to ask patients, their supporters, and the public, when they think it is acceptable to use patients' data in this way.

➤ **Am I suitable to take part?**

You have indicated that you are willing to take part in one of the focus groups and you are either:

- A radiotherapy patient
- Someone who has supported a patient during their radiotherapy treatment
- An interested member of the public

We hope to learn from your experience so that we can design future studies that are as inclusive as possible.

➤ **Will the outcomes of the research be published?**

At the end of the study, the results will be analysed and may be published in academic journals and/or presented at conferences. This may include direct quotations from the focus groups. 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 your confidentiality. If you would like to obtain a copy of the published results, please let the research team know on the consent form.

➤ **Who has reviewed the research project?**

This project has been reviewed by The University of Manchester Proportionate Research Ethics Committee.

➤ **Who is funding the research project?**

The National Institute for Health Research is funding this study.

**What would my involvement be?**

➤ **What would I be asked to do if I took part?**

If you agree to take part in a focus group, we will ask you to sign a consent form for this study. We will also ask you to provide contact details, and some details about yourself (year of birth, gender,

postcode, ethnicity). We may also ask you to tell us about your cancer and what level of support you received. We will use this information to make sure that the views and experiences collected reflect a diverse population.

Using your contact details you will be invited to take part in a focus group, to give your views on when it is acceptable to use patients' data to measure changes to radiotherapy treatments.

The focus group will last for 2-3 hours and will include a refreshment break. It will be held at a suitable venue in Manchester. If you have any additional access requirements, please let the researchers know and we will make arrangements to support you wherever possible.

We will audio-record the focus group discussions (voice only) so that we can fully consider and review all that is said. 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. All participants' names will be removed from the transcripts.

➤ **Will I be compensated for taking part?**

Yes, we are offering a £75 Love2Shop voucher to all participants in recognition of your time.

➤ **What happens if I do not want to take part or if I 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 email [the-christie.rapidrt.patients@nhs.net](mailto: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 focus groups that you have already taken part in 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.

## **Data Protection and Confidentiality**

➤ **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called “personal identifiable information”. Specifically we will need to collect:

- Your name
- Your contact details (telephone number and/or email address)
- Your year of birth, gender, postcode (optional), and ethnicity (if you agree to provide these)
- Your cancer type and the level of support you received from support groups
- A record of your consent
- Recordings of your voice during the focus group discussion

➤ **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

➤ **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](https://documents.manchester.ac.uk/display.aspx?DocID=37095).  
<https://documents.manchester.ac.uk/display.aspx?DocID=37095>

- **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

- People who do not need to know who you are will not be able to see your name or contact details. We will keep all information about you safe and secure.
- Your name and any other information that could identify you will be removed from transcripts and recordings will be deleted once the transcripts have been checked for accuracy.
- 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.

- Your consent form will be retained for 5 years in a locked cabinet on UoM premises for audit purposes.
- With your consent, we would also like to retain your contact details for 5 years in order to provide you with a summary of the findings for this study and also to inform you about future studies that you may be interested in. If you provide consent for this, your details will be safely stored on UoM servers in a digital folder only accessible to the study team and used only for the purposes described above.
- If you participate in a focus group 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.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

### **What if I have a complaint?**

- **Contact details for complaints**

If you have a complaint that you wish to direct to members of the research team, please contact:

**Professor Sarah Devaney on 0161 275 3565 or by emailing [rapid-rt@manchester.ac.uk](mailto:rapid-rt@manchester.ac.uk)**

**If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact**

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: [research.complaints@manchester.ac.uk](mailto:research.complaints@manchester.ac.uk) or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email [dataprotection@manchester.ac.uk](mailto:dataprotection@manchester.ac.uk) or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner's Office about complaints relating to your personal identifiable information](https://ico.org.uk/make-a-complaint/) Tel 0303 123 1113  
<https://ico.org.uk/make-a-complaint/>

## **Contact Details**

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s) on:

Email address: [rapid-rt@manchester.ac.uk](mailto:rapid-rt@manchester.ac.uk)

Telephone number - 0161 306 5464 (Catherine Bowden)