

**AUDIO RECORDING INFORMATION SHEET FOR PATIENTS,
FRIENDS AND FAMILY* version 1.1**

****Please make sure a copy of this information sheet is given to the patient AND all those supporting the patient who are present at the study consent discussion.***

Lite Therapy Effectiveness For ORal Mucositis Trial

The LiTEFORM Study

Audio Recording of LiTEFORM study discussion

Thank you for helping with this research by letting us voice record the conversation you and your family member/friend had with the study team.

If after reading this information sheet you have changed your mind about letting us keep the recording, you can contact any of the names at the end of this sheet. This will not affect the standard of care that you have now or in the future.

Why do we want to record the conversation?

There are two main reasons why we want to record these conversations:

1. We want to find out what kind of questions people have about the study and how they are answered.
2. We want to know the reasons patients do or do not decide to take part in LiTEFORM.

We can use this information to make sure that patients get the right information to make a decision and are supported in the best possible way. We can use it to make changes to the study if needed, and to help with staff training. It will also help us decide if more hospitals should be included in this study in the future.

How will the audio-recording be used?

The conversation will be written out in full and used by the researchers to improve this and future studies. Your name and any personal details will be removed from the written version to make sure you cannot be identified (anonymised). We hope to publish the results of the study in scientific journals, which may include anonymised quotes from the conversations.

Will the recording and written version of the conversation be kept confidential?

Yes.

- Any recordings of your voice and transcripts (written out version) will be kept securely at Newcastle University or on a secure password protected database.
- All recordings, and all your contact information, will be deleted at the end of the study.

- We will use a number to identify you instead of your name. We will remove anything else that could identify you (anonymised).
- The anonymised transcripts will be kept to help with future research. We may want to use quotes from the transcripts for future studies but they will not include your name. For example we may use them to train staff who are inviting patients to part in similar studies, or to help with other studies in head and neck cancer. We will always protect your identity.
- Information about you will be looked at by people directly involved in the study, as well as by people who are checking it is running as it should.

If you say something in the conversation that makes the researcher think either you or someone else is at risk of harm, we may need to tell someone else. We would tell you before we did this.

What will happen to the results of the study?

- The study is due to finish at the end of 2020.
- The results will be written in medical journals and presented in meetings to other doctors, nurses and researchers.
- The anonymised transcripts might be shared with other researchers and to help with future studies. Your identity will also be protected.
- A report will be written by the study funder and put on their website.
- The results will be available at the end of the study on our website www.liteform.org.uk.

Study team contact details:

If you have any further questions, if you have changed your mind about letting us keep the recording or if you are unhappy about any aspect of this study please contact one of our qualitative researchers in the first instance:

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If you should wish to make a formal complaint, you can do this through the National Health Service complaints procedure. Details can be obtained from the Patient Advice and Liaison Service (PALS www.nhs.uk) at your local hospital.