

Lite Therapy Effectiveness For ORal Mucositis Trial

The LiTEFORM Study

PATIENT TELEPHONE INTERVIEW CONSENT – CHECKLIST AND SCRIPT version 1.1

TO BE COMPLETED BY RESEARCHER: researcher to initial chosen boxes and sign the form

Identification Number -

Health Professional Initials

Name of Chief Investigator Mr Michael Nugent

Name of Lead Researcher, Interview Study Dr Nikki Rousseau

Name of Local Principal Investigator

SECTION 1 – BEFORE recording is started

Researcher to make introductions and follow the points below **BEFORE** the recorder is switched on:

**Researcher to initial box when
complete:**

| | | |
|----------|--|--|
| 1 | Check the patient has seen and read the LiTEFORM Interview Patient Information Sheet version _____ dated _____ (please complete) | |
| 2 | Check with the patient if they have any questions. | |
| 3 | Ask the patient if they are happy to be interviewed for this study. | |
| 4 | Check they understand that the interview will be audio-recorded. | |

SECTION 2 – AUDIO-RECORDER SWITCHED ON

Researcher to switch on the recorder and explain to the patient:

“What I’ll now do is to read a series of questions and ask you to say whether you agree with each one by saying yes or no. There are six questions. Are you ok for me to continue?”

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Researcher to initial box when complete:

| | | |
|-----------|---|--|
| 1. | Ask "have you read the LiTEFORM Patient Interview Information Sheet version _____ dated _____?" | |
| 2. | Ask "was everything in the information sheet clear?" | |
| 3. | Ask "have you had the chance to ask questions about the study and are you happy with the answers given?" | |
| 4. | Ask "do you understand that you do not have to take part in this interview and you can ask to stop the interview at any time" | |
| 5. | Ask "do you agree to take part in an interview for LiTEFORM and for me to audio record the interview?" | |
| 6. | Do you understand that after the study, anonymised data (transcripts only) will be kept to help future research and may be shared with researchers outside the LiTEFORM team? This means that data may be used for purposes not related to this study, but it will not be possible to identify you from these data. | |
| 7. | Explain "Thank you, that's the last consent question." | |

➤ **SWITCH OFF RECORDER**

Name of person taking consent

Date

Signature

When completed - 1 copy for researcher, 1 original copy for Investigator Site File and 1 copy for patient hospital records.