

Lite Therapy Effectiveness For ORal Mucositis Trial
The LiTEFORM Study

MAIN PATIENT CONSENT FORM version 1.0

Site ID number:

Participant ID Number:

Principal Investigator Name: _____

SECTION 1: All patients consenting to ANY part of the LiTEFORM study

Please **INITIAL** these boxes if you agree:

1.	I have read and understood the Main Study Patient Information Sheet version _____ dated _____ (please complete)	
2.	I have had the chance to ask questions about the study and I am happy with the answers given.	
3.	I agree for a copy of my consent form to be sent securely to the Newcastle University Clinical Trials Unit for checking.	

SECTION 2: Main study

Please **INITIAL** these boxes if you agree:

4.	I understand that any personal information collected for the study will be kept confidential and not be made public. I understand that data from the study will be published in medical journals, at research meetings and shared with other researchers.	
5.	I understand that information about me will be collected, recorded and used for this study unless I withdraw my consent. We will ask you if you are happy for us to use any information collected so far.	
6.	I understand that parts of my medical notes and information collected during the study may be looked at by responsible people. I give my permission for these people to have access to my medical records. This includes people from the Newcastle Clinical Trials Unit, study sponsor, regulatory authorities and local NHS Trust where it is relevant to my taking part in research.	

7.	I consent for my GP to be informed about me taking part in this study	
8.	I understand that I do not have to take part in this study. I know that I can withdraw at any time and do not have to give a reason. I know that this will not affect my standard medical care or legal rights.	
9.	I agree to take part in the LiTEFORM study.	

SECTION 3: Contact about Interviews (*All patients approached about the study can complete this section. This includes patients who decline consent to the main study*)

Please INITIAL if you agree:

I understand that I may be invited to take part in an interview about my experiences of taking part in the study. I am willing to be contacted about this.	
--	--

SECTION 4: Audio-Recording (*ONLY COMPLETE the boxes below if verbal permission was given for audio-recording at the start of the study discussion. All patients can complete these section, including patients who decline consent to the main study*)

Please INITIAL your chosen box:

YES: I do give my permission for the study team to keep the recording of my voice from this study discussion. I understand that anything that is written out from this will not include my name or identify me.	
NO: I do not give my permission for the study team to keep the voice recording of this study discussion. I understand it will destroyed and not be used for this study.	

STOP AND CHECK

Please make sure you have initialled the boxes if you agree.

Name of patient

Signature

Date

Name of person taking consent

Signature

Date

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