(To be printed on local headed paper)

INFORMED CONSENT FORM

Niraparib **E**fficacy in patients with un**R**esectable Mesotheli**O**ma: A randomised phase II trial of Niraparib versus active symptom control in patients with previously treated mesothelioma

Patient Identification Number for this trial: | | | | — | | | | | | | |

Name of Researcher:

	Please initial box
1. I confirm that I have read and understand the information sheet dated XX-XXX-XXXX (version X) for the above study and I fully understand what is involved in taking part in this trial. I have had the opportunity to consider the information, ask questions and these have been answered satisfactorily.	INITIAL
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected.	INITIAL
3. I understand that should I withdraw from the study then the information collected about me up to this point may still be used for the purposes of achieving the objectives of the study.	INITIAL
4. I consent to the storage of personal information (including electronic) for the purposes of this study. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the study report or other publication.	INITIAL
5. I give permission for a copy of my consent form to be sent to the Southampton Clinical Trials Unit, where it will be stored securely, to allow confirmation of my consent.	INITIAL
6. I understand that relevant sections of my medical records and data collected during the study, may be looked at by individuals from Southampton Clinical Trials Unit, Study Sponsor organisation or their delegates, regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	INITIAL

7. I understand that the information held and maintained by [Insert name of local NHS site] and my GP may be used to help contact me or provide information about my health status.	INITIAL
8. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.	INITIAL
9. I consent to give research blood sample(s) for analysis and use in future research studies at the University of Leicester, including genetic analysis: Blood DNA (extracted from blood)	INITIAL
10. I consent to the study doctor requesting tissue samples from my previous tumour biopsy and diagnostic biopsy tissue (where available). If this sample is not available, I agree to provide a re-biopsy. I understand that these samples will be stored and analysed at the University of Leicester and may be used for future research purposes, which may include genetic testing. I understand that giving this sample is required to participate in the NERO study.	INITIAL
11. I agree to my anonymised data being used in future ethically approved research.	INITIAL
12. I agree to my GP being informed of my participation in the study and understand that my GP may be asked to share information with the study team for the purposes of the research.	INITIAL
13. I agree to use effective contraception as detailed in the patient information sheet.	INITIAL
14. I understand that I shall not benefit financially even if future research leads to the development of new treatments or medical tests.	INITIAL

15. **WOMEN OF CHILD BEARING POTENTIAL:** I understand that I will need to take a pregnancy test at screening and every 3 weeks during treatment as detailed in the patient information sheet.	INITIAL

16. **OPTIONAL:** I agree to provide a second biopsy for research purposes at the University of Leicester if my cancer progresses. I understand that this sample will be stored and analysed at the University of Leicester and may be used for future research purposes, which may include genetic testing.	Yes INITIAL	No INITIAL
17. **OPTIONAL:** I agree to provide a stool sample for research purposes.	INITIAL	INITIAL

18. I agree to take part in the NERO study.	INITIAL

Name of Patient	Signature	Date

Name of researcher taking consent	Signature	Date

When completed:

- 1 for participant;
- 1 for researcher site file;
- 1 (original) to be kept in medical notes;
- 1 copy should be sent to the SCTU via a secure nhs.net account to uhs.sctu@nhs.net, or using the University of Southampton's SafeSend service (if participant provided consent for this)