Surgical and large bore pleural procedures in malignant pleural Mesothelioma And Radiotherapy Trial (SMART trial) - RCT evaluating whether prophylactic radiotherapy reduces the incidence of procedure tract metastases. Chief investigator: Dr. Nick Maskell. REC: 11/SC/0408

PATIENT CONSENT FORM

Surgical and large bore pleural procedures in malignant pleural Mesothelioma and Radiotherapy Trial (SMART)
A randomised controlled trial evaluating whether prophylactic radiotherapy reduces the incidence of procedure tract metastases.

1. I confirm that I have read and understand the patient information sheet dated ...../....../......... (Version .........) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

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 future medical care or legal rights being affected as a consequence.

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals involved in the running of the trial, from the regulatory authorities or from the NHS, where it is relevant to my taking part in the research. I give permission for these individuals to have access to my records.

4. I give permission for my trial data, some of which may identify me, to be transported from my hospital site to the trial co-ordinating centres at Bristol and Oxford for the purposes of analysis, monitoring and follow up.

5. I understand that information held by the NHS and records maintained by the NHS Information Centre and the NHS Central Register may be used to help contact me and provide information about my health status.

6. I agree to take part in this study.

7. I would like my GP (Dr…………………………………) to be notified about my participation in the study and I give my permission for you to contact them.

8. Would you like to know the results of the trial when they are published? Yes/No

_____________________________       ___ ___ ___
Name of patient                         Date (dd/mm/yyyy)             Signature

_____________________________       ___ ___ ___
Name of researcher                    Date (dd/mm/yyyy)            Signature

3 copies: 1 for the patient, 1 for recruiting centre trial notes, 1 for hospital notes

SMART Consent form Version 3, Date 11.01.2012