PIMDA Observational Study
Patient Information and Consent Form

We would like to invite you to take part in the observational study entitled '**Observational study to determine the rate of occurrence of invasive mould disease and treatment outcomes in at-risk patients: a European prospective invasive mould disease audit (PIMDA)'**.

Purpose

The main purpose of this Study is to allow us to make a better estimate of the rate of occurrence of invasive mould disease among patients like you who are at risk because of treatment for leukaemia or stem cell transplant.

Reasons for the Observational Study

Mould (fungal) spores are found everywhere in the environment and normally do us no harm whatsoever. However these moulds can cause invasive diseases among patients undergoing treatment for leukaemia and stem cell transplants. While every effort is made to prevent these diseases they still occur, and the earlier they are diagnosed and treated the better the outcome. Part of the information which doctors need to help achieve this is a better understanding of how often invasive mould diseases occur.

What are we asking you to do?

We are asking you to allow us to record information about your treatment during the 6 months of the Study.

We will be noting down any signs and symptoms that might be associated with an invasive mould disease, and recording the results of certain tests which will be done as part of your normal care. We will also note any antifungal drugs you may be given according to the standard of care adopted by your hospital. These data will be handled anonymously and your identify will be protected completely. Only your age and gender will be recorded, together with the information relevant to the Study.

Benefits and Risks

There will be no direct benefit to you for participating in this Study. However, by allowing us to use the information we collect, you may help us gain a better insight into the incidence, diagnosis and treatment of invasive mould disease. The treatment you receive will be the same, whether or not you take part in the Study.

Confidentiality

Only designated staff at *[name of clinical site]* will have access to your medical records for the purpose of entering the information in the electronic case report.

Access to the database will only be made available to members of the Study Steering Group and the sponsor - the European Confederation of Medical Mycology (ECMM). Study Records will be kept indefinitely for analysis and follow-up. The data will be stored in a secure manner and the database meets similar security standards as are required for online banking transactions.

Right to Withdraw

Your decision to allow us to use your medical information is entirely voluntary. You may withdraw your consent at any time, for any reason, and without notice. It will not affect your regular medical care in any way. Your data will be removed from the data set.

Voluntary Consent

Before you sign this form, please ask any questions about any aspect of the Study or your rights as a volunteer, a designated member of staff will be on hand to answer them before you sign this consent form.

Investigator's Statement

I have provided an explanation of the above research program. The participant was given an opportunity to discuss these procedures, including possible alternatives, and to ask any additional questions. A signed copy of the consent form has been given to the participant.

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Signature of Principal Investigator or Designee Date

Print name _____

Participant Statement

I certify that I have read, or had read to me, and understand the purpose and description of this Observational Study. I have received answers to all my questions and understand that I may ask further questions at any time. I will also receive a copy of this signed consent form for my records. I have had ample opportunity to carefully review the Informed Consent form and understand that I may withdraw my consent at any time. I voluntarily consent to the specific medical information about me being collected, stored and analysed in the Study.

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Signature of Participant Date

Print name _____

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Signature of Witness Date

Print name _____