

ACCEPT**INFORMED CONSENT FORM – TISSUE BLOCK SCREENING****Name of Researcher:****Title of Project:**

A Phase Ib/II combination trial of acalabrutinib with rituximab, cyclophosphamide, doxorubicin, vincristine and prednisolone (R-CHOP) for patient with diffuse large B-cell lymphoma (DLBCL).

*Please
initial each
box*

1. I confirm that I have read and understand the Tissue Block Screening patient information sheet dated **31-May-2018 version 1** for the transfer of my diagnostic tissue block to HMDS. I have had the opportunity to ask questions and these have been answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected.
3. I understand that relevant sections of my medical records may be looked at by the individuals from the Southampton Clinical Trials Unit (SCTU), the Sponsor or their delegates, from Regulatory Authorities, or from the NHS Trust where it is relevant to the transfer and storage of my tissue block. I give permission for these individuals to have access to my records.
4. I give my permission for a sample of my tissue, previously obtained for diagnostic purposes, to be sent to the Haematological Malignancies Diagnostic Service in Leeds in order to determine if sufficient tissue will be available for analysis of the pattern of genes expressed (molecular phenotype) of my lymphoma.

☐☐☐☐

5. I understand that agreeing to the transfer and storage of my tissue block does not commit me to taking part in the ACCEPT trial.

☐

6. I understand that all information about me and the results will be held in strict confidence.

☐

7. I consent to the Southampton Clinical Trials Unit monitoring the progress of my sample using secure NHS systems.

☐

8. I agree that the tissue sample and consent form will be stored on behalf of the ACCEPT Trial Management Group. If I choose to participate in the ACCEPT study, my tissue sample may be used in future ethically approved projects. I understand that some of these projects may be carried out by researchers other than the ACCEPT Trial Management Group. If I choose not to participate in the ACCEPT study, my tissue sample will be returned to my treating hospital and no analysis conducted.

☐

9. I give permission for a copy of this consent form to be sent to the Southampton Clinical Trials Unit (where it will be kept securely), to allow confirmation of my consent.

☐

Name of Patient

Signature

Date

Name of Person taking consent

Signature

Date

REMINDER FOR RESEARCH TEAM:

- **Original signed consent form in Investigator Site File**
- **One copy given to the patient**
- **One copy filed in the patient's medical records**
- **One copy to be emailed to SCTU via secure nhs.net email account, for central monitoring purposes**