

ACCEPT**INFORMED CONSENT FORM - PHASE I****Patient ID Number:**

(to be obtained post registration)

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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 patient information sheet dated **31-May-2018, version 5** for the above study and I fully understand what is involved in taking part in this trial. 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, and data collected during the study, may be looked at by individuals from the Southampton Clinical Trials Unit (SCTU), Sponsor or their delegates, from 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.
4. 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.
5. I agree to my General Practitioner being informed of my participation in the study.
6. I agree to give extra samples of blood for assessment of acalabrutinib levels in my blood (pharmacokinetic) as described in the patient information sheet for the above study. I give permission for these samples, and other information with my details, to be transferred to Acerta Pharma (USA-based company).

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7. 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 the pattern of genes expressed (molecular phenotype) of my lymphoma as described in the information sheet for the above study.

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8. I agree that the blood samples, tissue samples, consent form and information collected about me will be stored on behalf of the ACCEPT Trial Management Group and 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.

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9. I agree to use highly effective contraception as detailed in the patient information sheet and to refrain from donation of egg/sperm (if applicable) during the trial treatment and for 12 months after the last dose of trial drug.

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10. I understand that I shall not benefit financially in any way by taking part in this study.

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11. I agree to my pseudo-anonymised data being held on servers located in the EU and USA. Access to data managed by Southampton Clinical Trials Unit (SCTU) will be strictly controlled and applicable Data Protection Legislation will be abided by.

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12. 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.

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13. I agree to take part in the above study.

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OPTIONAL

14. I agree to have the two extra optional biopsies, at baseline and at cycle 2 day 8, as part of the ACCEPT study.

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15. I consent to my anonymised trial data being used in future research by third parties, including those both inside and outside the European Economic Area (for example the USA).

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Name of Patient

Signature

Date

Name of Person taking consent

Signature

Date

REMINDER FOR RESEARCH TEAM:

- **Original signed consent form in Investigator Site File**

<TO BE PRINTED ON LOCAL HOSPITAL HEADED PAPER>

- 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