

ACCEPT

PREGNANCY INFORMED CONSENT FORM

Patient ID Number of study participant:

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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 ACCEPT Pregnancy Patient Information Sheet dated 15-July-2019, version 3 for the above study. I understand that as I have become pregnant whilst my partner or I was receiving study treatment (or within the specified follow up timelines), I agree to my pregnancy and outcome of my pregnancy to be followed up in accordance with the procedure highlighted in the patient information sheet. 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 mine or my partner's medical care or legal rights being affected.
3. I give permission for relevant sections of my medical notes and data collected during this follow-up, to be looked at by individuals from Southampton Clinical Trials Unit, Study Sponsor organisation, regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research and understand that anonymised data will be held on trial specific database on servers located within and outside the EEA (for example, the USA).
4. I understand that the information collected about me will/may 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 follow-up.

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<TO BE PRINTED ON LOCAL HOSPITAL HEADED PAPER>

6. I understand that non-identifiable data collected about my pregnancy will be archived and stored securely at the end of the trial for up to 25 years, which may be on servers outside of the EEA (e.g. in the USA).

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7. I understand that I shall not benefit financially in any way by taking part in this follow-up.

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8. 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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9. I agree to take part in the follow-up necessary as a pregnant participant or partner of a study participant in the above study.

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Name of Pregnant Partner

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 pregnant participant or pregnant partner of the participant**
- **One copy to be emailed to SCTU via secure nhs.net email account, for central monitoring purposes**