(Form to be on hospital/institution headed paper)

Site Name: << insert site name>>
Patient ID: << insert patient ID>>

INCA TRIAL

PATIENT CONSENT FORM

A multicentre randomised phase II clinical trial of Inotuzumab Ozogamicin plus Rituximab and CVP (IO-R-CVP) versus Gemcitabine plus Rituximab and CVP (Gem-R-CVP) for the first line treatment of patients with diffuse large B cell lymphoma who are not suitable for anthracycline containing chemotherapy

Name of Principal Investigator: << insert name of Principal investigator>>

Part 1 – Consent to take part in the trial

Please initial box

1.	I confirm that I have read and understand the information sheet dated …… (version …….) for the above trial. 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, without my medical care or legal rights being affected.	☐
3.	I understand that relevant sections of any of my medical notes and data collected during the trial, may be looked at by appropriate individuals from the Cancer Research UK and UCL Cancer Trials Centre, University College London, the sponsor (and representatives of the sponsor), Pfizer Ltd, and relevant regulatory bodies, or from the institution 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 agree to my GP being informed of my participation in this trial and that they may be contacted to supply details of my progress.	☐
5.	**If you or your partner are of childbearing potential:** I agree to use birth control (1 reliable form of contraception as explained by my hospital doctor) as directed in the information sheet.	☐
	If you or your partner are not of childbearing potential, please initial box:	☐
6.	I consent to the collection, of personal information (including my initials, date of birth, gender and NHS number) for the purposes of this trial. I understand that any information that could identify me will be kept strictly confidential and that no personal information will be included in the trial report or other publication.	☐

7.	I understand that information held and managed by The Health and Social Care Information Centre and other central UK NHS bodies may be used in order to help contact me or provide information about my health status.	☐
8.	I agree to donate a blood sample during the screening process and allow the release of my existing diagnostic tissue sample for research purposes. I understand how this will be done, and that my participation is voluntary. I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected. I can request that any samples stored by the research team that can still be identified as mine should be destroyed.	☐
9.	I understand that samples I donate for this trial may be stored for use in future research. I understand separate ethics approval will be sought before the use of this material for future studies, but that I will not be contacted further about this and these samples are considered a gift. Future research may involve molecular, genetic and tissue microarray studies, or new techniques. I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected. I can request that any samples stored by the research team that can still be identified as mine should be destroyed.	☐
10.	I understand that my samples and data may be used in collaborations with scientists from other countries.	☐
11.	I agree to take part in the above trial.	☐

Name of Patient	Date	Signature
_____	_____	_____

Name of person taking consent (designated responsible person)	Date	Signature
_____	_____	_____

When completed: Take 2 copies. Original and 1 copy to be kept in medical notes and investigator site file, and a copy to be given to the patient.

Data Protection Act 1998: This research project is registered for data protection and the requirements of the Act apply in full. The information held will be used for medical research purposes only and will be stored and disposed of in a secure manner.

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Name of Principal Investigator: << insert name of Principal investigator>>

Part 2 – Consent for translational research samples (optional)

Please initial box

1.	I agree to donate additional blood samples for FLT-3 research. I understand that my participation is voluntary. I am free to withdraw my approval for their use at any time without giving a reason and without my medical treatment or legal rights being affected. I can request that any samples stored by the research team that can still be identified as mine should be destroyed.	☐

Name of Patient	Date	Signature
_____	_____	_____

Name of person taking consent (designated responsible person)	Date	Signature
_____	_____	_____

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