

Rituximab in Graves' Disease 2 (RiGD-2)

Patient 16+ Years Consent Form v2.0 28 MAY 2025

CONFIDENTIAL ONCE COMPLETED

Site ID Participant ID

Principal Investigator: _____

Please
INITIAL

the boxes if
you agree:

1.	I have read and understood the RiGD-2 Patient Information Sheet 16 + Years, version _____, dated _____.	
2.	I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
3.	I understand that my participation is voluntary. I am free to withdraw from the trial at any time without giving a reason and my medical care and legal rights will not be affected.	
4.	I understand that if I am female, I will need to provide a urine/blood sample for pregnancy testing. This will allow the doctors to confirm my eligibility for the trial. (Male patients please put 'N/A')	
5.	I understand that Tuberculosis and Hepatitis screening will take place as part of the eligibility assessment.	
6.	I agree to use a highly effective contraception method for the duration of the trial if I am sexually active (information can be found in appendix of Patient Information Sheet).	
7.	I agree to my General Practitioner being informed of my participation in the trial.	
8.	I agree to have blood taken at each visit to check how I am doing and see if my medication dose needs to be changed.	
9.	I agree to complete the trial questionnaires over the duration of the trial.	
10.	I agree for information about me to be stored on an external secure database called Ennov™. I will be identified on this database by a unique code instead of my name. My age, sex at birth, height, weight, ethnicity, postcode, health information, blood results, current medications and information related to my Grave's Disease will be collected and stored.	
11.	I agree for my email address and mobile number to be collected and stored on Ennov™ for the trial research team to contact me for the purpose of completing trial questionnaires. Only the trial research team at my hospital will be able to see this information about me.	

12.	I agree that the research team can email trial documents/ trial links to me at my email address, mobile phone or can post trial documents to my home address, if required.	
13.	I agree to the continued research use and long-term storage of all my de-identified information and samples already collected should I lose capacity or withdraw from the trial.	
14.	I understand that relevant sections of my medical notes and data collected during the trial, may be looked at by individuals from the Sponsor (who has overall responsibility for the trial), from Newcastle Clinical Trials Unit (who is managing the trial), from regulatory authorities such as the Health Research Authority or the Medicines and Healthcare products Regulatory Agency or from the NHS Trusts undertaking the trial, where it is relevant to me taking part in this research. I give permission for these individuals to have access to my records and data collected during the trial.	
15.	I agree that the information collected about me for the trial can be shared with other researchers (including researchers outside of the UK) at the end of the trial. I understand this information will be anonymised and transferred securely.	
16.	I agree to the information provided and this signed consent form being stored for 25 years after the end of the trial.	
17.	I agree for a copy of this consent form to be sent securely to the Newcastle Clinical Trials Unit (NCTU) for safety purposes. I understand the copy will be destroyed once it has been checked by NCTU.	
18.	I understand that anonymised data from the trial will be published in medical journals and at research meetings both within and outside the UK.	
19.	I understand that data from the trial will be de-identified and some anonymised data will be stored in public databases, but that I will not be directly identified in this dataset or published results.	
20.	I understand that any personal information collected about me for the trial will be kept confidential and will not be made public.	
21.	I agree to take part in the RiGD2 trial.	

Please **tick Yes**
or No in the
boxes.

OPTIONAL for ALL participants		
22.	I agree to some of my blood samples being stored in the Newcastle laboratory and understand that the samples may be used for future research.	Yes ☐ No ☐
23.	I agree to have an extra sample of blood taken (2.5mls) which will be sent to Newcastle laboratory for additional analysis for this trial. I understand that this sample of blood will be used for RNA analysis.	Yes ☐ No ☐

OPTIONAL for Newcastle participants ONLY		
24.	I agree to have an extra sample of blood taken (2.0mls) which will be sent to Newcastle laboratory for additional analysis for this trial. I understand that this sample of blood will be used for DNA analysis.	Yes ☐ No ☐

STOP and check that you have initialled/ ticked relevant boxes

Name of Patient

Signature

DD MMM YYYY

Name of person receiving
consent

Signature

DD MMM YYYY

Please file the consent form in the Investigator Site File and a copy in the patient medical record.
Give a copy to the patient.