

CONSENT FORM (RCT)
(Patient Consent RCT V2-0 10Oct2011)

Participant study ID:

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Title of Project: CONSTRUCT

Name of person taking consent:

	Please initial each box
1. I confirm that I have read and understand the information sheet dated 10 October 2011 Version 18 for the above study. 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 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 my medical notes may be looked at by a research nurse, regulatory authorities or 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 agree to the research team holding personally identifiable information	
5. I agree that a copy of this Consent Form is sent to the CONSTRUCT Trial Office	
6. I agree to the random selection of my drug treatment	
7. If I am a woman of child-bearing potential, I agree to use adequate contraception during treatment and for 6 months afterwards if given Remicade.	
8. I agree to data being collected through the research computer	
9. I agree to the completion of questionnaires for two years	
10. I agree to complete an annual questionnaire and my progress being followed for a further eight years using information taken from my NHS records	
11. I agree to my GP being informed of my participation in the study	
12. I agree to aspects of my anonymised data being used for reports about the research	
13. I agree to take part in the above study	
14. I agree, if requested, to take part in two telephone interviews (optional)	
15. I agree to the telephone interviews being audio recorded (optional)	

Your name in capitals	Date	Signature

Name of person taking consent in capitals	Date	Signature

When completed, the original should be kept in the Trial Site File, a copy should be given to the patient, one kept in the medical notes and one sent to the CONSTRUCT Trial Office.