

BSRBR

The British Society for
Rheumatology
Biologics Registers

Rheumatoid Arthritis



Observational Study Site File

BSRBR-RA Observational Study Site File

Contents

Section 1: Protocols	<ul style="list-style-type: none"> • BSRBR-RA Main Study Protocol • Tocilizumab Sub-study Protocol • Certolizumab Sub-study Protocol
Section 2: Regulatory and other essential documents	<ul style="list-style-type: none"> • Main NHS MREC Application • Original MREC Approval Letter • <i>SSI Form including signature page(s)</i> • <i>Trust Approval Letter</i> • Notice of Substantial Amendment & Approval Letters (SA01-SA25) • Sponsor Approval Letter • Sponsor Confirmation of Insurance Letter
Section 3: Patient information sheet and consent form	<ul style="list-style-type: none"> • Patient Information Sheet • Patient Consent Form • BSRBR Patient Invitation Letter • BSRBR-RA Outreach Consent Invitation Letter • BSRBR-RA Outreach Re-consent Covering Letter (Switchers) • BSRBR-RA Direct Patient Re-consent Letter • BSRBR-RA Direct Patient Re-consent Reminder
Section 4: Patient master file	<ul style="list-style-type: none"> • BSRBR-RA Patient Screening Log • <i>Copies of consent forms</i> <i>(another copy to be kept in the patient notes)</i>
Section 5: Study team documentation	<ul style="list-style-type: none"> • Delegation Log • <i>CV of Principal Investigator and other staff working on the study</i>
Section 6: Ethics progress reports	<ul style="list-style-type: none"> • Annual Progress Reports (2006-2016)
Section 7: Correspondence and additional forms	<ul style="list-style-type: none"> • BSRBR-RA Contact Information • <i>Correspondence</i> • <i>Any other relevant study material</i>