



**British Society for  
Rheumatology**

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Rheumatoid Arthritis Register

# Observational Study Site File

## BSRBR-RA Observational Study Site File

### Contents

Section 1: Protocols	<ul style="list-style-type: none"> <li>• BSRBR-RA Main Study Protocol</li> </ul>
Section 2: Regulatory and other essential documents	<ul style="list-style-type: none"> <li>• Main NHS MREC Application</li> <li>• Original MREC Approval Letter</li> <li>• <i>SSI Form including signature page(s)</i></li> <li>• <i>Trust Approval Letter</i></li> <li>• Notice of Substantial Amendment &amp; Approval Letters (SA01-SA27)</li> <li>• Sponsor Approval Letter</li> <li>• Sponsor Confirmation of Insurance Letter</li> <li>• BSRBR-RA Stakeholder Responsibilities</li> </ul>
Section 3: Patient information sheet and consent form	<ul style="list-style-type: none"> <li>• Patient Information Sheet</li> <li>• Patient Transparency Information Sheet</li> <li>• Patient Consent Form</li> <li>• BSRBR Patient Invitation Letter</li> <li>• BSRBR-RA Outreach Consent Invitation Letter</li> <li>• BSRBR-RA Outreach Re-consent Covering Letter (Switchers)</li> </ul>
Section 4: Patient master file	<ul style="list-style-type: none"> <li>• BSRBR-RA Patient Screening Log</li> <li>• <i>Copies of consent forms</i> <i>(another copy to be kept in the patient notes)</i></li> </ul>
Section 5: Study team documentation	<ul style="list-style-type: none"> <li>• Delegation Log</li> <li>• <i>CV of Principal Investigator and other staff working on the study</i></li> </ul>
Section 6: Ethics progress reports	<ul style="list-style-type: none"> <li>• Annual Progress Reports (2006-2017)</li> </ul>
Section 7: Correspondence and additional forms	<ul style="list-style-type: none"> <li>• BSRBR-RA Contact Information</li> <li>• <i>Correspondence</i></li> <li>• <i>Any other relevant study material</i></li> </ul>