

BADBIR INVESTIGATOR SITE FILE

CONTENTS

Section 1: Protocol	BADBIR Protocol (Version 22, dated 19/03/2026) <i>Previous versions of the protocol should be marked as superseded</i>
Section 2: PIL	• Patient Information Sheet • Consent Form • Patient Invitation Letter
Section 3: Regulatory & other essential documents	• Main NHS REC Application Form (including Chief Investigator and Sponsor signatures) • Main NHS REC Approval • SSI Application Form (including signatures) • R&D Approval Letter (and LREC approval if applicable) • Notice of Substantial Amendment & Approval Letters • Sponsorship Agreement
Section 4: Finance	• Centre Agreement (including signatures and Appendix 4) • Finance Set up Details Form • Appendix 1 Finance Details
Section 5: Standard Operating Procedures	• Waist Measurement SOP
Section 6: Enrolment	• Patient Enrolment Log • Original Copy of Consent Form
Section 7: CVs	• Delegation Log of all staff involved in study • CV's • GCP Certificates
Section 8: Pathology	• Laboratory Ranges
Section 9: Monitoring	• CRA Visit Log • Audit Reports
Section 10: Correspondence & Additional Forms	• Correspondence
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