



BADBIR INVESTIGATOR SITE FILE

CONTENTS

Section 1: Protocol	BADBIR Protocol (Version19, dated 01/06/2020) <i>Previous versions of the protocol should be marked as superseded</i>
Section 2: PIL	<ul style="list-style-type: none"> • Patient Information Sheet • Consent Form • Patient Invitation Letter
Section 3: Regulatory & other essential documents	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Centre Agreement (including signatures and Appendix 4) • Finance Set up Details Form • Appendix 1 Finance Details
Section 5: Standard Operating Procedures	<ul style="list-style-type: none"> • Waist Measurement SOP
Section 6: Enrolment	<ul style="list-style-type: none"> • Patient Enrolment Log • Original Copy of Consent Form
Section 7: CVs	<ul style="list-style-type: none"> • Delegation Log of all staff involved in study • CV's • GCP Certificates
Section 8: Pathology	<ul style="list-style-type: none"> • Laboratory Ranges
Section 9: Monitoring	<ul style="list-style-type: none"> • CRA Visit Log • Audit Reports
Section 10: Correspondence & Additional Forms	<ul style="list-style-type: none"> • Correspondence
Section 11: Annual Ethics Progress Reports	