



## BADBIR INVESTIGATOR SITE FILE

### CONTENTS

Section 1: Protocol	<ul style="list-style-type: none"> <li>• BADBIR Protocol (version 18, dated 01/06/2018)</li> </ul> <p><i>Previous versions of the protocol should be marked as superseded</i></p>
Section 2: PIL	<ul style="list-style-type: none"> <li>• Patient Information Sheet</li> <li>• Consent Form</li> <li>• Patient Invitation Letter</li> </ul>
Section 3: Regulatory & other essential documents	<ul style="list-style-type: none"> <li>• Main NHS REC Application Form (including Chief Investigator and Sponsor signatures)</li> <li>• Main NHS REC Approval</li> <li>• SSI Application Form (including signatures)</li> <li>• R&amp;D Approval Letter (and LREC approval if applicable)</li> <li>• Notice of Substantial Amendment &amp; Approval Letters</li> <li>• Sponsorship Agreement</li> </ul>
Section 4: Finance	<ul style="list-style-type: none"> <li>• Centre Agreement (including signatures and Appendix 4)</li> <li>• Finance Set up Details Form</li> <li>• Appendix 1 Finance Details</li> </ul>
Section 5: Standard Operating Procedures	<ul style="list-style-type: none"> <li>• Waist Measurement SOP</li> </ul>
Section 6: Enrolment	<ul style="list-style-type: none"> <li>• Patient Enrolment Log</li> <li>• Original Copy of Consent Form</li> </ul>
Section 7: CVs	<ul style="list-style-type: none"> <li>• Delegation Log of all staff involved in study</li> <li>• CV's</li> <li>• GCP Certificates</li> </ul>
Section 8: Pathology	<ul style="list-style-type: none"> <li>• Laboratory Ranges</li> </ul>
Section 9: Monitoring	<ul style="list-style-type: none"> <li>• CRA Visit Log</li> <li>• Audit Reports</li> </ul>
Section 10: Correspondence & Additional Forms	<ul style="list-style-type: none"> <li>• Correspondence</li> </ul>
Section 11: Annual Ethics Progress Reports	