Standard Operating Procedures for Sponsorship Approval

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Any printed versions of this document will be classed as uncontrolled

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Contents

1.0 PURPOSE & SCOPE

1.1 TheUK Policy Framework for Health and Social Care Research

3.0 RESPONSIBILITIES

3.1 TheChief Investigator

b. satisfying itself that the investigators, research team and research sites are suitable;

c. ensuring that roles and responsibilities of the parties involved in the research and any delegation by the sponsor of its tasks are agreed and documented;

d. ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project; and

e. ensuring appropriate arrangements are made for making information about the research publicly available before it starts (unless deferral is agreed by or on behalf of the research ethics committee); agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished; and ensuring arrangements for information about the findings of the research to be made available, including, where appropriate, to participants;

f. ensuring that, where expected or required, the research has approval from a research ethics committee and any other relevant approval bodies before it begins;

g. verifying that regulatory and (r)-6.39 (o(y)-3.6 (ande)-t)2.1 (t)-8.9 (hv -1.581.3r)-524 Tm [(v)-4.5 (eg)1.6 (
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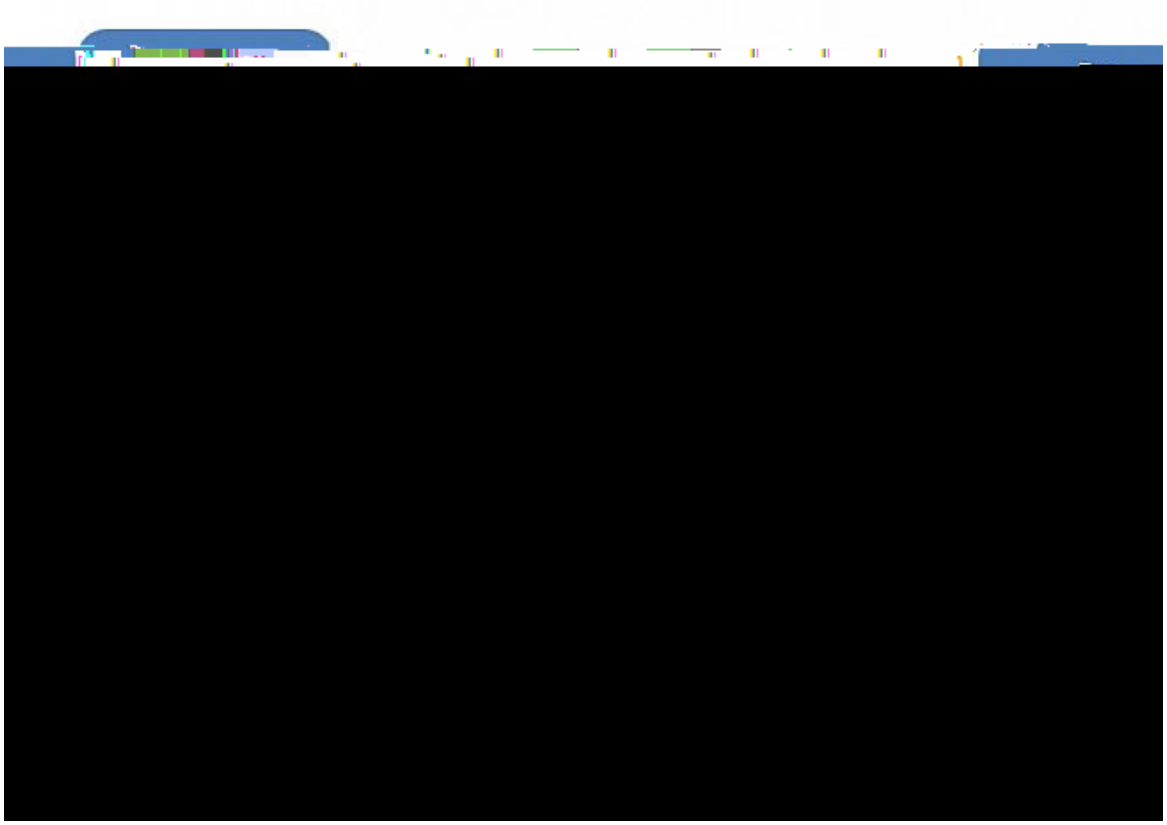
3.4.3 Through the provision of expert review of the study proposal, the Panel will provide feedback and advice to researchers to meet the quality and safety criteria expected by sponsoring organisations. The Panel will then make recommendations of each application for sponsorship to the sponsoring organisation.

3.4.4 The aim of the Panel is to improve the quality of sponsorship applications whilst avoiding delays due to revisions and resubmissions to Sponsorship Committees, the HRA and Ethics Committees.

3.5 ***The Research Ethics, Integrity and Governance Team in Research and Enterprise***

3.5.1 TheResearch Ethics, Integrity and Governance Team provides administrative oversight and leadership of sponsorship processes, servicing the Sponsorship Committee and representing the university on the Pre-Sponsorship Review Panel

4.0 PROCEDURE



4.0.1 The Chief Investigator (CI) is required to submit a formal application for Sponsorship.

4.0.2 Applying for sponsorship occurs in a two-stage process:

4.2.3 The University's Sponsorship Sub-Committee has oversight of all new sponsorship approvals and business related to the maintenance of sponsorship through the study's lifetime.

4.3 Applying for University Sponsorship – the Pre-Sponsorship Review Panel (PSRP)

4.3.1 The Pre-Sponsorship Review Panel (PSRP) is a joint venture by the University of Sussex, University of Brighton, University Hospitals (Sussex) NHS Trust (UH(s)) and Sussex Partnership NHS Foundation Trust (SPFT).

4.3.2 The PSRP is made up of academics, clinical researchers, quantitative and qualitative researchers, research governance representatives, disease area and specialist experts, research nurses, patient and public involvement members, statisticians and trial and data managers. The panel inclh8Ss s8.7 (linv)-4.6-29.034

4.4 Applying for University Sponsorship – the Sponsorship Sub-Committee

4.4.1 Upon recommendation by the PSRP, applicants should submit documents that have been reviewed and signed off by the PSRP and a covering letter to researchsponsorship@sussex.ac.uk setting out how each point raised by the Panel has been

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Source: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/

4.5 Right to withdrawal of Sponsorship

4.5.1 In line with its responsibilities as a recognised Sponsor of research, the University may withdraw Sponsorship that it has granted if there has been a breach of the 'Conditions of Sponsorship Agreement' or if matters come to light through the study that have significant legal, regulatory, financial or reputational consequences to the University.

5.0 SPONSORSHIP OF CLINICAL TRIALS OF INVESTIGATIONAL OR MEDICINAL PRODUCTS (CTIMPS)

5.1 To find out if the study is a CTIMP applicants should use the MHRA's algorithm ***Is it a clinical trial of a medicinal product?***

5.2 In cases where the University is asked to assume full and sole responsibility for a CTIMP the University will usually expect the CTIMP to operate within a Clinical Trials Unit (CTU).

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