Study title, Chief Investigator
Sponsor Ref, IRAS no., date of approval

UNIVERSITY OF SUSSEX

Conditions of Sponsorship Agreement

The University of Sussex will act as Sponsor, as defined by the Medicines for Human Use (Clinical Trial) Regulations 2004, UK Policy Framework for Health and Social Care Research (2017) for the above research project provided that the Chief Investigator adheres to the following conditions of sponsorship in addition to those mandated by the HRA and (where applicable) the responsible NHS REC:

a) HRA approval has been received for the study.

b) Confirmation of Capacity & Capability is received from relevant NHS Trusts before any patients or participants are recruited.

c) The CI (Chief Investigator) and members of the research team will comply with all applicable regulations; including the principles from the UK Policy Framework for Health and Social Care Research (2017) the Medicines for Human Use (Clinical Trials) regulations 2004 and subsequent amendments (if a CTIMP), ICH GCP, the Data Protection Act2018, the Human Tissue Act 2004 and any other relevant regulations and/or legislation.

d) The CI and members of the research team will comply with the University's *Code of Practice for Research*[1] and any funder requirements relating to research.

e) All research team members are appropriately GCP trained throughout the duration of the study.

f) Ensuring that the study is registered on an appropriate registry prior to recruitment of the first patient if applicable. For clinical trials (as defined by the HRA) this *must be* within six weeks of recruiting the first research participant.

g) Ensuring that the clinical trial data is generated, documented and reported in accordance with the protocol, GCP and regulatory requirements.

h) A delegation log is completed and kept up to date throughout the duration of the trial.

i) A Trial Master File (TMF) must be set up containing essential documents in accordance with the Trial Master File Index provided and must be maintained throughout the research study.

[1] https://www.sussex.ac.uk/webteam/gateway/file.php?name=code.pdf&site=377

j) If deemed appropriate by the Sponsor, a site initiation meeting is performed before the study commences and research staff training in the protocol is documented.

k) The research study is conducted in accordance with the protocol and any significant deviations are reported to the Sponsor (researchsponsorship@sussex.ac.uk).

l) Any proposed amendments to the research study are submitted to researchsponsorship@sussex.ac.uk for review and approval as per the Sponsorship Approval SOP.

m) Serious Adverse Events (SAEs) are reported to the Sponsor immediately and according to the protocol.

n) All SAEs are assessed in order to determine whether the SAE is a Suspected Unexpected Serious Adverse Reaction (SUSAR) as well as any new safety information that becomes available during the trial.

o) If the study is a CTIMP, *Development Safety Update Reports* are submitted annually to the Sponsor prior to review by the relevant authorities.

p) Annual Progress Reports are submitted to the Sponsor and the REC promptly and in accordance with HRA requirements.

q) Urgent Safety Measures (USM) must be notified to the Sponsor, MHRA and the REC within 3 days of implementing the measure.

r) Any serious breaches of GCP or the protocol must be reported to the Sponsor, MHRA and the REC immediately.

s) Any other correspondence between the MHRA and the REC is copied to the Sponsor (researchsponsorship@sussex.ac.uk).

t) The Trial Master File (TMF) and other associated documentation must be made available for monitoring, auditing or inspection purposes.

u) At the end of the study, an End of Trial Notification/Declaration is sent to the Sponsor, the MHRA (if applicable) and the REC within 90 days of the end of the study, or within 15 days if the trial is terminated prematurely with an explanation of the reasons for early termination.

v) Applications for study extensions to the originally agreed periods will be submitted to the Sponsor *prior* to expiry of previous approvals.

w) A final report on the research must be submitted to the Sponsor, the MHRA (if applicable) and the NHS REC within one year of the end of the trial.

x) Except for research undertaken for student qualifications, all research results and findings should be made accessible and public, with adequate consent and privacy safeguards in a reasonable time period on completion of research.

y) The study documentation must be archived in accordance with the applicable

University policies.

z) The Chief Investigator will ensure appropriate oversight of the study at all times and agrees to meet for a Sponsor Review Meeting at intervals agreed at the time of sponsorship.

By signing the declaration on IRAS form, I agree to adhere to the above conditions of sponsorship.

Please notify researchsponsorship@sussex.ac.uk when the first participant has been recruited