University of Warwick

Division of Sponsor Responsibilities Form

Study Title:

Chief Investigator:

Student:

Sponsorship Reference Number:

The parties have agreed to undertake responsibilities as attributed in the table below:

N.B Rows in bold font should be completed for Clinical Trials of Investigational Medicinal Products (CTIMPs) only

Item	Responsibility	Responsible Party (Department or role)
1	**Study preparation**	
1a	Secure funding for the study.	
1b	Ensure that there are adequate insurance/ indemnity arrangements in place.	
1c	Administer funding for the study.	
1d	Secure the supply of resources including devices / Contract Research Organisation services.	
1e	Contract for the supply of resources including devices / Contract Research Organisation services.	
1f	Ensure study products and relevant devices are available free of charge to participants.	
1g	Ensure that the appropriate contracts and agreements are in place.	

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1h	Ensure that the terms and conditions of the contracts and agreements are adhered to.	
1i	Notify the substantive employers of investigators in writing, in advance of the study commencing, sponsorship agreement, their participation in the study and sponsor functions that have been delegated to the employers of investigators.	
2	**Applications and Registrations**	
2a	Ensure that the protocol has undergone independent scientific and statistical review and is compliant with the relevant regulations/ guidelines.	
2b	Ensure that a satisfactory risk assessment is carried out and any significant changes to the risk profile or risk: benefit ratio of the study are considered in the ongoing study procedures.	
2c	Prepare participant information sheet and consent form, including where appropriate consent to providing participant tissue, samples, medical data or other material to the Sponsor and other relevant documents prior to ethics submission.	
2d	Prepare and submit HRA and ethics application as appropriate.	
2e	**Obtain a Clinical Trials Authorisation from the regulatory authority (MHRA in the UK) and ensure that any conditions of the CTA are met (CTIMPs only)**	
2f	Register the study with an appropriate protocol registration scheme where required.	
2g	Obtain Ethics / HRA approval as appropriate.	
2h	Obtain Management permission to conduct the research at each participating site.	
2i	Obtain Administration of Radioactive Substances Advisory Committee (ARSAC) approval (where applicable).	
2j	Obtaining and providing advice and recommendations on clinical issues that arise involving the management of participants in the study and the interpretation of study data/ analyses.	

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3	**Study Conduct**	
3a	Maintain a Study Master File, containing all essential documents for the Study.	
3b	Ensure that the Study is conducted in accordance with the principles of Good Clinical Practice (GCP) and the University of Warwick SOPs for University of Warwick Sponsored Studies, available via the following link: https://warwick.ac.uk/fac/sci/med/research/ctu/conducting/planning/sop2016	
3c	Ensure that legislation in relation to research is followed within the Participating Site(s).	
3d	Ensure that any requirements for training of study staff are met	
3e	Ensure that the Participating Site team members are appropriately qualified and experienced to undertake the conduct of the Study.	
3f	Ensure that University of Warwick staff working at participating sites have current substantive or honorary employment contracts in place, where required.	
3g	Ensure that no Participant is recruited to the Study until satisfied that all relevant regulatory permissions and approvals have been obtained and authorisation to commence is received from the Sponsor.	
3h	Obtain written informed consent from participants and ensure consent forms are retained in appropriate site files.	
3i	Put and keep in place arrangements to allow all investigators to conduct the Study in accordance with the Protocol and applicable guidance and regulations.	
3j	Have systems in place to ensure accurate transposition of any Study instructions into additional documentation required by the NHS Organisation, other than that provided by the Sponsor.	
3k	Ensure that the Study is managed, monitored and reported as agreed in the Protocol, in particular patient safety and study progress and that adequate cover is in place by a suitably qualified member of staff during any absence of the CI or Local Site PI or lead for NHS Site	
3l	**Ensure that Investigational Medicinal Product (IMP) is not used for any purposes other than the conduct of the Study and is used in strict accordance with the Protocol. (CTIMPs only)**	

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3m	**Have adequate systems in place to ensure drug dosing and administration is carried out as detailed in the Study Protocol. (CTIMPs only)**	
3n	**Ensure IMP is provided and labelled in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004. (CTIMPs only)**	
3o	**Ensure that any generic brand of IMP used in the Study is licensed for commercial use within the UK or a European Member State and that the IMPs are prescribed, dispensed, labelled and accounted for in accordance with the Study Protocol and Clinical Trial Authorisation. (CTIMPs only)**	
3p	**Ensure that IMP is stored in appropriate and secure conditions and that detailed records are maintained regarding its movement from delivery to return/destruction. (CTIMPs only)**	
3q	**Ensure that the Reference Safety Information (RSI) for the trial, and any updates, present information in compliance with The Medicines for Human Use (Clinical Trials) Regulations (2004). (CTIMPs only)**	
3r	**Ensure that the RSI is reviewed for updates in accordance with the Study Risk Assessment, or minimally once a year. (CTIMPs only)**	
3s	**Ensure any IMP recalls are managed in accordance with the protocol and advice given by the MHRA. (CTIMPs only)**	
3t	Be responsible for the collection and management of Study data and the quality of the data produced, ensuring that it is of high quality, accurate and held/processed securely and confidentially.	
3u	Ensure that the rights of individual participants are protected.	
3v	Ensure that participants receive appropriate medical care whilst participating in the Study.	
3w	Maintain and archive Study documentation at the Participating Site.	
3x	Ensure that all data and documentation are available for the purposes of monitoring, inspection or audit including inspection and audit by the sponsor, and that the appropriate consent has been provided by the Participant.	

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3y	Ensure adequate facilities, resources and support are available to conduct the Study at the Participating Site and that appropriate site files are maintained at each Participating Site.	
3z	Monitor and record details of all incidents of protocol non-compliance, and assess all in relation to the risk posed to study participants, the study (and its data) and the organisation.	
3aa	Inform the Sponsor of Protocol violations according to the Sponsor's standard procedure.	
3bb	Report suspected research misconduct and potential Serious Breaches of the Protocol and / or GCP to the Sponsor	
3cc	Expedite reports of Serious Breaches of the Protocol and / or GCP to the Ethics Committee and NHS R&D Department and other appropriate parties (e.g.TSC/DMC) (as applicable)	
3dd	Develop and manage a Corrective Action and Preventative Action Plan related to any non-compliances and confirmed Serious Breach Serious Breaches of the Protocol and / or GCP	
3ee	Ensure annual progress reports (including any relevant safety information) are submitted to all relevant bodies, including the REC and Sponsor	
3ff	Notify all relevant bodies of the end of the Study within the specified timeframes.	
3gg	Inform the regulatory authority, relevant Ethics Committee, Sponsor and participating NHS Organisation if the Study needs to be temporarily suspended for any reason, according to the organisations' standard procedures.	
3hh	Notify the regulatory authority(ies) and relevant Ethics Committee if the Study is terminated early.	
3ii	Report the results of the Study on the EudraCT Database within the required timelines (Randomised Controlled Trials only)	

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4	**Amendments**	
4a	Prepare and submit proposed amendments of the Protocol and other approved study documentation to the regulatory authority(ies), relevant ethics committee and Participating Site(s) and maintain records of this.	
4b	Categorisation of amendments as substantial / non-substantial.	
4c	Ensure all required approvals are obtained prior to implementation of amendments.	
4d	Ensure participating site personnel are aware of dates of approval and implementation of amendments.	
5	**Adverse Events**	
5a	Keep records of and report all adverse events relating to the study which are reported by Investigators as specified in the protocol.	
5b	Ensure that all Serious Adverse Events (SAEs), other than those specified in the Protocol as not requiring immediate reporting, are promptly assessed as regards their relatedness and expectedness and therefore their requirement for expedited reporting to the relevant Regulatory Authority, Ethics Committee and other parties as applicable.	
5c	**Ensure that Study pregnancies are reported according to the protocol, the Study drug stopped immediately (if required by the Protocol) and the patient followed up according to the Protocol. (CTIMPs only).**	
5d	**Ensure that all Suspected Unexpected Serious Adverse Reactions (SUSAR) are identified and fully reported to the regulatory authority, relevant ethics committee and Sponsor within the required timelines. (CTIMPs only).**	
5e	**Ensure that investigators and the Sponsor are aware of any SUSARs occurring in relation to the IMP. (CTIMPs only).**	
5f	**Ensure that SUSARs arising from other trials using the same IMP(s) that are being sponsored by the University of Warwick are reported to the appropriate CIs in a timely manner. (CTIMPs only).**	

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5g	**Ensure that all SAEs are reviewed by an appropriate independent committee (e.g. the DMC) for the monitoring of trial safety in accordance with the Protocol and / or committee requirements. (CTIMPs only).**	
5h	Promptly inform regulatory authorities, Ethics Committees, investigators and Sponsor of any urgent safety measures taken to protect Participants in the Study.	
5i	Ensure that procedures are in place for emergency unblinding of the randomisation code as necessary.	
5j	**Ensure that annual Development Safety Update Reports (DSUR) are generated and submitted to the regulatory authority, relevant Ethics Committee and the Sponsor within the required timeframes. (CTIMPs only).**	
5k	**Ensure that all investigators are, at all times, in possession of the current study-approved Reference Safety Information (RSI) for the Study. (CTIMPs only).**	
6	**Data Management**	
6a	Design of case report forms and database.	
6b	Ensure all study files, records data and documents relating to the study are stored securely and in accordance with General Data Protection Regulation 2018 and are retrievable throughout the Study and archive period.	
6c	Ensure appropriate analysis of data.	
7	**Publication**	
7a	Initiate and coordinate review and submission of abstracts, posters and publications.	
8	**Archiving**	
8a	Ensure that all Study records are prepared for archiving appropriately on conclusion of the Study and retained for a minimum of 10 years following the reporting of the primary outcome, or in accordance with applicable regulatory requirements.	
8b	Ensure all study records are archived in accordance with applicable regulatory requirements.	

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Signed on behalf of The University of Warwick, as Research Sponsor of the project:

Name:

Job Title:

Signature: _____

Date:

Signed by Chief Investigator

I confirm that I understand and accept the delegated responsibilities detailed above:

Name:

Job Title:

Signature: _____

Date:

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Signed on behalf of Warwick Clinical Trials Unit (if applicable)

I confirm that I understand and accept the delegated responsibilities detailed above on behalf of the Warwick Clinical Trials Unit:

Name:

Job Title:

Signature: _____

Date:

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