UNIVERSITY OF LEICESTER

Chief Investigator Roles and Responsibilities Agreement

The Chief Investigator (CI), as the lead researcher, is responsible for the overall conduct and management of the trial and ensuring it is conducted in accordance with the following (together with any amendments thereof):

- UK Policy Framework for Health and Social Care Research (UKPF)
- All applicable legislation (including but not limited to that defined within Appendix 2 of the UKPF, the Medicines for Human Use (Clinical Trial) Regulations and Medical Devices Regulations) and that which is applicable to the territory within which the research is being conducted
- Good Clinical Practice (GCP)
- University of Leicester (UoL) Sponsor Standard Operating Procedures (SOPs) Human Tissue Act SOPs and Trusted Research SOPs (as applicable).
- Funder Terms and Conditions

The CI must confirm their understanding and agreement to assume the roles and responsibilities outlined below, and where applicable, accept the following activities as delegated to them by the University of Leicester as the Sponsor by signing the final page to agree to the document as a whole.

	I confirm that;	
General	1.	I understand the duties required of Investigators, Funders and the Sponsor as defined within the UKPF and appropriate legislation.
	2.	I am appropriately qualified by education, training and experience and have adequate resources and facilities to properly conduct the trial.
	3.	I agree to comply with the University's research policies and procedures as detailed within the SOPs.
	4.	The research team will give priority at all times to the dignity, rights, safety and wellbeing of participants.
	5.	I will maintain regular contact with the Sponsor and will include the Sponsor in relevant decision making and correspondence including the provision of meeting minutes and funder reports, to ensure they can maintain comprehensive oversight of the research project.
	6.	I will ensure research accruals will be updated on the CPMS and EDGE database(s), as appropriate.
Research Management and Reporting	7.	I will ensure that the protocol is (1) appropriately peer reviewed to ensure it is scientifically sound, and (2) will make effective use of patient, service user and public involvement (PPI), where appropriate.
	8.	Essential records will be maintained in a secure location with access restricted to members of the research team. This includes (but is not limited to) the creation and maintenance of a Trial Master File (TMF). These will be kept inspection ready at all times.
	9.	I understand that the Sponsor operates a risk-based monitoring program to which this trial is subject. I agree that the essential records and all other associated data and/or samples will be made available and that I will assist with any audit, inspection or monitoring whether undertaken by the Sponsor, external auditor or a regulatory body.
	10.	I will ensure a thorough feasibility assessment (as defined in SOP S-1033) of a potential research location(s) is undertaken prior to (a) naming the location(s) on the research application, and/or (b) adding a location(s).

	I confirm that;	
	11.	I understand that all regulatory approvals and permissions must be in place prior to the trial commencing and prior to the implementation of any modifications at each individual location.
	12.	I understand that the trial must be registered in a public registry within 90 days of approval and before the first participant is recruited.
	13.	I understand that within the period of 12 months, beginning with the day after the conclusion of the trial, I must publish a summary of the results in the same public registry or registries (if more than one) as the trial was registered, and, where applicable, to participants (written in a manner that is understandable to laypersons).
	14.	I will comply with the agreed procedures and arrangements for reporting (e.g., progress reports, safety reports) and for monitoring the trial, including its conduct, the participants' safety and well-being and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.
Staff/Delegation of Activities	15.	I will ensure students and researchers working on the trial will have appropriate supervision and training as detailed in Section 9.3 of the UKPF and SOP S-1020.
	16.	Where I wish to delegate specific activities to other persons or parties, I will ensure they are appropriately qualified by education, training and experience to undertake those activities.
	17.	I understand that robust processes must be place for the set-up, management and oversight of all parties to whom activities have been formally delegated (this includes research staff, research locations, and internal and/or external service providers).
Long Term Storage	18.	I will ensure there are appropriate arrangements to archive the TMF and data for the defined archive period, ensuring it is accessible and available in the event of an audit or inspection. I will keep Sponsor informed of the location of all archived records and data.
	19.	I will ensure there are appropriate arrangements for the long-term storage of samples and that the storage and future use will comply with the appropriate regulatory approvals, contracts/agreements, the protocol and UoL Sponsor SOPS and Human Tissue SOPs.

Chief Investigator Roles and Responsibilities Approval:

By signing this Roles and Responsibilities Agreement, you are confirming your understanding of your responsibilities and agreement to accept the activities delegated to you.

Sponsor Ref:	
Trial Title:	
Chief Investigator:	
Date:	
Signature:	