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 research project 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) and Human Tissue Act SOPs
- Funder Terms and Conditions

The CI must confirm their understanding and agreement to accept the following responsibilities 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 trained and qualified to undertake the duties of the Chief Investigator as laid out in SOP S-1010 and defined in Section 9.2 of the UKPF.
	3.	I agree to comply with the University's Sponsorship 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 confirm research accruals will be updated on the CPMS and EDGE database(s), as appropriate.
Research Management and Reporting	7.	I will ensure that the research 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 documentation 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) and, where applicable, Site-Specific File(s) in the case of a multi-site study. These will be kept inspection ready at all times.
	9.	I understand that the Sponsor operates a risk-based monitoring program to which this study is subject. I agree that the essential documentation and all other associated research 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.

	I confirm that;	
	10.	I will ensure a thorough feasibility assessment (as defined in SOP S-1033) of a potential research site(s) is undertaken prior to (a) naming the site(s) on the research application, and/or (b) adding a site(s).
	11.	I understand that all regulatory approvals and permissions must be in place prior to the research commencing and prior to the implementation of any amendments at each individual site.
	12.	I understand that research must be registered and the findings of the research must be made publicly available including, where appropriate, to research participants. This includes the provision of data and tissue (with adequate consent and privacy safeguards) in a timely manner after the research has finished.
	13.	I will comply with the agreed procedures and arrangements for reporting (e.g., progress reports, safety reports) and for monitoring the research, including the study 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 Duties	14.	I will ensure students and researchers working on the research project will have appropriate supervision and training as detailed in Section 9.3 of the UKPF and SOP S-1020.
	15.	Where I wish to delegate specific functions to another individual, I will ensure they are appropriately qualified by education, training and experience to undertake those functions.
	16.	I understand that all delegated functions must be detailed and signed off on the Delegation of Authority and Signature Log (SOP S-1010 Appendix 2) prior to an individual undertaking those functions.
Long Term Storage	17.	I will ensure there are appropriate arrangements to archive the TMF/ISF 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 documents and data.
	18.	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 Sponsor's Human Tissue SOPs.

Chief Investigator Roles and Responsibilities Approval:

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

Sponsor Ref:	
Study Title:	
Investigator Name:	
Date:	
Signature:	