|  |  |  |  |
| --- | --- | --- | --- |
| **Form Title:** | Chief Investigator Responsibilities Declaration Form | | http://www.lancaster.ac.uk/media/lancaster-university/content-assets/images/inlu/LU-Logo-new---web.jpg  This is the Lancaster University logo. |
| **Form Ref.:** | HSCR-FORM004 | | |
| This form must be completed after sponsorship approval has been granted, but before the offer can be classed as valid. Please return this completed form to [sponsorship@lancaster.ac.uk](mailto:sponsorship@lancaster.ac.uk) before you submit your application to the regulators. | | | |
| **Lancaster University agrees to undertake the role of sponsor for the project described below. This offer of sponsorship is conditional. This document outlines the conditions the offer is based upon, and the responsibilities Lancaster University as sponsor delegated to its Chief Investigators (CIs). Any breach of the below may result in withdrawal of sponsorship and the project being halted.** | | | |
| **Section 1-Project Information** | | | |
| **IRAS ID:** | |  | |
| **Full Title** (as it appears on IRAS)**:** | |  | |
| **Short Title** (as it appears on IRAS): | |  | |
| **CI Name:** | |  | |
| **Lead Researcher Name** (for student projects where this differs from the CI)**:** | |  | |
| **Section 2-CI Responsibilities** | | | |

|  |  |  |
| --- | --- | --- |
| * The Chief Investigator (CI) is responsible for ensuring that the research project and all researchers supporting the project comply with **all** applicable internal and external regulations and policies, such as the UK Policy Framework for Health and Social Care (2017), the Human Tissue Act (2004) and the General Data Protection Regulation (2016), Data Protection Act (2018) and all Lancaster University policies, Standard Operating procedures and Guidance. | | |
| * Sponsorship is offered on the basis that the final documentation approved by the Sponsor is the documentation that will be submitted to the Research Ethics Committee (REC) and/or the Health Research Authority (HRA), and that only the final versions approved by the REC and/or the HRA and the Sponsor, will be used in the conduct of the research. The CI will ensure that the versions of all documents listed on the final REC and/or HRA approval letter are sent to the Clinical Research Governance Team before the start of the study. | | |
| * Lancaster University expects the CI to ensure that a study master file is created and maintained throughout the course of the study. The study file may be electronic or hard copy but must be available to the sponsor and any regulatory authorities during monitoring visits/audits. The CI is expected to retain copies of all documentation relevant to the study, including approval documentation, all versions of the protocol and supporting documentation and relevant correspondence. Template indexes for study master files can provided upon request. | | |
| * Lancaster University as sponsor, delegates the responsibility for site set up to the CI and their research teams. The CI (or delegate) must provide sites with the necessary documentation from the local information pack in line with agreed site set-up processes. They will ensure all approvals/permissions for activities taking place at external organisations are in place prior to the research commencing at the site. Guidance on local information packs and site set up can be found on our [Site Setup and Study Management](https://www.lancaster.ac.uk/research/research-services/clinical-research/site-setup-and-study-management/). | | |
| * The CI is responsible for ensuring that any amendments made to the design, management and/or conduct of the study after sponsorship has been approved, is submitted to the Sponsor for approval **prior to** submission to the REC/HRA for approval. For all changes, the sponsor expects an [amendment tool](https://www.myresearchproject.org.uk/help/hlpamendments.aspx) to be completed and emailed to: sponsorship@lancaster.ac.uk , along with tracked version of any amended documents. | | |
| * The CI should in all cases of amendments ensure that all necessary permissions and approvals have been obtained prior to implementation. | | |
| * The CI is responsible for ensuring that appropriate funding and/or resources have been secured for the duration of the study and this has been accurately demonstrated for the sponsorship committee. All applications for external funding or use of internal funds must follow the appropriate institutional, faculty and departmental processes. Any changes which may affect the funding and/or resources of the study should be discussed with the post-award team and clinical research governance team as soon as possible. | | |
| * The CI must ensure that **all** REC/HRA, Sponsor(s), Funders, regulatory authority reports are completed in an accurate and timely manner and shared with the sponsorship committee via the [sponsorship@lancaster.ac.uk](mailto:sponsorship@lancaster.ac.uk) email. | | |
| * If any one of the first four categories are selected on question 2 of the IRAS application, indicating the study is a clinical trial, the CI is responsible for ensuring the projects is registered on clinicaltrials.gov, ISRTCN or another public database. The CI is responsible for maintaining the study registration throughout the lifecycle, and that results/ outputs are uploaded to the registry as soon as they are available. | | |
| * Where the study will be registered on the NIHR portfolio, the CI is responsible for ensuring that they work to time and to target and report any delays or issues with study activation or recruitment to the sponsor and local Clinical Research Network (LCRN) as soon as possible. Under the new DHSC agenda, any studies that are consistently underperforming or fail to maintain contact with the LCRN can be closed prematurely. In these instances, the sponsor is unable to override this decision. | | |
| * The CI is responsible for ensuring that any contract or agreement is referred to the RSO Contracts team for consideration where necessary. Site agreements that have already had authorisation do not require referral, but a copy should be provided to the clinical research governance team once executed. | | |
| * The CI will ensure that where appropriate they will follow the policies and procedures in place at research sites. This may include pre-employment checks, conditions of Honorary Research Contracts/Letters of Access, training requirements. It also includes conditions imposed by the REC/HRA along with their approval, reporting requirements and requests to assist partners or the university with internal or external audits/inspections. | | |
| * The CI will ensure that members of the research team are aware of and accept their roles and responsibilities and are appropriately qualified/ trained to undertake the research. Any delegation of CI tasks to members of the research team will be documented in a delegation log, or equivalent. | | |
| The CI is responsible for the management of all data/ samples generated by the study until the point of destruction. CI responsibilities extend to data/ samples generated and retained at a research site, unless formally delegated to the PI/ site management organisation. If the study CI is no longer able to manage the research records, the custodianship of the data/ samples must be formally transferred to another Lancaster University member of staff.  It is expected that the CI will ensure the study is closed fully when recruitment ends, by notifying the HRA and/or REC, as well as the sponsor. The CI should also ensure that all sites are notified of the closure of the study and provided with the end of study declaration. | | |
| **Section 3-Chief Investigator Declaration** | | |
| **I sign to confirm that I have read and accept the conditions of Sponsorship as outlined above and will adhere to all Lancaster University Policies and SOPs.**  **I understand that non-adherence to the conditions may be considered a breach of sponsorship, which will result in the suspension of the research and could result in withdrawal of sponsorship.** | | |
| **Name:** |  | |
| **Signature** (electronic signature accepted)**:** |  | |
| **Section 4-Lead Researcher Declaration** (educational Project Only) | | |
| **I sign to confirm that I have read and accept the conditions of Sponsorship as outlined above and will adhere to all Lancaster University Policies and SOPs.**  **I understand that non-adherence to the conditions may be considered a breach of sponsorship, which will result in the suspension of the research and could result in withdrawal of sponsorship.** | | |
| **Name:** | |  |
| **Signature** (electronic signature accepted)**:** | |  |