

Working with ICR-CTSU: Chief Investigator's Responsibilities

You are expected to work in close collaboration with the ICR-CTSU methodology lead, clinical trial programme managers, trial managers and trial statisticians on all aspects of study design and conduct from concept development through to final analysis and reporting. Specifically, you are expected to:

At study set up

- Ensure trial proposals have received high quality peer review via NIHR or an NIHR partner (e.g. CRUKs Clinical Research Committee) by contributing significantly to the development of funding or endorsement applications
- Ensure adequate research funding is available to cover all aspects of trial conduct, including central trial management and local site participation
- Contribute significantly to protocol development, providing approval and sign off for final versions and any subsequent amendments
- Contribute to the development of patient information sheets, consent forms and any additional patient material as required, providing approval of final versions and any subsequent amendments
- Contribute to the development of trial risk assessments and risk management strategies, providing approval and sign off for final versions
- Contribute to the development of the case report forms, providing approval and sign off for final versions and any subsequent amendments
- Contribute to the completion of ethics applications, providing sign off for final versions and written approval of any amendments
- Attend ethics committee meetings and contribute to any relevant correspondence

During trial recruitment and follow-up

- Encourage timely recruitment, contributing to launch meetings, ad hoc investigator/research nurse meetings, contacting/visiting participating sites if required, and contributing to the development of newsletters and promotional materials
- Encourage high levels of data and sample compliance
- Provide safety oversight, promptly assessing SAEs to enable reporting within regulatory timeframes, and contributing to the SAE reconciliation process where required
- Respond to clinical queries from ICR-CTSU and provide clinical review of trial data as required
- Contribute to the selection of Trial Management Group (TMG), Trial Steering Committee (TSC) and Independent Data Monitoring Committee (IDMC) members
- Chair regular TMG meetings
- Attend annual (or more frequent if required) TSC and, where appropriate, IDMC meetings
- Assist in the preparation of reports to funders, oversight committees, regulators and sponsors
- Contribute to and, where required, attend regulatory inspections
- Provide clinical review and interpretation of statistical analyses
- Contribute the preparation of manuscripts, abstracts and presentation materials, agreeing authorship/publication policy with the TMG
- Ensure due recognition is given to all stakeholders in any publication or presentation materials in accordance with terms and conditions of trial grant funding
- Present at national/international symposia as required

At all times

- Ensure ICR-CTSU is copied into all relevant correspondence and is informed of any developments that could impact on the conduct of a trial at the earliest opportunity

I have read and understood my responsibilities as a Chief Investigator working with ICR-CTSU

Signed: _____

Name: _____

Date: _____

Affiliation: _____