ICR The Institute of Cancer Research

Working with ICR-CTSU: Clinical Coordinators Role

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

At study set up

- Contribute to the development of funding or endorsement applications
- Contribute to protocol development and any subsequent amendments
- Contribute to the development of patient information sheets, consent forms and any additional patient material as required, and any subsequent amendments
- Contribute to the development of trial risk assessments and risk management strategies
- Contribute to the development of the case report forms, and any subsequent amendments
- Contribute to the completion of ethics applications, and any amendments

During trial recruitment and follow-up

- Contribute 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
- Where delegated, 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
- Attend 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
- Contribute to clinical review and interpretation of statistical analyses
- Contribute the preparation of manuscripts, abstracts and presentation materials
- 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 if 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 Clinical Coordinator working with ICR-CTSU

Signed: _____ **Name:** _____

Date: _____ **Affiliation:** _____

Please return a signed copy of this form to ICR-CTSU at email: ctsu@icr.ac.uk