SDRN: Scottish Diabetes Research Network

Site Selection Visits

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CHIEF SCIENTIST OFFICE

DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Shona Brearley	
1.1	Minor changes made	Louise Greig	June 2012

Site Selection Visits

1. Introduction

ICH GCP states that 'systems with procedures that assure the quality of every aspect of the trial should be implemented'. This SOP details the procedure to be followed to ensure that any Sponsor who visits the unit on a site selection visit is given standard information so that they can make an informed decision as to whether to place their study in that site or not.

2. Background

The site selection visit by a Sponsor is a crucial meeting as first impressions of the Research Unit can affect the future relationship between site staff and Sponsoring Companies/Charities. It is important that both parties appreciate what is being asked of them in conducting the study and that expectations from both sides can be delivered within realistic timeframes.

3. Procedure

- When arranging the site selection visit, ensure that the Principal Investigator and the research nurses can all attend. If other allied professionals e.g., dietician podiatrist etc., are involved in the study ensure they are invited to attend the site selection visit.
- Agree on any questions or practical issues that you wish to discuss with the sponsor.
- Preferably arrange a visit to the appropriate R and D Manager so that the Sponsor can meet the person dealing with the contract and R and D approval process.
- Arrange a visit to the Clinical Trials Pharmacist and demonstrate the drug storage and handling procedure.
- Ensure that everyone involved in the meeting has read the study protocol and arrange a team briefing before the visit occurs to agree any questions/practical issues to do with the study/recruitment strategies.
- Usually the Sponsor will provide an agenda for the meeting but if they do not, construct an agenda so that all the relevant information is conveyed to the Sponsor.
- Ensure the meeting is held in an office with minimal distractions, eg phones on answering machine, do not disturb sign on door.
- Give the Sponsor a conducted tour of the research unit, emphasising where study visits will take place.
- Show the Sponsor where you will keep study supplies and CRFs (CRFs must be kept in a locked cupboard). Locations where study documentation will be stored and where the CRA can monitor
- Demonstration of the SCI-DC database to show up to date patient information shows the Sponsor that you can recruit eligible patients for the trial.
- Discuss study timelines so that the workload of the unit can be managed.

- Ensure that recruitment strategies are discussed and set reasonable targets for participation in the study.

- A member of the study team should minute the meeting so that you can refer back to what was discussed when the study starts, usually several months later.

- Discuss the costing of the trial, ensuring that it is commercially viable. Special attention should be paid to travel expenses for patients and any expensive tests, e.g. CT or MRI scans, which may be required.

- Discuss archiving arrangements. Wherever practicable, encourage the sponsor to archive all study-related documents or to cover the costs of archiving in a secure warehouse.

- It is important to remember that Sponsor companies often visit several more sites than they require for each trial, so this visit is not just a formality but an opportunity to demonstrate the efficient professional approach to conducting clinical research within the Unit.