

Research Guidance Sheet No. 11 Monitoring of Research Studies

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Introduction

Under the Research Governance Framework for Health and Social Care, University Hospitals Bristol (UH Bristol) has a responsibility to monitor research studies conducted on its premises; additionally under ICH-GCP it has a responsibility to monitor studies for which it is sponsor. As a result the Research Management Office (RMO) has designed and implemented processes to meet these requirements.

Purpose - The purpose of monitoring is to ensure that:

- The rights and well being of subjects participating in the study are protected
- The conduct of the study is in compliance with the current approved protocol/protocol amendments, with Good Clinical Practice (GCP) and with the appropriate regulatory requirements

Identification of studies for monitoring

Studies will be assessed for monitoring once approval has been given by the Research Management Office.

Criteria: Studies that meet any or all of the following criteria may be selected for monitoring:

- Projects for which UH Bristol is the sponsor
- Clinical Trials using Investigational Medicinal Products (CTIMPs)
- Randomised studies
- High risk studies, e.g. studies where there is a high risk of Serious Adverse Events (SAEs)/Suspected Unexpected Serious Adverse Reactions (SUSARs) or studies where the occurrence of SAEs/SUSARs/ Toxicity measurements is being used as an endpoint
- Large intake studies
- Blinded studies
- Research involving children

These criteria will not, however, be considered exhaustive and studies may be selected for monitoring on the basis of individual circumstances alone. Whilst the criteria above may be used to identify studies, the individual reason for the department selecting a study for monitoring will not be disclosed.

Staff concerned about study conduct or compliance of a study with GCP/Regulatory requirements may request that a study is monitored by emailing the Research Management Office.

Monitoring Process

Staff from the UH Bristol Research Management Office will visit the study site at a pre-arranged time to perform the monitoring visit. It is important that during the visit at least one member of the research staff is present at the site. The staff member will not be required to accompany the monitor(s) throughout the duration of the entire visit (unless they wish to) but will need to be available during some parts of the monitoring process to answer questions and discuss any findings. Monitoring will cover all aspects of the study conduct, although particular emphasis will be paid to essential documentation, the Investigator Site File (ISF) or equivalent and consent documents.

Findings

The findings of each site visit will be collated and a visit report produced; this report will be sent to site within one month of the visit and will include but not be limited to the following:

- The date(s) of the visit
- The site
- The names of all individuals present
- A list of all findings observed by research management staff during the visit
- Recommendations for any actions that the site staff should take in order to address the findings, where possible these recommendations will be developed in conjunction with site staff
- References to any applicable sections of the ICH-GCP guideline
- A summary of the visit

The CI/PI will be required to provide the Research Management Office with a response within 28 days of receiving the report detailing the actions taken/actions to be taken to remedy the findings. The CI/PI may be requested to provide evidence that the required actions have been taken; additionally the RMO may conduct further monitoring visits to re-assess the site.