University Hospitals Bristol NHS
NHS Foundation Trust

Research Guidance Sheet No. 3[a]
Suggested standard wording for Investigational Medicinal Product (IMP) protocols for which University Hospitals Bristol (UH Bristol) is sponsor

v3.4_05.10.2010

In order to comply with the Medicines for Human Use (Clinical Trial) Regulations 2004 all protocols for IMP studies must include information on the headings given below. Where UH Bristol is the sponsor this information will be, with few exceptions, the same for all protocols. Researchers may use their own wording but in an effort to assist researchers, standard wording is provided below. **All protocols, patient information sheets, consent forms and data collection sheets, must also include a version number and date (in the format dd/mm/yyyy) within the header or footer.**

UH Bristol is unable to assume the role of sponsor for IMP studies that do not have adequate information under these or similar headings in the protocol.

Please note that this is not an exhaustive list of what to include in an IMP protocol; for further and more extensive guidance please see our guidance sheet IS1a "Guide to writing a protocol for IMP studies"

Protocol Headings	Standard wording
Details of Sponsor	University Hospitals Bristol NHS Foundation Trust, Research and Innovation, Level 3, UH Bristol Education Centre, Upper Maudlin Street, Bristol BS2 8AE. Tel: 0117 342 0233
CI and Research Team Contact Details	*Enter the Chief Investigator's contact details, including correspondence address and emergency contact details. Include contact details for relevant/key members of the research team.*
Study medication	*In addition to description of study medication, dose, regimen etc.* Study medication will be stored and dispensed by the trial site's pharmacy department in accordance with Good Clinical Practice and Good Manufacturing Practice.
Safety Reporting	Adverse events will be recorded in accordance with UH Bristol's Research Related Adverse Event Reporting Policy. *NB identify events that should not be reported as unexpected. Identify reference documents used to justify this decision e.g. Product Information.*
Monitoring and Audit	The study will be monitored and audited in accordance with UH Bristol's policy. All trial related documents will be made available on request for monitoring and audit by UH Bristol, the relevant Research Ethics Committee and for inspection by the Medicines and Healthcare products Regulatory Authority or other licensing bodies.
Data Protection	Data will be collected and retained in accordance with the Data Protection Act 1998.
Storage of records	Study documents (paper and electronic) will be retained in a secure location during and after the trial has finished. All source documents will be retained for a period of 15 years following the end of the study. Where trial related information is documented in the medical records – those records will be identified by a 'Do not destroy before dd/mm/yyyy' label where date is 15 years after the last patient last visit.
Indemnity	This is an NHS-sponsored research study. For NHS sponsored research HSG(96)48 reference no. 2 refers. If there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.
Ethics & R&D approvals	The study will be performed subject to Research Ethics Committee (REC) approval, including any provisions of Site Specific Assessment (SSA), and local Research and Development (R&D) approval.
Research Governance Statement	This study will be conducted in accordance with: • The Medicine for Human Use (Clinical Trial) Regulations 2004. • International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines. • Research Governance Framework for Health and Social Care.

For further information please see www.ct-toolkit.ac.uk

© University Hospitals Bristol NHS Foundation Trust