Research & Innovation

Research Governance Framework Factsheet

Health & Safety

Every contract of employment and honorary contract with the Trust requires staff to abide by the Trust Health and Safety policies including fire safety and training. In addition to usual levels of risk, research may involve the use of potentially dangerous or harmful equipment, substances or organisms in new ways. The safety of participants and of research and other staff must be well protected.

Research using hazardous processes and materials

The Control of Substances Hazardous to Health Regulations (COSHH) are the main piece of legislation covering the control of risks to employees and other people from exposure to harmful substances. These regulations should be adhered to when research involves materials or processes that could be hazardous to health. A COSHH risk assessment must be completed and appropriate controls in place before any hazardous substance is brought on to UHBristol premises.

UH Bristol incident forms should be submitted to the Safety Department if an accident occurs and the Research Ethics Committee should be informed.

Standard Operating Procedures

To ensure that data are collected consistently and accurately Standard Operating Procedures (SOPs) should be written for specific research processes and for individual items of equipment. SOPs should be written in simple language and be readily accessible. In some cases these may be the manufacturer's operating instructions.

It is encouraged to use SOPs to document the appropriate process of requesting informed consent for participation in the study. SOPs are also important in research where strict adherence to regulations/licences is necessary, for example, in research involving tissue.

Equipment used in research

Every contract of employment and honorary contract with the Trust requires staff to be aware of and adhere to the Trust Medical Devices Management Policy.

Equipment used to generate data should be:

- safe
- suitable for the purpose
- of appropriate design
- of adequate capacity

Appropriate personnel should calibrate it so that the results can be trusted. Records should be kept of calibration, servicing, faults, breakdowns and misuse of equipment, including unauthorised modifications.

A standard operating procedure (as above) should be available for each piece of equipment together with easily accessible instructions for the safe shutdown of equipment in case of emergency. Users must be appropriately trained in the use of any equipment supplied and training records kept.

All electrical and portable electrical medical equipment used in research at UH Bristol should have an acceptance check by MEMO before use. Non-medical equipment should be safety tested by the Estates Office.

Lone working

Researchers should take particular care to secure their personal safety when working in isolated circumstances. A safety protocol should be written where individual researchers are interviewing people at home. At least one colleague should be made aware of where and when the interviews are taking place and should be informed when the interview is over and the researcher has left the interviewee's home.

A standard risk assessment form is available from Trust website for managing Violence and Aggression.

Adverse events

A 'Serious Adverse Event' (SAE) or 'Serious Adverse Drug Reaction' (Serious ADR) as defined by The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use - Tripartite Guideline for Good Clinical Practice - (ICH-GCP) is

'any untoward medical occurrence that at any dose:

- results in death;
- is life-threatening;
- requires inpatient hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability/incapacity, or
- is a congenital anomaly/birth defect'

This also applies to studies not involving drugs and reporting is required whether or not the investigator considers the adverse reaction to be related to the study.

All SAEs and ADRs which occur in the course of research must be reported to the Sponsor and where applicable to regulatory authorities. More information on this process can be found on the R&I website under ‘safety reporting’. A UH Bristol incident form should be submitted to the Safety Department if an adverse incident occurs.

See also the Trust's policy for reporting research related adverse events.

Links:

•Information on COSHH

•Health and Safety Executive

•Medicines and Healthcare products Regulatory Agency

Health & Safety Advisers and Infection Control Advice
UH Bristol H&S Office Ext. 20136

Medical Equipment Acceptance Central Response
UH Bristol MEMO Ext. 23333

Medical Device Management Issues
UH Bristol MEMO Ext 24786

Testing of non-medical equipment
UH Bristol Estates Office Ext 22339