PARTICIPATING IN CLINICAL TRIALS

Proper governance of research is essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements (Dept. of Health (2001) Research Governance Framework for Health and Social Care). Governance of research is of direct relevance to all those who host, conduct, participate in, manage health and social care research. It is not restricted to principal investigators, managers or to any one professional group. All service and academic staff, no matter how senior or junior, have a role to play in the proper conduct of research. (Dept. of Health (2001) Research Governance Framework for Health and Social Care)

What is a Clinical Trial?

A clinical trial is an experimental study with patients as participants. The true experimental method is conventionally referred to as a randomised controlled trial with randomisation between experimental and control groups. The project usually aims to evaluate the effectiveness of new drugs or combinations of drugs or other health technologies. The research projects are usually large multi-centre funded projects that recruit from hospitals country wide and sometimes internationally.

The majority of clinical trials research carried out at the Hillingdon Hospital is in the form of a participating site and not the lead organisation. This means that Hillingdon Hospital professionals recruit patients to research projects and they are supported by the lead organisation.

All Clinical Trials research projects undertaken in the Hillingdon Hospital are required to adhere to Good Clinical Practice Guidelines. Anybody participating in clinical trials research in the Hospital will be expected to have a copy and adhere to the MRC ‘Guidelines for Good Clinical Practice in Clinical Trials’ (copies available from the R & D Office).

Principal Investigator

All projects have a principal investigator who has overall responsibility for the project, which includes setting up, establishing funding, managing and disseminating the research projects findings. The project team at the host institution is responsible for the designing the project, producing the protocols and gaining Multi-centre Ethics approval and recruiting and supporting the participating sites.

Role of Participating Site

The role of the participating site is to recruit the patients into the study. They are required to obtain local ethics approval (SSI) before they start the study. A local Investigator will be appointed (usually a Consultant within the speciality) who will be responsible to ensure that the protocol is adhered to, participants freely give informed consent and that all documentation is kept accurately and securely to maintain confidentiality.
Ethics Approval

All clinical trials require ethics approval where more than four sites are involved in the study firstly Multi Centre Ethics Committee (MREC) and then Local Ethics Committee (LREC) considerations. The MREC looks at the study as a whole and its suitability as a project involving human subjects and the LREC considers the suitability of the local researcher, the approval of the local research environments and facilities and specific issues relating to the local community.

Recruiting Patients

The local investigator or designated agent would identify patients who fit the criteria for a particular trial. Patients are given the information sheet and asked to discuss the implications of being a participant in the trial with their next of kin. Foreseeable risks should be weighed against the benefits and inclusion in the trial should only be considered if benefits justify the risks. Usually at their next appointment, if they are willing to be included in the trial, the patient is asked to sign the consent form, randomisation takes place as per the protocol and the patient is then formally entered into the trial.

Maintaining Records and Local Documentation

This relates to all records of the trial, such as protocol, amendments, submissions, agreements, approvals, forms, reports, correspondence, reference material, results etc., which must be kept securely and be available at all times for verification. Case Report Forms should be completed accurately and clearly and returned with a photocopy kept where necessary.

The Trust has agreed a standard method of record keeping that complement the documentation requirements of the clinical trials offices. This includes general records, the participant research records and patients’ hospital records. For further details please contact the R&D Office. The Trust has also developed a number of Standard Operating Procedures (SOP) to help researchers undertaking clinical trials. Please see intranet (R&D Pages) or contact R&D Office for copies.

Audit

A percentage of all non-commercially research and development projects will be audited annually by the Research and Development staff

Some principles of Good Clinical Practice in Trials

Good Clinical Practice in Trials is essential if the public is to have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements (Doh 2001 Research Governance Framework for Health and Social Care). This is the responsibility of all those who host, conduct, participate in, manage health and social care research. It is not restricted to principal investigators, managers or to any one professional group. All service and academic staff, no matter how senior or junior, have a role to play in the proper conduct of research.
Key principals

- Informed consent must be a minimal requirement for patient participation on any research project: patients must be given adequate time to read the project information sheet, be given the opportunity to discuss the project with the local researcher and his/her relatives before making a decision.
- Foreseeable risks should be weighed against the benefits and the trial only continued if benefits justify the risks.
- With regard to trial participants their safety, well-being and rights should take precedence over interests of science and society.
- A clear detailed protocol that has received ethical approval should be adhered to.
- Medical care given to participants should be the responsibility of a qualified professional.
- Confidentiality in every aspect should be maintained with regard to Patient’s records and identity. All data held on computer should be compliant with the Data Protection Act.
- All information recorded should be stored and handled with attention to detail and accuracy maintained for later verification.
- Health and safety issues should be identified and advice sort if necessary to enable the project to comply with the Health and Safety Act.
- All Projects must have the agreement of the Trust’s R&D Director to proceed before commencing to ensure that patients are safeguarded by the trusts indemnity policy.

<table>
<thead>
<tr>
<th>Who are they</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator and other researchers</td>
<td>- Developing proposals that are ethical and seeking research ethics committee approval&lt;br&gt;- Conducting research to the agreed protocol and in accordance with legal requirements and guidance e.g. on consent&lt;br&gt;- Ensuring participant welfare while in the study&lt;br&gt;Feeding back results of research to participants</td>
</tr>
<tr>
<td>Research Ethics Committee –</td>
<td>- Ensuring that the proposed research is ethical and respects the dignity, rights, safety and well-being of participants</td>
</tr>
<tr>
<td>Sponsor</td>
<td>- Assuring the scientific quality of proposed research&lt;br&gt;- Ensuring research ethics committee approval obtained&lt;br&gt;- Ensuring arrangements in place for the management and monitoring of research</td>
</tr>
</tbody>
</table>
**Employing organisation**

**Sponsor** - the organisation(s) employing the principal investigator and/or other researchers. The organisation employing the principal investigator will normally hold the contract(s) with the funder(s) of the study. Organisations holding contracts with funders are responsible for the management of the funds provided.

**Care Organisation** - the organisation/s responsible for providing care to patients and/or users and carers participating in the study

- Promoting a quality research culture
- Ensuring researchers understand and discharge their responsibilities
- Taking responsibility for ensuring the research is properly managed and monitored where agreed with sponsor

**Care organisation/ Responsible care professional**

The doctor, nurse or social worker formally responsible for the care of the participant while they are taking part in the study

- Ensuring that research using their patients, users, carers or staff meets the standard set out in the research governance framework (drawing on the work of the research ethics committee and sponsor)
- Ensuring research ethics committee approval obtained for all research
- Retaining responsibility for research participants’ care

**Participants / Research subjects**

Patients, users, relatives of the deceased, professional carers or members of the public agreeing to take part in the study.

**Funder(s)**

Organisation(s) providing funding for the study through contracts, grants or donations to an authorised member of either the employing and/or care organisation.

---

**For further information**

MRC Guidelines for good clinical practice in clinical trials (1998)

ICH / CPMP GCP guidelines Notes for guidance on good clinical practice (1996)

Declaration of Helsinki

MRC: A framework for development and evaluation of RCT’s for complex interventions to improve health (April 2000)

Research Governance framework for health and social care. (2001)