GOOD CLINICAL TRIAL PRACTICE

Everybody involved in the conduct of clinical research, from whatever discipline, should adopt the highest possible standards in order to protect patients.

These should follow from adoption of the principles of Good Clinical (Research) Practice set out in a number of different published guidelines. Within Europe a directive (91/507/EEC) from the European Commission effectively requires pharmaceutical industry clinical trials for purposes of registration of medicines to be conducted in accordance with these principles. The Association of the British Pharmaceutical Industry (ABPI) has already published its guidance for investigators, clearly setting out their responsibilities when taking part in industry sponsored clinical trials.

When researchers wish to conduct their own research, they and their respective Local Research Ethics Committees (LRECs) should adopt the principles of Good Clinical Research Practice which is a requirement in pharmaceutical industry sponsored trials. The following guidelines set out these general principles which should apply to all clinical research, avoiding those regulatory requirements specific to the pharmaceutical industry.

The investigator/researcher must:

- be aware of and understand the Declaration of Helsinki.
- ensure that he/she is fully familiar with the known properties of the medicine, device or procedure which is the subject of the proposed research.
- ensure that he/she has sufficient time to conduct and complete the research.
- obtain any necessary approval (i.e. a DDX from the licensing authority if pharmaceuticals are involved).
- inform any other clinicians who have current care of the patient.
- where appropriate and with the subject's consent, inform the family doctor, preferably before starting the research.
- ensure that he/she has adequate support staff and appropriate facilities (e.g. laboratories and archive space) which are available for the duration of the research project and beyond.
- ensure that new research projects do not divert essential subjects or facilities away from the research in hand.
- ensure that a formal detailed protocol is written and submitted to the LREC for approval.
- consider the need for retrospective data on numbers of patients who would have satisfied the proposed entry criteria during preceding time periods, when appropriate, in order to ensure a realistic but adequate recruitment rate for the research.
- obtain LREC approval, and, if necessary, approval of the relevant management, before the research study commences.
- abide by the protocol approved by the LREC, and accept that no changes should be made to the protocol without agreeing them with the committee.
- obtain informed consent from trial subjects in accordance with the Declaration of Helsinki before including them in the research.

- provide information to all staff members involved in the trial, ensuring that they are competent to undertake the tasks delegated to them.
- ensure that subjects enroled in a research project are provided with appropriate information about the research, which should include contact addresses and telephone numbers where further information can be obtained in case of action needed at another place.
- ensure that the confidentiality of all identifiable information about the subject is respected by all persons concerned.
- ensure that, where medicines are involved, their use is supervised by a responsible person such as a pharmacist, and is monitored and recorded.
- ensure that such medicines are handled and stored safely and properly and are only dispensed to research subjects in accordance with the protocol.
- ensure that there are appropriate case report forms and that all data recorded on them are complete and accurate and in accordance with the protocol, with any corrections to the data (which must be dated and initialled) made in such a way so as not to obscure the original entry, and with the reason for the change clearly stated.
- maintain for as long as required by the LREC or hospital management all subject or patient files and other source data relating to the research project, including where appropriate copies of the case report forms.
- ensure that subjects are told about any information which becomes available during the research which may be of relevance for them.
- document all adverse events within the patient's notes.
- notify the LREC, and the relevant authorities, promptly of any serious adverse reactions.
- submit reports on the progress and completion of the research, as required, to the LREC.
- maintain an accurate set of clinical records which should clearly and prominently indicate that the subject is taking part in a research project; this is to provide essential source material for auditing purposes.
- ensure appropriate medical care/follow-up of research subjects after the research is completed.
- ensure that indemnity insurance and insurance arrangements in the event of injury to research subjects are in place.
- ensure that publications or reports on the study accurately reflect the findings of the study.

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