

ABPI GUIDANCE NOTE

PATIENT INFORMATION AND CONSENTS

FOR CLINICAL TRIALS

This guidance provides a checklist as to the items which ought to be covered when a Member Company is designing (for use in connection with a company-sponsored clinical trial in the United Kingdom) (a) an information leaflet to be provided to patients as candidates for inclusion in a clinical trial and (b) the form of consent for signature by patients prior to inclusion. Both forms should be provided separately and be approved by an appropriate Ethics Committee. It is not intended to recommend any particular format for these purposes. Some sponsoring companies prefer most information to be in the information leaflet, and the consent form merely to recite that consent has been given. Although this note suggests recitation of key matters in the Consent Form this is not critical provided the relevant information is drawn to the patient's attention in the leaflet. Obviously it is desirable that whatever the format, it is 'user friendly' and as comprehensive as possible for lay readers.

In preparing this guidance consideration has been given to legal, medical and ethical principles, the requirements of the Declaration of Helsinki, and to other relevant texts including the Report of the Royal College of Physicians of London entitled 'Research Involving Patients' (January 1990) ('the RCP Report'); CPMP/ICH guidelines on 'Good Clinical Practice'; (CPMP/ICH/135/95).

Compliance with the recommendations in this guidance note does not obviate the need to add to or adjust any documents to take account of any unusual features in a trial. Moreover, it is always important to ensure that all other aspects of 'Good Clinical Practice' are followed.

This guidance is designed for patients proposed for entry into a clinical trial as distinct from volunteers for a Phase I Study.

The checklists follow, (words in italics are ancillary notes to each main item):

(a) Patient Information (to be provided to candidates for inclusion in a clinical trial)

- (i) Identify main items and describe the purpose of the study
Link with reference to the Protocol Number. Always state the study concerns 'a medicine, audit or device under research'. Provide the name and contact details of the study doctor and refer to the name of the sponsor on whose behalf the study is being conducted.
- (ii) Explain participation is voluntary **but why invitation has been issued.**
- (iii) Explain who is involved in the study
*Indicate how many patients in the study. **Some ethics committees have apparently wanted to know in addition how many patients have received the study drug so far and generally want this communicated in the patient information. This would only be relevant in Phase II and III trials.***
- (iv) Explain what is involved (for the patient) by participation in the study
If, in addition to treatment, the patient has to undergo other procedures (e.g. blood tests), this must be explained also. If the study involves a placebo or comparison treatments, this must be clearly stated. Indicate number of times visits must be made to doctor, hospital and/or elsewhere, and what will be involved.
- (v) State the expected duration of the study.
- (vi) Provide any instruction about record-keeping.
- (vii) Indicate where and how further information can be obtained (*Note that the patient will be informed of new information material to the consent if this becomes known during the progress of the study*).
- (viii) Describe possible side-effects and what to do if concerned
Explain what to do about unexpected side-effects.
- (ix) Provide any instructions relating to consumption of other medicines, food, drinks etc whilst in the study.
- (x) Provide any instructions relating to any restrictions on driving, using machinery, sport or other activities whilst in the study.
- (xi) **In exceptional circumstances, where it is applicable to the patient population, instructions should be provided for pregnant patients or patients who might become pregnant. Such patients are normally excluded from clinical trials.**
- (xii) Explain benefits of and risks (as reasonably foreseen) of participating in the study
Benefit can be for the patient, society at large or both. Refer to potential benefits and risks of alternative therapies, if applicable. Inform the patient of the physical and psychological risks both in terms of the magnitude of the risk (chance of it arising) and its potential seriousness.

- (xiii) Explain rights to withdraw from study without giving a reason and without any prejudice to continuing rights to treatment and alternative therapy
Explain that the doctor may also decide to withdraw a patient from the study and why. If possible patients should be told what the alternative treatments are.
- (xiv) Explain how data is recorded and who may have access to it **and the source documentation.**
*Record that the patient's general practitioner will be informed about the patient's participation in the study. Access may be available to Doctors, Study monitors and clinical-trial auditors, ethics committees and regulatory authorities.
The study results may be publicised. The patient's identity will not be disclosed in publication.*
- (xv) Explain that compensation may be available for **any injury attributable to administration of a medicinal product within the trial or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial.**
Record that compensation will be considered in accordance with the 'Clinical Trial Compensation Guidelines' issued by ABPI (1991, reprinted 1994), where applicable, and inform the patient that a copy of the guidelines can be made available on request.
- (xvi) Explain if travel or other costs will be reimbursed and, if so, to what extent and how, and specify any other payment made to patients who participate.

Other information may be included if appropriate. Updates should be provided when necessary.

As a final note, the following extract is re-produced from the RCP Report.

'It is unreasonable to ask a patient to agree on the spot to take part in research which either involves more than minimal risk or involves extended inconvenience or discomfort. Time should be allowed for the patient to consider the position, to read the Information Sheet in unhurried circumstances and to discuss it with a friend or relative. The time required for this will depend on what seems appropriate in the circumstances. For research which is low risk or undemanding it might, for example, be quite acceptable for a patient attending a hospital clinic or a general practitioner to have a cup of tea and to reach a decision within a few minutes. In other circumstances it might seem appropriate for the decision to be declared at a different visit on a different day.'

(b) Patient Consent Form (to be signed by patients prior to inclusion within a clinical trial)

- (i) Refer to the Study by name and the Protocol by number as well as the name of the patient.
- (ii) Confirm the patient has read **and understood** the Patient Information Leaflet which should be attached to the Consent Form for identification purposes.
- (iii) Confirm name, address and phone number of the Study Doctor for the patient.
- (iv) Confirm discussion of the patient's possible participation with study (or other nominated) Doctor.
- (v) Confirm the patient's duties to report possible side-effects, other health changes, and/or changes to medical treatment.
- (vi) Confirm (when Study Doctor is not the patient's GP) that Study Doctor may contact General Practitioner to obtain medical records.
- (vii) Confirm the patient's understanding about access to data.
- (viii) Confirm the patient has had an opportunity to ask questions and has received satisfactory answers.
- (ix) Confirm the patient has received enough information about the Study to ensure the patient appreciates what the research entails.
- (x) Confirm the patient's right to withdraw from the trial at any time, without having to give a reason, and without any prejudice to continuing treatment.
- (xi) Confirm the patient is agreeing to participate on a voluntary basis.
- (xii) Confirm the retention of all legal rights for the patient and, where applicable, eligibility for compensation in accordance with the 'Clinical Trial Compensation Guidelines' issued by ABPI (1991).

The patient should sign and date the consent form personally to be followed by a signature and date from the doctor who has conducted the discussion about participation in the study to confirm that proper counselling has taken place and the consent was freely given. For patients who cannot read, or have intellectual or other difficulties in speech or understanding, an impartial witness should also sign and date the form to confirm that (s)he was present when the counselling took place and that in the opinion of the witness the consent of the patient was based upon a reasonable understanding of what the research involved. Further guidance (eg the RCP Report) should be sought and followed where the patient is a child or suffering from incapacity. The patient should be given a copy of the patient information and consent form when signed for future reference.



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