SCHEDULE 3 Regulation 14(6), 17(2), 24(9) and 27(3)

PARTICULARS AND DOCUMENTS THAT MUST ACCOMPANY AN APPLICATION FOR AN ETHICS COMMITTEE OPINION, A REQUEST FOR AUTHORISATION, A NOTICE OF AMENDMENT AND A NOTIFICATION OF THE CONCLUSION OF A TRIAL

PART 1

APPLICATION FOR ETHICS COMMITTEE OPINION

1. An application document including the following information or, in each case, an explanation of why that information is not being provided—

(a) the reference number of the ethics committee to which the application is made;

(b) particulars identifying the trial including—

(i) the number allocated to the trial on the European database referred to in Article 11 of the Directive, and

(ii) full and short titles of the trial;

(c) the following particulars relating to the trial design—

(i) a summary of the trial, including justification and relevance, and the methodology to be used,

(ii) the primary, and any secondary, research hypothesis,

(iii) statistical analysis and justification for the numbers of subjects to be recruited for the trial, and

(iv) details of the process for peer review of the scientific value of the trial;

(d) brief details of any plans to conduct the trial outside the UK and any authorisation given in relation to the trial by a competent authority of an EEA State in accordance with Article 9 of the Directive;

(e) the name and address of the sponsor;

(f) details of any arrangements under which the sponsor has delegated any of his responsibilities in relation to the proposed trial;

(g) the financial arrangements for the trial, in particular—

(i) sources of funding for the trial and information on financial or other interests of the applicant relevant to the trial,

(ii) the arrangements for remuneration of, or re-imbursement of expenses incurred by, subjects,

(iii) any provision for compensation in the event of injury or death attributable to the trial,

(iv) details of any insurance or indemnity to cover the liability of the sponsor and investigator, and

(v) summary details of any financial arrangements between—

(aa) the sponsor or person funding the trial and the investigator, and

(bb) the sponsor or person funding the trial and the owner or occupier of the trial site;

(h) arrangements for the recruitment of subjects, including the materials to be used;

(i) the criteria for inclusion and exclusion of patients, including justification for recruiting from vulnerable groups;

(j) in the case of Phase I trials, methods for recording and verifying health status for healthy volunteers;

(k) procedures for checking simultaneous or recent involvement of potential subjects in other trials;

(l) details of any relationship between subject and investigator which may be relevant for the purposes of an ethical opinion;

(m) details of—

(i) any proposed additional investigational procedures or other interventions over and above those required for normal clinical care, and

(ii) any aspect of normal clinical care to be withheld or other deviation from normal treatment, and

(iii) the plan for treatment or care of subjects once their participation in the trial has ended;

(n) the procedures for—

(i) providing information to potential subjects, including a contact point where additional information can be obtained about the trial and the rights of trial subjects,

(ii) providing subjects with updated information during and (where relevant) after the trial, and

(iii) obtaining informed consent;

(o) details of the arrangements for access to confidential data about the subjects and the arrangements to protect subjects' privacy;

(p) the rules for terminating or concluding the trial before—

(i) the date for the conclusion of the trial specified in the protocol, or

(ii) the event specified in the protocol as the event which indicates that the end of the trial has occurred;

(q) any agreement on—

(i) the access by the investigator or his team to the data produced by the trial, and

(ii) the policy for publication of that data;

(r) an assessment of the ethical issues relating to the trial, including—

(i) the importance of the trial and of the new knowledge to be gained,

(ii) an assessment of the potential benefits, and

(iii) an assessment of the possible risks for the subjects;

(s) details relating to the chief investigator and each investigator, including—

(i) experience in conducting research, and

(ii) any potential conflicts of interest; and

(t) details of any proposed trial site and its suitability for conducting the trial.

2. A document containing the particulars specified in paragraphs 1 to 4 and 6 to 9 of Part 2 of this Schedule.

3. The following documents or, in each case, an explanation of why that document is not being provided—

(a) the protocol;

(b) the investigator's brochure for the proposed trial or, where the investigational medicinal product has a marketing authorisation and the product is to be used in accordance with the terms of that authorisation, the summary of product characteristics relating to that product;

(c) any document providing evidence of any insurance to cover the liability of the sponsor and investigator;

(d) copies of the advertisement material for recruitment of research participants;

(e) in the case of advertising contained on video or audio cassettes, a copy of the script for that advertising;

(f) a copy of any letter inviting a subject to participate in the trial;

(g) a copy of any questionnaire, diary or sample card to be completed by the subject in writing;

(h) a copy of all written information to be given to a potential subject or their legal representative prior to seeking informed consent;

(i) a copy of the form to be used to record the consent of a subject or their legal representative;

(j) a copy of any letters or other written information to be sent to any person who normally provides a subject's clinical care;

(k) a summary curriculum vitae for the chief investigator and each investigator.

PART 2

REQUEST FOR AUTHORISATION

1. The name and address of—

(a) the sponsor,

(b) if the sponsor is not established in the European Community, his legal representative,

(c) if any person has been authorised by the sponsor to make the request on his behalf, that person,

(d) if the persons taking responsibility for the initiation, management and financing (or arranging the financing) of the clinical trial have allocated responsibility in accordance with regulation 3(4), any person responsible for carrying out the functions of the sponsor under Part 4 or 5 of these Regulations, and

(e) any other person to whom the sponsor has delegated any of his responsibilities in relation to the proposed trial.

2. If any person is specified as a person responsible for the duties of the sponsor under regulation 28(2) and (3) in relation to the trial—

(a) the name and address of that person; and

(b) the trial sites in relation to which they are so responsible.

3. The address of each trial site and the names and address of the investigator responsible for the conduct of the trial at each site.

4. Where the trial is to be conducted at trial sites in another EEA State, a list of the competent authorities to which a request for authorisation has been made.

5. A copy of the ethics committee opinion in relation to that trial, if available.

6. A description of any investigational medicinal product to be used in the trial.

7. The name and address of the person responsible for the manufacture or importation of any finished investigational medicinal product to be used in the trial and the details of any authorisation referred to in Article 13 of the Directive held by that person.

8.—(1) The address of any premises at which any batch of finished investigational medicinal products to be used in the clinical trial has been, or is to be, checked in accordance with Article 13(3) of the Directive.

(2) If an investigational medicinal product to be used in the clinical trial has been, or is to be, imported from a third country, a statement from the qualified person at the disposal of the person holding the authorisation referred to in Article 13 of the Directive in relation to that importation specifying—

(a) the address of any premises outside the European Economic Area at which the product was manufactured or assembled; and

(b) the manufacturing or assembling operations performed at those premises.

9. A description of the proposed clinical trial.

10. The protocol for the proposed trial.

11.—(1) Subject to sub-paragraph (7), a dossier on each investigational medicinal product to be used in the trial ("investigational medicinal product dossier"), compiled in accordance with the following sub-paragraphs.

(2) In all cases the dossier must contain a summary assessment of the potential risks and benefits of the use of the product in the proposed trial.

(3) In the case of an investigational medicinal product, other than a product referred to in sub-paragraphs (4) to (7), the dossier must contain—

(a) summaries of the chemical, pharmaceutical and biological data on the active substance and the finished product;

(b) summaries of the non-clinical pharmacology and toxicology data on that product, if available; and

(c) summaries of the available data from previous clinical trials of, and human experience with, that product.

(4) In the case of an investigational medicinal product which has a marketing authorization, the dossier must contain—

(a) a copy of the summary of product characteristics;

(b) if there has been a change—

(i) to the process of manufacture of the product or its active substance, or

(ii) of manufacturer of that product or substance,

the summaries referred to in sub-paragraph (3)(a);

(c) if the product is to be used in the trial after it has been blinded, the summaries referred to in sub-paragraph (3)(a), in so far as they relate to the blinded product; and

(d) if the product is to be used other than in accordance with the terms of the summary of product characteristics under that authorization, the summaries referred to in sub-paragraphs (3)(b) and (c), in so far as that data relates to such use.

(5) In the case of an investigational medicinal product which does not have a marketing authorization, but where—

(a) another pharmaceutical form or strength of that product has a marketing authorization; and

(b) the investigational medicinal product is supplied by the holder of that authorization,

the dossier must contain the summaries referred to in sub-paragraph (3)(a), in so far as they relate to the finished product to be used in the trial, and the summaries referred to in sub-paragraph (3)(b) and (c), in so far as they relate to the product to be used in the trial.

(6) In the case of an investigational medicinal product which does not have a marketing authorization, but where—

(a) another medicinal product containing the same active substance has a marketing authorization; and

(b) the investigational medicinal product is supplied by the manufacturer of that other product,

the dossier must contain the summaries referred to in sub-paragraph (3)(a), in so far as they relate to that other product, and the summaries referred to in sub-paragraph (3)(b) and (c), in so far as they relate to the product to be used in the trial.

(7) Where the investigational medicinal product is a placebo, the dossier must contain the summaries referred to in sub-paragraph (3)(a), in so far as they relate to that product.

(8) A dossier relating to an investigational medicinal product is not required if—

(a) the product has been used in a clinical trial that has been authorised, or is to be treated as having been authorised, by the licensing authority for the purposes of these Regulations; and

(b) the sponsor of that trial authorises the licensing authority to refer to the dossier submitted in relation to that trial.

12. A description or sample of the labelling which is to appear on each investigational medicinal product when supplied to a subject in the trial.

PART 3

NOTICE OF AMENDMENT

1. The name and address of—

(a) the sponsor,

(b) if the sponsor is not established in the European Community, his legal representative, and

(c) if any person has been authorised by the sponsor to send the notice on his behalf, that person.

2. Particulars identifying the trial, including—

(a) the title of the trial; and

(b) the number allocated to the trial on the European database referred to in Article 11 of the Directive.

3. A description of the proposed amendment.

4. A statement of the reasons for proposing that amendment.

5. A copy of the proposed changes to—

(a) the clinical trial protocol; or

(b) any other particulars or documents accompanying the request for authorisation or the application for an ethics committee opinion.

6. Summaries of—

(a) any data submitted in support of the proposed amendment; and

(b) any change to the assessment referred to in paragraph 11(2) of Part 2.

PART 4

NOTIFICATION OF CONCLUSION OF A CLINICAL TRIAL

1. The name and address of—

(a) the sponsor, and

(b) if the sponsor is not established in the European Community, his legal representative.

2. Particulars identifying the trial, including—

(a) the title of the trial; and

(b) the number allocated to the trial on the European database referred to in Article 11 of the Directive.

3. The investigational medicinal product tested in the trial.

4.—(1) The date on which the trial ended in the United Kingdom.

(2) If the trial was conducted at more than one trial site in the United Kingdom, the dates on which the trial was ended at those sites, if different from the date referred to in sub-paragraph (1).

(3) If the trial was conducted at any trial sites outside the United Kingdom, a statement as to whether the trial has ended at any of those sites and, if so, the date on which the trial was so ended.

5. If the trial is terminated as specified in regulation 27(2), the reasons for terminating the trial early.