

SCHEDULE 12

TRANSITIONAL PROVISIONS

Ethical approval given before 1st May 2004

- 1.—(1) This sub-paragraph applies where—
 - (a) a clinical trial is conducted after 30th April 2004;
 - (b) no ethics committee has given a favourable opinion in relation to that trial in accordance with regulation 15; and
 - (c) a committee established or recognised for the purpose of advising on the ethics of research investigations on human beings has before 1st May 2004 given a favourable ethical opinion in relation to that trial.
- (2) Subject to the following sub-paragraphs, where sub-paragraph (1) applies—
 - (a) the trial shall be treated for the purposes of these Regulations as if an ethics committee has given a favourable opinion in relation to that trial in accordance with regulation 15;
 - (b) regulations 12, 24(3) and 29 shall apply in relation to the trial with the modification that references to the application for an ethics committee opinion shall be read as references to the application for approval made to the committee referred to in sub-paragraph (1)(c); and
 - (c) regulations 24, 25, 27, 30 to 35 and 48 shall apply in relation to the trial with the modification that references to the relevant ethics committee shall be read as references to the committee referred to in sub-paragraph (1)(c).
- (3) This sub-paragraph applies where the committee referred to in sub-paragraph (1)(c) has not been recognised by the Authority in accordance with regulation 7—
 - (a) for the area in which the trial sites are situated, or
 - (b) for the description or class of clinical trial into which the trial falls,before 1st September 2004.
- (4) Where sub-paragraph (3) applies—
 - (a) the sponsor of the clinical trial may make an application to an ethics committee established or recognised by the Authority in accordance with Part 2—
 - (i) for the area in which the trial sites are situated, or
 - (ii) for the description or class of clinical trial into which the trial falls,for an amendment to the protocol for the trial within the meaning of Part 3 of these Regulations; or
 - (b) the chief investigator may make an application to an ethics committee in accordance with regulation 14.
- (5) Where an ethics committee receives an application for an amendment in accordance with sub-paragraph (4)(a), it shall consider the amendment as if it was a valid notice of amendment under regulation 24.
- (6) Where an ethics committee gives a favourable opinion in relation an application for amendment made pursuant to sub-paragraph (4)(a)—
 - (a) sub-paragraph (2)(c) shall cease to apply; and
 - (b) regulations 24, 25, 27, 30 to 35 and 48 shall apply in relation to the trial with the modification that references to the relevant ethics committee shall be read as references to the committee which gave that favourable opinion.

Status: This is the original version (as it was originally made).

(7) Where an ethics committee gives a favourable opinion in relation to an application pursuant to sub-paragraph (4)(a), sub-paragraph (2) shall cease to apply in relation to that trial

(8) Where sub-paragraph (3) applies and before 1st May 2006 no favourable opinion has been given as specified in sub-paragraphs (6) and (7), sub-paragraph (2) and (4) shall cease to apply from that date.

(9) If the committee referred to in sub-paragraph (1)(b) is abolished or ceases operation before 1st May 2006—

- (a) the Authority shall nominate an ethics committee as responsible for the work of the committee which is abolished or which ceases operation; and
- (b) regulations 24, 25, 27, 30 to 35 and 48 shall apply in relation to the trial with the modification that references to the relevant ethics committee shall be read as references to the committee so nominated.