

SCHEDULE 2

ADDITIONAL PROVISIONS RELATING TO ETHICS COMMITTEES

Committees, meetings and proceedings

6.—(1) An ethics committee may—

- (a) appoint sub-committees consisting of members of the committee; and
- (b) make arrangements for the exercise, on behalf of the committee, of any of its functions by such a sub-committee,

in accordance with the standing orders and operating procedures adopted under sub-paragraph (3).

(2) Subject to sub-paragraph (4), the meetings and proceedings of an ethics committee and its sub-committees shall be conducted in accordance with the standing orders made, and standing operating procedures adopted, under sub-paragraph (3).

(3) An ethics committee—

- (a) shall, subject to approval by the Authority, make standing orders, and adopt standing operating procedures, for the regulation of its proceedings and business; and
- (b) may, subject to approval by the Authority, vary or revoke such orders or procedures,

including provision for the suspension of the standing orders or operating procedures or any of them.

(4) No business shall be transacted at a meeting of an ethics committee, or a sub-committee of an ethics committee, to determine, in accordance with regulation 15, the opinion of an ethics committee in relation to a clinical trial, unless at least seven members of the committee (including any members co-opted under paragraph 8) are present, including at least—

- (a) one lay member who is not and never has been—
 - (i) a health care professional, or
 - (ii) a chairman, member, director, officer or employee of a health service body; and
- (b) one expert member.