

SCHEDULE 4

APPEAL AGAINST UNFAVOURABLE ETHICS COMMITTEE OPINION

1.—(1) Subject to the following sub-paragraphs, where the United Kingdom Ethics Committee Authority (“the Authority”) receive a notice pursuant to regulation 16(3) or (7) that a chief investigator wishes to appeal against an ethics committee opinion which is not favourable, the Authority shall, subject to sub-paragraph (2)—

- (a) direct that the application for that opinion may be considered by another ethics committee specified in the direction; or
- (b) appoint a panel in accordance with paragraph 3 (“an appeal panel”) and refer the opinion to that panel.

(2) Subject to sub-paragraph (4), the Authority may refuse to give a direction or appoint a panel pursuant to sub-paragraph (1) where it considers that the grounds for appealing against the opinion are unfounded.

(3) Where the Authority refuse to give a direction or appoint a panel pursuant to sub-paragraph (1), the Authority shall send a notice to the chief investigator setting out their reasons for refusal.

(4) Where the opinion was given by the Gene Therapy Advisory Committee, the Authority must appoint a panel in accordance with paragraph 3 and refer the opinion to that panel.