

FROM: NATIONAL RESEARCH ETHICS ADVISORS' PANEL

TO: NRES Committee Chairs and Members

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STATEMENT FROM THE NATIONAL RESEARCH ETHICS ADVISORS' PANEL

The Panel have been made aware that RECs are being inconsistent in their opinions concerning the use of addenda to information sheets used to alert existing participants to changes made to the research. It was noted by the Panel that there are no NRES policies, nor existing guidance, prohibiting the use of addenda in such situations.

The Panel consider that RECs have a responsibility to promote best practice with regard to the provision of relevant information in a timely manner to research participants. The prime ethical issue in such circumstances is the provision of important new information to research participants as quickly as possible and that it is not helpful to hinder this by entering into a prolonged debate regarding the specific format of the information or by prohibiting certain formats such as addenda to information sheets.

It is perfectly acceptable for participants to be notified, by a separate record, letter or addendum to the information sheet, of amendments. It is NOT necessary for RECs to insist that the information sheet is redrafted and sent to all research participants.

Document Control

Change Record

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1.2	01/02/2012	Revised to read as a statement rather than as a response Rebranded HRA