

National Research Ethics Service

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TO: REC Chairs / RECs

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Title of document: Follow-up contact of potential participants who have not responded to an initial invitation to take part in research

Background: This guidance addresses the issue of the follow-up of “non-responders” by telephone or in writing after they have been initially approached to consider taking part in the research. Some basic principles should be taken into account when considering research involving follow-up contact of “non responders”.

Follow-up contact of potential participants who have not responded to an initial invitation to take part in research

Some RECs have taken the position that potential participants, who have not replied to an initial invitation to take part in research, should not be contacted again to find out if they had come to a decision regarding their participation.

This guidance addresses the issue of the unsolicited follow-up of 'non-responders' by telephone, or in writing, after the initial approach. Some basic principles should be taken into account when considering following-up 'non-responders'.

Consideration of the principle of respect for autonomy along with the right to privacy suggests that individuals should not be subject to undue persuasion and unsolicited communication. Indeed, with respect to marketing messages, individuals have the legal right to refuse such unsolicited messages by phone, email, fax and text. Whilst every case would need to be taken on its own merits, however, RECs should be wary of being too paternalistic and overprotective of patients' rights in this regard, particularly where initial contact has already been made and potential participants have not replied.

Maximising access to a public good such as ethically approved clinical research is an important aim, grounded by the principle of justice involving the distribution of research benefits and burdens, and that non-coercive communication aimed at facilitating this is desirable.

Unsolicited follow-up communication by investigators is not in itself coercive nor does it fail to adequately respect an individual's privacy. It is the REC's responsibility to ensure that appropriate procedures for any such follow-up contact are detailed in the research protocol and to ensure that these procedures are non-coercive and respect the individual's right to autonomy. Unless there are good reasons not to, potential participants should be made aware that the investigators might contact them again in the future and be given the opportunity to opt out of any further communication.

There may be instances where unsolicited follow-up contact may not be desirable due to the nature of the research and/or the vulnerability of the research participants. For example, it might not be considered appropriate for researchers to follow-up an initial invitation to recently bereaved parents, without telling the parents that they intended to do this. Whilst any such intrusion into their grief would need to be balanced against the potential for direct benefit to the parents and the wider social interest in the research, the threshold at which researchers would be permitted to follow-up an invitation in this case would be set far higher than for other less potentially distressing research.

The following principles should be taken into consideration:

- The initial contact with the potential participant must be made by an individual with the right to access their personal information. The following guidance from the Academy of Medical Sciences is considered useful in relation to this principle:

"4.5.2 Consent for consent...If the first approach to the patient is made after prior checking, it will be clear that the person making the approach must have had access to a patient's personal medical information. Some patients may be offended, not by the invitation to take part in research, but by the knowledge that someone has had access to their personal medical records". (Academy of Medical Sciences: Personal data for public good: using health information in medical research, January 2006)

- Subsequent follow-up contact should also only be undertaken by an individual with the right to access their personal information (unless the potential participants have previously agreed that a third party may access their personal details for the purpose of follow up).
- If relevant, potential participants should be informed that they will be contacted again and given the opportunity to decline this follow-up contact.
- Follow-up communication with potential participants must not be persistent and should be neutral in relation to the real or perceived benefits of the proposed research. The primary reason for the follow-up contact should be to ascertain whether the individual had made a decision.
- RECs should be assured that if an individual indicates that they do not wish to take part in research at any stage they would not be contacted again or have pressure put on them to reconsider their decision in any way.

These principles are by no means exhaustive and every case must be reviewed on its own merits but it is hoped that they will assist RECs in their discussion of this issue.

The National Research Ethics Advisors' Panel is an independent panel hosted and appointed by NRES. It was established under direction of the four UK Health Departments and the United Kingdom Ethics Committee Authority.