

Information for participants at the end of a study:

Guidance for Researchers

Background

Historically researchers have not consistently provided the results of studies to participants, however participants increasingly expect findings to be made available to them at the end of study.

Even when researchers intend to share results, participants are often uncertain as to how they might access this information. The time lag between the end of patient participation in a study and the availability of the results may also increase this uncertainty. Furthermore most patients are often unable to access published literature and need access to summary findings in a format they can understand.

Participants in health research studies may be unsure about what will happen to them when the study comes to an end; it is possible that their feelings about participation and the degree to which they feel they have benefited from the treatment may have changed over time.

Whilst participants should have already been told at the time of consent what will happen to them when the study stops via the participation information sheet (PIS), some may require reminding and further detail. 'End of study' here refers to the end of the individual's participation in a health research study.

This guidance sets out how and what information should be supplied to participants (including children and their parents/ carers) at the end of a study and is aimed those undertaking clinical trials and other interventional or diagnostic studies.

End of study information should cover:

- what participants can expect to happen to them at the end of a study including the arrangements in place for treatment when the study stops and any requirements for ongoing monitoring of side effects.
- how those that have participated in the research can access the study results. As a rule, all participants should be routinely informed as to how they can access the study findings.

- how those who would rather not see the findings can opt out of the process, if this has not been covered already.
- An acknowledgement of the contribution they have made to research and the improvement of healthcare.

This guidance should be read in conjunction with the Health Research Authority (HRA) guidance on informed consent in clinical trials <http://www.hra-decisiontools.org.uk/consent/>

The HRA would be pleased to receive any comments and/or references to other published work in these areas to inform this review. Please send your comments to:

endofstudyinfo@nhs.net *The deadline for comments is 30th September 2014.*

How does this information sheet fit in with other previously supplied participant information sheets (PIS)

Information provided at the end of study is not intended to replace information supplied to the participants at the beginning of the study in the form of the original PIS; rather it is intended to supplement this and provide further detail as the study is coming to a close.

Some information, such as how the study findings will be communicated to participants, may not be known in detail at the study outset and this information sheet allows for more up-to-date information to be made available. In addition, the end of a study can often be an anxious period for participants and this guidance aims to ensure that they are provided with clear information concerning the options available to them at the end of their participation.

It is anticipated that this end of study information sheet will be given out to participants as their involvement in the study is coming to a close. For example, it could be given to participants at their last study visit, thus enabling participants to ask investigators in person any questions they may have. At this point, participants can be asked if they would like to see the study findings when they become available or would they rather opt out.

Investigators will need to decide what the most appropriate timing is for sending out end of study information for their particular study. In some trials, different arms of the study may have different end points and, therefore, consideration will have to be given regarding the best time to communicate with each individual patient.

Does this information sheet require ethical review?

If the end of study information sheet builds on the information provided in the original PIS and is in line with the arrangements agreed by the REC as part of their approval, then the end of study information sheet **does not require ethical review**. The REC responsible for the approval of this study will have agreed arrangements for the end of the study and this information should comply with these. There is no need to go back to the REC to seek further approval.

If the information provided at the end of study contradicts any previous information in the original PIS and/or does not follow the original arrangements agreed with the REC, then this may require you to submit an amendment to the REC. If in doubt you should check with the manager of the REC concerned.

There is no need to seek to REC review of the end of study information sheet simply because you did not reference the end of study information sheet in the initial documentation reviewed by the REC. Similarly, any material used for the dissemination of the study findings should not be submitted for ethical review.

Guidance for the design of information sheets at the end of a study

Heading and study title/ Study reference numbers for future information

The heading and study title should match those used in the original PIS. It is recommended that you include all the necessary study reference numbers that a participant might need in the future in order to access the study findings if they are going to be placed on a website. The reference numbers required may vary depending on how and where you decide to make the findings available but might include the IRAS number and/or a company reference number.

Introduction

The end of study information sheet should start with a short explanation of its purpose. You should use this section to explain to participants that the study is drawing to a close with some description of the timing for this event.

This sheet should help to set the study participants' expectations about what will happen at the end of the study and inform them as to how and when they may access a summary of the study findings, if they so wish.

Thank you

You should take the opportunity to thank participants for their time and interest and acknowledge the contribution that they have made to research and the improvement of healthcare. It is important that all research participants feel valued and that their contribution has made a difference. This may seem obvious but it is frequently neglected.

What happens when the study stops

The arrangements for treatment after a therapeutic trial must be spelt out, particularly if this differs from that they would normally receive for their medical condition. These arrangements are part of responsible transition at the end of a study¹. It must be clear whether the participant will have continued access to any benefits or interventions that they may have had access to during the research.

If a significant clinical effect has been observed there may be plans to offer the treatment to those in the placebo or control arm as well. If the treatment will not be available after the research finishes, you should explain to the participant and provide information on what treatment will be available instead. Different information may be required for different sub-groups of patients.

Arrangements for further treatment / access to the study intervention beyond the end of the study should match those set out in the original PIS. Arrangements which conflict with the original PIS will require further ethical review. Further information about care after research can be found on the HRA website: <http://www.hra.nhs.uk/documents/2013/08/care-after-research.pdf>

Depending on the nature of the research, participants may have a need for further support when the study finishes; this might take the form of counselling or other types of support.

¹ Further information about this topic can be found in 'Care after research: A framework for NHS RECs' published in the [BMJ](#).

Reporting of side effects after the study has ended

If there is a possibility of long term side effects as a result of a drug, device or procedure, you should explain what arrangements are in place to report these. It might be necessary to provide a list of potential side effects. If participants suffer these or any other symptoms, you should provide them with clear guidance on when, how and to whom to report them. Provide contact numbers clearly and boldly.

How will the results of the research be made available to me?

Participants have an expectation that they will be given access to the results of a study and investigators should normally provide them.

There may be occasions when study results should not be made available to participants. For example, a study using anonymised tissue samples or a study using patient identifiable data without patient consent (approved by the Confidentiality Advisory Group under Section 251 of NHS Act 2006) would not be required to make the research results available to participants. In such cases these arrangements should have been presented to, and approved, by the Research Ethics Committee

Whilst most participants wish to see the study results, some people would rather not know. This means that study findings need to be made available in such a way that those who do not wish to see them are not inadvertently exposed to them. Ideally participants should be offered the opportunity to confirm whether they wish to see the study results or to opt-out of receiving them either at the last visit or by some other means (e.g. in writing, by telephone or email).

For example, if you wish to use a newsletter to communicate the study results and you intend to post this to the homes of participants, it is advisable to give participants the opportunity to opt-out in advance. Alternatively you may wish to make study results available on a website which participants can choose to access if they so wish. Links to the website where the study results will be available, in a patient friendly format, should be provided.

Consideration also needs to be given to exactly how the study results will be made accessible; whilst many participants now have access to the internet, some older participants do not have access and so hard copies may need to be made available. You may want to consider other ways of delivering study results to participants, for example, through the use of videos sent in the post on CD/DVD.

Study results to be given to participants should be made available in summary form. However, you may also want to inform participants how to access the results in more detail at a later stage if they so wish. The summary should be written in 'lay' language and should be easy to read without the use of scientific language or unexplained acronyms. Further information on writing summaries in plain English can be found on the [INVOLVE website](#).

If participants will require study references numbers in order to search for the results of their study on a website then they need to be included in this sheet.

In many cases there is a long period of time between the study coming to an end and the study results becoming available. If this is the case information may need to be shared with the patient on a staged basis as it becomes available. You will need to make clear the expected timing for the availability of the results.

You should not assume that if a participant dies before the publication of results that it would always be inappropriate to make contact with their family. Immediate family members/carers may wish to understand the contribution that their loved one has made and would appreciate being thanked and receiving the results on their behalf. If a participant has passed away in the period between the end of a study and the publication of results, the immediate family members and/or carer, if known to the local investigator, could be contacted and asked if they would like to receive the summary of results.

Will I be given any results about me as an individual?

At the end of the study participants may want to know what the results mean for them.

You may want to consider giving participants their individual health-related results. These might include those directly related to their condition as well as results not related to their condition often referred to as "incidental findings" (e.g. abnormal results obtained from imaging procedures used during the study).

As with group findings, any information communicated to participants should be in line with the arrangements agreed by the REC at the start of the study. Occasionally there will be studies where the REC has stated that individual outcomes should **not** be made available to participants, such as genetic diagnostic studies where there is no available treatment. In such cases, the researcher must abide by the original conditions they agreed with the REC.

For further information about feeding back health related findings to study participants please see the 'Framework on the feedback of health-related findings in research' available on the Wellcome website:

http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtp056059.pdf

Which arm of the study was I in?

Many participants are keen to know if they have been in the intervention arm or a control arm of a study. Breaking the code at the end of study may not be possible for a variety of reasons including the possibility of influencing future linked studies with the same participants. Where it is feasible to break the code and communicate this information to participants without impacting on subsequent studies, then consideration should be given to how to make this information available to individual participants if they request it. It is likely that a considerable period of time may elapse before it is possible to break the code and so participants should be made aware of the likely timing so that they know when and how to expect this information.

Invitation to take part in patient involvement

There is an increasing requirement to involve patients and public in the design and conduct of health research. Well-structured involvement can lead to more robust study designs with improved recruitment and lower dropout rates. One way of recruiting people to take part in this type of activity is to invite participants as they coming to the end of study to join a patient involvement group to help provide advice on future studies.

Participation in a health research study may have sparked an interest in research and this information sheet offers an opportunity for such patients to be invited to continue their involvement.

If I have any questions who should I contact?

Participants might have questions about what will happen to them at the end of a study or how they will be able to access the study results. You should provide participants with clear contact details so that they can seek further information.