

The HRA has reviewed this text to ensure greater consistency in the use of language in conveying standards that should be followed (ethical obligations or best practice) or must be followed (legal requirements) although readers are advised that the HRA holds both in high regard.

**The HRA website material is a statement of the HRA understanding. Whilst the reader is encouraged to seek further clarification from the HRA in respect of any queries [via the queries line](#), it will be for the reader to take their own legal advice as to what their legal duties are.**

## Information for participants at the end of a study:

### Guidance for Researchers/Sponsors/ Chief Investigators/Principal Investigators

#### Background

This guidance sets out how and what information should be supplied to participants, and their legal representatives, consultees, close relatives or close friends (where applicable), at the end of a study. 'End of study' here refers to the end of the individual's participation in a clinical trial or 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 who 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.

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 further increase this uncertainty. In addition most patients are often unable to access published literature and need access to summary findings in a format they can understand.

Participants in lengthy 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 through the participation information sheet (PIS), those in longer studies may need reminding and further detail

This guidance is aimed at chief investigators and sponsors for studies in England. Principal investigators may also have a role in the communication of the end of study findings and subsequent information such as the summary results as they normally hold the participants' contact details.

Patients, investigators and sponsors have all contributed to the development of this guidance; it should be read in conjunction with the Health Research Authority's (HRA) guidance on informed consent and participant information sheets [[HRA information about consent and participant information](#) and 'Care after research: a framework for NHS Research Ethics Committees']

## **What type of research does this guidance apply to?**

This guidance is aimed at those undertaking clinical trials and other interventional<sup>1</sup> or diagnostic studies involving patients. This includes studies which are terminated early and there is little likelihood of published findings. This guidance applies to all relevant active studies from 1 April 2015 and will apply prospectively to all participants who have yet to leave the study.

Very short interventional studies (for example, single dose or single visit studies) may not require a separate end of study information sheet, if all the required information, including how and when participants can expect to access summary study results, was clearly stated

---

<sup>1</sup> The term 'interventional' here refers to a clinical intervention, not a research intervention such as an interview or questionnaire.

in the original Participant Information Sheet (PIS). If this level of detail was not included in the original PIS, then this should be communicated to the participants at a later stage.

This guidance does not apply to early phase clinical trials in healthy volunteers. Some Phase 1 studies include patients; consideration should be given to whether the provision of an end of study information sheet to patients would be beneficial in these circumstances.

Given the wide range of settings involved in clinical trials and other interventional studies, sponsors/chief investigators will need to use their judgement in applying this guidance to their specific situation. If in doubt, you should consult the manager of the REC concerned.

### **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 so this end of study 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 in the study.

### **When should the end of study information be given to participants?**

It is anticipated that this end of study information sheet should be given 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.

In multi-site studies with multiple principal investigators, the decisions about the content of the end of study information, its delivery and timing will need to be made centrally, by the chief investigator or sponsor. Similarly decisions about the content, delivery and timing of summary results will also need to be made centrally.

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 patients in each arm. Whilst end of study information could be given out on a staggered basis, sponsors and principal investigators might want to release summary results at one point in time across all study participants.

## **Does the end of study information sheet require review by a Research Ethics Committee (REC)?**

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 favourable opinion, then the end of study information sheet **does not require ethical review** by a REC. 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 seek 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.

You should seek REC review if the information provided to participants at the end of the study or summary results:

- is likely to be particularly sensitive or distressing;
- contradicts any previous information in the original PIS;
- does not follow the original arrangements agreed with the REC.

In these circumstances you may need to submit an amendment and a copy of the end of study sheet information sheet to the REC. If in doubt you should check with the manager of the REC concerned.

**Please note that copies of the end of study information sheets which have been provided to participants should be included in the final report sent to RECs. Copies of summary results provided to participants should also be included, if they are available at this point in time.**

**We will review this guidance in late 2015. Any comments on this version should be sent to [amanda.hunn@nhs.net](mailto:amanda.hunn@nhs.net) by 30 September 2015.**

## **Guidance for the design and content of information sheets at the end of a study**

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.

### **Heading and study title/ Study reference numbers for future information**

The heading and study title should match those used in the original PIS and should always include the IRAS ID. We recommend 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 a company/sponsor 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 and short 'lay' summary of the trial design and objectives.

### **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, if any, for treatment after a therapeutic trial should be spelt out, particularly if this differs from that they would normally receive for their medical condition. It should be clear whether the participant will have continued access to any benefits or interventions which they may have had access during the research. These arrangements are  
Version 4.1, dated 20 August 2015

part of responsible transition at the end of a study<sup>2</sup> and should have been agreed with the REC before the study started and set out in the original participant information sheet (PIS). 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>

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 this to the participant and provide information on what treatment, if any, will be available instead.

If the investigator is not responsible for the participant's normal care, then this may involve a referral back to their treating physician; this might mean that descriptions of future treatment options are generic rather than specific.

Ideally all participants in the same study should be given the same information but different information may be required for different sub-groups of patients to allow for alternative options when the study stops.

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

### **How to report side effects after the study has ended (if applicable)**

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.

---

<sup>2</sup> Further information about this topic can be found in 'Care after research: A framework for NHS RECs' published on the HRA website [link to <http://www.hra.nhs.uk/resources/during-and-after-your-study/care-after-research/>].

## 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 sponsors or investigators should normally provide them. Sponsors or chief investigators are not expected to include summary results in the end of study information sheet itself as in most cases they will not be available at that point, but they are expected to explain how participants will be able to access this information when it does become available and when to expect this. This information can be communicated to participants in many different ways and this is a decision for the sponsor or the chief investigator.

Study results could be communicated by:

- post in a letter or newsletter
- email
- DVD
- website.

Alternatively sponsors might want to consider the development of a password protected participant portal, that would enable individuals to state their preferences for communication such as language and allow for updates on an ongoing basis.

Consideration should must be given to exactly how the study results will be made accessible; for example participants may not have access to the internet or may need the information in a particular format

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. We would encourage you to involve patients in the review of this 'lay' summary before it is finalised. Further information on writing summaries in plain English can be found on the [INVOLVE website](#).

In some cases there is a very long 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 participant on a staged basis as it becomes available. You will need to make clear when the results will be available.

Whilst most participants wish to see the study results, some people would rather not see them. 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 invited 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.

Principal investigators normally hold participants' contact details and they would also therefore be best placed to record details of who has opted out of receiving summary information where this is going to be delivered directly to participants. Alternatively communication of summary results via the web would not require an opt-out system to be put in place.

There may be occasions when study results should not be made available to participants. In some scenarios it may be considered unethical to share the findings with participants, for example, in studies with very high mortality rates. In such cases, these arrangements should have been presented to, and approved, by the Research Ethics Committee.

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 the individual has made and would appreciate being thanked and receiving the results on their behalf. If a participant has died 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 a summary of the 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.

If it is appropriate, 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). This may take place during the trial itself if the urgent action is required.

As with group findings, any information communicated to participants on individual health related results including incidental findings should be in line with the arrangements agreed by the REC at the start of the study and as explained in the participant information sheet

(PIS). 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. If the researcher feels that there are now good reasons to go back to an individual ( e.g. new treatments have now become available) the chief investigator would need to go back to the REC to seek an amendment to the protocol.

For further information please see the [‘Framework on the feedback of health-related findings in research’](#) available on the Wellcome Trust website.

### **Which arm of the study was I in?**

Many participants are keen to know the outcomes specific to them including 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. If it is not possible to break the code and tell participants what arm of the study they were in then this needs to be explained in the end of study information sheet and should have been covered in the original PIS. 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 this information could be made 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. Participants should be made aware of the likely timing so that they know when and how to expect this information, if at all.

### **Invitation to take part in patient involvement**

It is good practice to involve patients and public in the design and conduct of health research. Well-structured patient and public involvement in the design and conduct of health research can lead to more robust study designs with improved recruitment and lower dropout rates.

Participation in a health research study may have sparked an interest in research and this end of study information sheet offers an opportunity for such patients to be invited to take an active role in advising on future studies.

### **Invitation to take part in future research**

If appropriate, you might want to invite participants to indicate if they are willing to be approached about taking part in future studies.

### **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 either at sponsor, chief investigator or principal investigator level depending on which is most appropriate.