Communication with research participants who stop participating early – guidance for researchers

Version 2.0

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See appendices for author list and acknowledgements

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1. Summary of contents

Research participants who stop taking part in studies early deserve – as do all participants – good information as they progress through the study and as their involvement in the study changes over time. Good information means information to help participants understand what they need to do, what will happen next and what their rights and choices are. It also helps to keep them updated about the study, towards which they have contributed their time and energy, and it can make clear to them the difference they have made by deciding to take part. Participants who stop taking part early may not often get good or sufficient information, partly due to uncertainty or sensitivity around the appropriateness of researchers contacting participants once they have made a decision to stop taking part.

We (a collaborative group of patients and researchers) have prepared this guidance from our experiences and expertise, with the results of a comprehensive literature review providing material for our discussions. Our guidance can be used in a range of situations where individually consenting participants stop taking part in a study before their participation was originally planned to end, including where this is their decision and where it is someone else's. We suggest the guidance is most relevant for situations where it will be obvious from the participant's point of view that their participation has stopped or substantially reduced. Our guidance is primarily aimed at developing written communications (in any format) for participants.

Our guidance includes a suggested process for developing the communication materials, including with the involvement of patients and with adequate support given to those involved in delivering the information to participants. It is important to ensure the planned communication is accessible, appropriate for the particular study and its participants in general, and fits with other information the participants will receive. Measures should be in place to ensure the information individual participants receive is accurate and suitable for them, and the overall approach must have ethical approval before it is put into practice.

Finally, we provide detailed guidance about the sorts of information to include in a participant communication, with justifications and example wording where researchers might find these useful. Participants stopping taking part will usually have been given some relevant information already, so an important task for researchers is to help participants find this again through clear signposting.

2. Introduction

What is this document and who is it for?

This document gives guidance for researchers[1] to provide information to research participants who stop their participation early (including those who 'withdraw' from a research study) while the study continues. It is primarily for use in healthcare research involving individually consenting participants who contribute over a period (rather than where participants only make a one-off contribution).

It can apply to a range of situations where participants stop taking part in some or all of a research study before their participation was originally due to end. This includes both where this was their decision and where it was someone else's. It also includes where participants do not tell researchers that they want to stop taking part, but instead stop taking part by no longer responding to researchers' attempts to contact them.

Although the guidance can be used across a range of situations, we suggest it is most relevant where it will be obvious from the participant's point of view that their participation in a study has stopped or substantially reduced. It may be less useful where their level of participation has changed but they still feel they are 'in' the study (for example, if they stop a study treatment but will continue with all other elements of participation).

The guidance is not intended to cover the situation where a participant stops taking part in a study due to loss of capacity to consent (i.e. where any communication might be with the participant's family/carer, if appropriate). However, many of the points raised may also be relevant in that situation, and might give the family/carer clarity about the implications of the participant's involvement in the study ending. Clearly, cases like these would need to be handled sensitively, particularly if the family/carer were not aware of the participant's involvement in the study, or were not happy about it (for example).

Our guidance is not intended to be relevant to communication with a participant's family/carer when the participant has died during their time taking part. Many of our recommendations would not (and could not) apply in that situation. We suggest researchers consider this issue separately, especially for studies where a large proportion of the participants may be at risk of dying before the end of the study.

Although some information can and should be provided to participants verbally, the focus of this guidance is on providing information in writing. As with other types of information for participants, giving information in writing has several advantages. This includes that the participant can read and digest the information in their own time (which may be particularly important for some, for example neurodiverse people) and that they have a copy of the information to keep. It also allows review of proposed wording by an independent ethics committee prior to use. We nonetheless suggest that participants should also be given the

[1] Here "researchers" includes anyone running or overseeing a research study who might want or need to provide information to research participants stopping their participation early.

opportunity to receive information verbally where they would like this, and get the chance to discuss the information (and ask any questions they may have).

Why should research participants who stop taking part get good information?

In general, it is right that participants in research projects are kept up to date with what is happening during their time taking part. People who stop taking part in research studies early likely also have particular information needs.

Participants often give considerable time and energy to their participation. Their participation may be very important to them, especially if they are taking part to receive a new treatment that may improve the quality or length of their life. It could therefore be seen as a basic courtesy for researchers to provide participants with information during the study, whenever they want or need it. Absent or inadequate information, on the other hand, may affect participants' trust and confidence in a study, and their willingness to take part in research in future. A recent report of the NIHR's annual Patient Research Experience Survey[2] recommended that participants should get "the right information…in the right place at the right time as [they] proceed through the study."

People who stop taking part in research studies early also have particular information needs. Although they will get some information at the start of the study about what would happen if they stopped taking part early, this may not prepare them fully for when it actually happens. Ending participation can be a stressful experience and participants can sometimes feel unsupported or even 'abandoned'.[3]

While there is existing guidance about providing information to participants at the end of a study (for example from the Health Research Authority[4]) there is limited guidance specifically about providing information to participants when they stop their participation early.

We suggest at least the following key areas of information that could be important to this group of participants:

- Clarity about exactly how their participation has changed: which aspects of participation have ended and which have not, and the choices now available to them.
- Communication of gratitude and appreciation for their participation; some participants may have concerns that ending their participation early means they have not made an important contribution, so it is important to make clear that they have, and to thank them for it.

[2] https://www.nihr.ac.uk/documents/research-participant-experience-survey-report-2018-19/12109
[3] Cox K, Wilson E, Arthur A, Elkan R, & Armstrong S (2005). A randomised controlled trial of nurse-managed trial conclusion following early phase cancer trial participation. British Journal of Cancer, 93(1), 41–45.
[4] https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-guidance-end-study-pis-v4-1_20-august-2015.pdf

- A reminder of what stopping early means for them, and for any information and biological samples they have given; these topics will have been covered in the information they received before they consented to the study, but a reminder could be useful for some.
- Information about what happens next from their point of view, particularly regarding their care.
- Any other information that individuals might want or need: this includes how to get the results of the study, when they are available.

Can research participants be contacted after they withdraw from a study?

We accept that there can be sensitivities around researcher contact with participants after they have stopped taking part. However, it is not right to conclude that we cannot or must not provide any further information to these participants. Instead, we should aim to provide information but take care to do it sensitively and with appropriate oversight and guidance, including from independent ethics committees.

In putting together this guidance, we have found evidence that participants who stop taking part early might be less likely than those who 'complete' a study to receive important messages at the end of the study, such as appreciation for having taken part, and information about how and when the study results will be made available. This may in part be due to uncertainty or confusion about whether it is acceptable to communicate with participants after they have 'withdrawn' from a study.

Providing no further information means participants do not get information that they want to have and may end up feeling 'abandoned'. In modern research ethics, it is widely accepted that research participants have the right to withdraw their informed consent at any time and without negative consequence. We suggest that withholding information that participants want or need after they stop participating in a study could be considered a negative consequence of withdrawing informed consent, and therefore is not compatible with this ethical standard.

How should this document be used?

This document supports researchers through a comprehensive process to produce patient-facing materials specific to their study.

We aimed to make guidance that can apply to many different types of research study, including clinical trials and other medical research. We are conscious that there can be no 'one size fits all' approach to this, so an important step in preparing participant information for a given study is to consider the specific study, its participants and their 'pathway' through the study (an example pathway is given in **Appendix D**). An important part of the process is also to factor in what is known about each participant's specific circumstances.

In the sections that follow, we describe a general process for planning and drafting written communications for participants who stop taking part in research early. This includes specific topics to cover in the communications and, where it might be helpful, examples of ways to present or word certain topics. We have also provided explanations for the inclusion of some topics, which could be useful in justifying the approach to others.

3. Suggested process for developing communication strategy and materials

This section covers a suggested process for developing a communication strategy and materials for giving information to study participants who stop participating early. We strongly recommend that the details of this approach are considered during the setup of a study, rather than trying to introduce a new participant communication approach part-way through, and our guidance is written from that point of view.

Involve patients	The patients contributing to the running of a study should be involved in developing and agreeing the overall approach to communicating with participants who stop taking part early, as well as any specific templates or wording that will be used.

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Give adequate training and support	If research sites are expected to communicate the information to participants, research sponsors (or their representatives) should give clear training and guidance to the sites (for example, via the study protocol) about what is expected of them. This includes the expectations that research sites retain a copy of any written communications shared with individual participants.

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Consider the study and its participants	Working with the involved patients, consider the specifics of the study you are working on, and how this sort of communication fits into it. This will be important context for devising your overall strategy. For example: - What features of the study and its design or setting might be relevant to consider? For example, is it a 'double-blind' study, and, if so, how might this affect the planned communication? - How many participants do you predict will stop taking part early? Is there a risk that a relatively large number of participants will do this? - Do you expect most participants who want to stop taking part early to tell the researchers this, or do you suspect some will indicate their wishes by no longer replying to researcher contact? - Might participants stop taking part because their health is deteriorating? - Are participants at relatively high risk of losing the ability to make their own decisions during the study (also known as losing 'capacity to consent')?

	- Who are participants mostly in contact with during the study – a healthcare professional such as their doctor or nurse, or research staff in a university or other institution, or both, or someone else? How might they interact with this contact if they stop participating? - Who are participants most likely to feel comfortable talking to about aspects of their study participation? Might this change if participants stop taking part? - What other factors might be important in how you will communicate with participants (such as issues of culture, language or disability)? You might also consider the expected 'pathways' of participants who stop taking part in the study. Who might they interact with, and when? Who will be informed about the change in their involvement in the study, how and when? An example pathway is given in **Appendix D.** Based on the possible pathways, consider how the information will be delivered in a way that is convenient and minimises the burden for participants as well as research staff. Will the information be given as a paper document (often still preferred) or might it be appropriate to give participants a link to a website (with a paper copy on request)? Might email be the best method?

Consider formatting and how to make information accessible	As with any patient-facing materials, you should take necessary steps to ensure everyone will be able to access the information. This means the default version of any materials should be accessible to most people through use of large-enough font size (at least size 12), clear layout and avoiding reliance on colours to convey meaning (to avoid disadvantaging colour-blind people). You should also consider adding a prominent statement offering materials in different formats on request (and be prepared to offer these in a timely manner). In line with the approach taken within the rest of the study, you should also consider offering the information translated into other languages. Involve patients in deciding the best approach to accessibility, as well as advice from any other local or national organisations relevant to the study and its participants. There are various resources available about ensuring information is accessible; a non-exhaustive list is given in **Appendix F.**

Make sure the information provided to *potential* participants is right	The information given to participants (verbally and in writing) before they agree to take part in a study should make clear to them what will happen if they stop taking part early. Participants should have good information to inform their decisions about stopping or reducing their level of participation in the study. Participants should not be surprised by any limitations on what they can stop or 'undo' – any such limitations must be made clear to potential participants before they agree to take part. The contents of pre-study information sheets are out of the scope of this current guidance. However, we have included some suggestions in **Appendix E.** Template wording is also available via the PeRSEVERE project website: https://perseverepriciples.org/template-wording-for-patient-information-sheets/ If some of these points are not included in the pre-study information, it can be inappropriate (or even unethical) to mention them only later when a participant stops taking part.

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Ensure the information aligns with other participant/ patient information	Communication with participants at the time they stop participating is not given in isolation. Think about how the proposed communication will fit with other information for participants or potential participants. These should all fit together well, both in terms of the content, and the style and tone. This includes the pre-study information (see above), but consider as well how this proposed communication fits alongside others used in the study. This might include newsletters for participants, messages of thanks given to all participants at the end of the study, and messages communicating the results of the study. Where there will also be a general 'end of study' information sheet for participants, ensure it will be clear when to give participants that and when to give the information about ending participation early (for example, which one would you give to a participant who stops taking part before the end of the study, but very close to the end of the study?)

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Develop a template for any written communications	We suggest that using a study-specific template is an efficient approach to providing information, compared to writing each participant a bespoke message. However, it is important to include some "personalisation" where necessary, for example: clear and correct details about how the specific participant's involvement in the study has changed, details of the participant's

study centre (for example, a paper document may be presented on hospital headed paper) and a reminder of contact details for the study doctor or nurse.

Draft the template using this guidance, as well as any other relevant guidance for producing participant communications. Use plain, accessible language and consider graphics and diagrams where these might help convey important information.

The communication's length is also important. The primary written communication for participants should ideally not be longer than 2 sides of well-spaced A4 paper (or an equivalent length for emails or online materials). If there is more information to make available than this, then these 2 sides should be used to summarise the key points from the longer content and guide individual participants towards the information they might be most interested in.

Ensure the communication contains basic elements such as a date, a clear trusted source (i.e. decide who the communication should come from and who 'we' is if that is the pronoun used), the study name and identifiers, and links to the study website and public registry page.

The communication should also have a clear, engaging title. An example title might be: **"[Study name]: what happens now that your involvement has ended?"**

The first sentence(s) of the communication (possibly after an initial 'thank you' message) should make clear what it is for, why it has been given to the participant and what they are expected to do with the information (if anything). For example:

> **"This message explains some of the things you might want or need to know, now that you have stopped taking part in the [study name] study.**
>
> **You do not have to do anything in response to this message. It is yours to keep, so please read as much of it as you want to, to help with any questions you may have. But there may be things mentioned here that you might want to talk to your study doctor or nurse about. You will find a reminder of their contact details [below]."**

Communications should include (e.g. at the end) a general invitation to contact an appropriate person (with that person's contact details) if the participant has further questions or would like to discuss anything.

Allow for different situations	Participants stop taking part in studies in a range of ways and circumstances. There may need to be a flexible template (or more than one template) to allow for different situations. For example, a written communication for participants who have stopped participating because they have lost contact with the research team (if this is being used) will need to be different to one for participants who have communicated a decision to stop participating. The tone and content of a communication might also need to differ depending on whether stopping participation was the participant's choice or someone else's. Consider the most likely scenarios and develop template(s) to suit each.

Get ethical approval	Request ethical review of both the overall approach to communicating with participants when they stop taking part, and any specific wording to be used in written materials. Approval by a research ethics committee must be received before carrying out any of the approach. It is not feasible to get ethical approval for each individual communication to be sent to each participant, so the overall approach must be presented clearly to the committee, and it must be clear for any templates which wording would be the same for every participant, and which would vary (and how it would vary). At the time of developing this guidance, it is likely uncommon to provide any sort of communication to participants who stop taking part in a study early. It is therefore possible that a given research ethics committee may not have been asked to review this sort of thing before, and may not see why it is necessary. In the accompanying cover letter (or equivalent) to the ethics committee, consider making clear that this sort of communication is about ensuring participants get the information they need and want, at the right time. You could also explain that part of the process around providing the information will help ensure that individuals' needs are considered, and no participants will be given information where it is not agreed to be appropriate to give it to them. It may also be important to highlight that the information is in no way aiming to encourage or pressure participants to reconsider or explain a decision to stop taking part in some or all of the study. If our guidance has been followed, receiving one final communication at the time of stopping should not be a surprise to most participants, and this could be made clear to the committee too. Finally, consider mentioning that you followed this guidance, which was developed by patients working with researchers, to develop the patient-facing materials.

	Where relevant in this guidance, we have explained why we think some topics should be included in a communication for participants. These may be useful in explaining the approach to ethics committees to inform their review.

Assess each participant's circumstances before making contact	The circumstances around an individual stopping study participation can vary, and in some cases may be complex or sensitive. It is important that any process of communicating with these participants includes a check that it is appropriate to make the proposed contact and share the proposed information. In most cases it may be the participant's clinical/care team that is in the best position to make this judgement, given what they know about the participant and their situation. Decisions about this should be documented (for example in a participant's medical notes), particularly if the decision was not straightforward. If the participant's clinical/care team advises that it is not appropriate to contact the participant at this time, those running the research (e.g. research sponsors or their representatives) must respect this. Care may also be needed if some time has passed since a participant had stopped taking part, to make sure planned communication is still relevant, useful and appropriate to be given at this later time.

Quality control	As mentioned above, some of the topics for inclusion in a communication for participants will need to be 'personalised'. It is critical that any information reflecting a participant's specific situation is correct. Quality control is therefore an important part of the process of developing such communication. The most suitable methods of quality control will depend on the study, but are likely to include good design of any templates, and suitable review of any communications before they are shared with participants to ensure they are correct. It may often be necessary for research sites and sponsors (or their representatives) to work together to ensure the information is correct.

Review and refine	It is sensible to review how well the participant communication is working, once it has been implemented. This might include trying to find out if participants value and appreciate it, and checking they receive it in the first place. Those involved in developing and delivering the information could also feed back about what worked well or not from their perspective. All this feedback can be used to improve the communication and the processes around it.

4. What information do research participants need when they stop taking part early?

Topic areas

In putting together this guidance, we have considered information that participants might want or need to know about when they stop taking part in a study early, as well as information that researchers might want or need to tell participants about. There is therefore a wide range of possible things to communicate to participants.

In this guidance, we have suggested that information can be grouped into the following areas (covered in more detail in the sections that follow this one, with examples where helpful).

- **Important new information about changing involvement in the study (Section 5.1) and important new information about post-study arrangements and the transition to these (Section 5.2):**
    - This is information that is particularly relevant to the participant's current situation, i.e. because they have recently stopped taking part in some or all of the study. It is 'new' in that it might not have been provided before (because it was not relevant or applicable before) or might be expanding on information previously given, now that the participant has reached this point.
    - This information should be provided soon after it is confirmed that the participant is stopping taking part in the study. It should be given at this time because it is not appropriate to delay it. It may not be necessary (or practical) to give all this information on the same day as the participant stops taking part in a study, but it should not be delayed for long after this.
    - It should include information that the participant may need to know at that time, or information they are very likely to want to know.

- **Important reminders and signposting (Section 5.3):**
    - Some other information may be just as important to participants, but either was provided already (particularly as part of the pre-study information) or is available elsewhere. Signposting to this information, rather than repeating it, means we can reduce the length of a communication given to participants after they stop taking part. This approach also allows participants to seek out and find the information they want to find, rather than having to receive all of it by default.
    - These reminders and signposts address questions that might be important to a given participant, so they should also be provided soon after the participant stops taking part.

- **Other information (Section 5.4):**
    - Some other types of information might be useful to some participants, but are perhaps less likely to be important to everyone.
    - These can be provided immediately after the participant stops taking part, but a delay is possible if it is more practical to do so for a given study, or to avoid making the initial communication too long. It should nonetheless be provided to participants within a timeframe that is reasonable in the context of the study.

We acknowledge there may well be some overlap between some of the topics covered in these areas. However, we might assume many participants may not read all of the information front-to-back, but instead use it to understand the key points and find information they are particularly interested in. On this basis, a small amount of duplication means participants are more likely to find answers to their questions (because there is more than one 'route' to the answers).

Organising the information

The best ways to organise the information will depend on the study, and involved patients can advise about what works for the study and its participants.

As mentioned above, we suggest the initial communication given to participants is no longer than 2 sides of A4 paper (in at least 12-point font) or equivalent for email and online formats. If there is more information to convey, this can be provided in an accompanying leaflet or webpages with an invitation to read on if the participant is interested.

If information will be provided in layers (e.g. a summary then more detail about the same points), we suggest that the shorter and the more detailed layers present information in a similar order to help participants navigate through the material. Contents pages can also be used to help participants find their way through any longer layers.

Links between different layers of information should be meaningful, rather than just basic signposts. So rather than just "You can read about what will happen to your information in [the longer information]", consider "As we mentioned before you agreed to take part in the study, the information we have collected about you so far will still be used in the study analysis. You can read more about this in [the longer information]."

Who should the information come from?

It may be appropriate and practical for important new information and signposting to come from the participant's primary contact for the study, for example the doctor or nurse they usually see, rather than from a research sponsor who may not usually be in contact with them.

Good study-specific templates and guidance will be important in allowing standardised information to be delivered to participants in a timely manner. It is also important for research sponsors to engage with research sites to agree how the information can feasibly be delivered to participants in a timely manner.

The 'other information' could come from the research sponsor or their representative, or the study Chief Investigator, if that is appropriate within the specific study setting. If a second contact is planned (e.g. an initial communication showing the important information then another more general communication later on), the second contact and its contents could be mentioned in the first one, so that participants know to expect it. The second communication could reiterate some of the key points from the first one, if that might be useful.

Reminding participants of the pre-study information

A lot of relevant information about stopping participation will have been contained in the information each participant was given before they agreed to take part in the study. It might be appropriate to give participants another copy of this (or the last version that they gave consent to, if they updated their written consent during the study) when they stop taking part. However, this might not be necessary if it has not been long since they gave their original consent.

In that case, participants might be advised to ask for another copy if they need one. Each study should work out its own approach that finds a balance between providing access to information without barriers (such as needing to ask) and not overburdening participants with information they are likely to already have access to.

Pre-study information sheets can also be made available online. If this is done it must be clear to each participant which version of the information sheet is relevant to them, if several versions are available. The same information must also be available in hard copy for those who need or want it.

5. Detailed topic-specific guidance

5.1. Important new information about changing study involvement

Message of thanks and appreciation for having taken part

The participant should have a brief, general message of thanks for their contribution to the study. Some participants who stop taking part early may feel that they have not made an important contribution or, depending on the circumstances of their stopping, that they have somehow 'let the study down'. It is important that they are reassured that they have made an important contribution.

If the message will be sent to participants who have contributed to the study for a long time or a very short time, make sure it is suitably generic (while avoiding the risk it is perceived as being meaningless). Alternatively, consider a few different template statements if you would like to communicate something slightly different to those who have made a larger contribution to the study.

There may sometimes be some sensitivities about ending participation, for example if the participant is angry or upset about some aspect of the study and has stopped taking part because of this. This needs to be considered when participants are contacted, but we still suggest that a message of thanks and appreciation is always important, regardless of any changes in participation.

Participants may have a variety of feelings about stopping participation. We suggest that it is not helpful for a written communication to reflect too much on how participants may or may not be feeling, as there is too much scope for it to be received in unintended and unpredictable ways. For example, statements about the possibility of negative feelings might be perceived as insensitive, or might even *induce* negative feelings in some participants. Statements encouraging positive feelings such as 'pride' in participation might be seen as patronising, or might negatively impact participants who do not feel this way. If there are opportunities for participants to talk to someone about ending their participation and how they feel about it, this could be signposted (see also below: "What support is available while I end my participation in the study?")

Example

Thank you again for choosing to take part in this study and for the time and effort you put into the study until now. By deciding to take part you have made an important contribution to improving the healthcare of patients like you in future.

Losing contact (where applicable)

Researchers may have a set process to follow when they cannot contact a participant. For example, they might make three attempts to contact a participant (possibly using different methods), and if none are successful then they will consider the participant to have stopped taking part, and make no further attempts (or no attempts until a later time when they might try again). A written communication could be sent when no further attempts will be made – if it is considered appropriate and if the participant's contact details are considered still likely to be correct – to confirm to the participant what has happened. This can include that no further attempts will be made to contact them, or when further attempts might happen, if that is the plan.

If the study has the ethical approval and participants' consent needed to attempt other ways to get back in contact with participants, such as through contacting the participant's GP, participants could be reminded of these in this communication.

The message could also include an invitation for the participant to get back in touch with the researchers if they want to, with a reminder of the contact details for the primary research contact (e.g. their study doctor or research nurse). Researchers might also think about how else to make it easy for participants to get back in touch, for example including a pre-paid, pre-addressed envelope for anything that might need posting back.

Finally, researchers might think about a simple way for participants to communicate that they (participants) want all their involvement in the study to stop, without having to discuss with anyone. This could include an email address, online form, or phone number for sending text messages. If there is anything like this in place, then the communication could mention it.

Example

Unfortunately, we have not been able to get in touch with you since **[date of last contact]** about your involvement in the **[study name]** study. We therefore assume that you have stopped taking part in the study for now. This means:

- You will no longer receive any study questionnaires
- You will no longer receive any invitations to any hospital visits for the study for now
- See below for what this means for the **[study payments]** you may still be owed

We hope you are doing as well as possible since your last involvement in the study. We would encourage you to contact your study doctor or nurse if you need anything from them, or to let them know how you are doing, if you are happy to do that. You can find their contact details **[below]**.

As you have not specifically said you want to stop all your contributions to this study, we may try again in future to contact you or the doctors looking after

you, to see how you are doing. You can ask for us not to do any of these things at any time, if you want to. Please just get in touch with your study doctor or nurse **[add any alternative contact methods]** and we will make sure you and your doctors are not contacted again about your involvement in the study.

You can find out more about the ways we may try to get back in touch in the information sheet you got before you took part in this study. They are:

- If you do get back in touch with your study doctor or nurse and attend any routine hospital appointments, any relevant information from these appointments will still be used for the study.
- We may get in touch with your GP to find out how you are doing.
- We may try to get in touch with you again in future for the same reason.

Summarising exactly how the participant's participation has changed: "How has my participation in the [study] study changed?"

Participation in many types of studies has several elements, and in some cases only some of these will have stopped. It is important that participants understand exactly how their participation has changed, and they should have this clarity as soon as possible. This includes where participants are considered to have stopped taking part because they have lost contact with the study (see above).

It is important for the participant's primary study contact to discuss this with them, if possible, to find out exactly what they want to do. Confirming this in writing provides helpful clarity for both the participant and all involved in running the research study. It also allows the participant to say if what is recorded does not actually reflect their wishes. If the study has an optional form or any other way for participants to clarify exactly what they want to do, this could be mentioned.

One way to show participants how their participation has changed is to display the range of types (or 'levels') of participation possible for the study and clearly indicate which are still applicable and which have stopped. The summary should be presented in a basic way and not specifically refer to a discussion between the participant and study team unless this has happened.

As mentioned above, it is essential that the information in this section is correct, so it may often be necessary for research site staff and research sponsors to work together to ensure this. It must also align with the content of the information sheet the participant was given before they agreed to take part in the study.

Example:

This is our understanding of what is happening with your participation in the **[study name]** study now:

- You have stopped taking the study medication
- You will no longer be asked to complete any study questionnaires
- You won't attend any more hospital visits specifically for the study
- You are still happy for relevant information about you from future routine healthcare appointments to be used for the study
- You are still happy for the information collected about you so far to be used for further research projects, as long as this is done in a way that means your identity is not shared with anyone outside the research team

If this does not look right, please contact your study doctor or nurse. Otherwise, we will assume that this information is correct.

Remember that there are some limits on completely ending all your involvement in the study. You can find more information about these in **[further information]** and in the information you were given before you agreed to take part in this study**.** The key points are:

- We need to keep the information that we have collected about you until now and use it in the study analysis.
- The **[biological samples]** that you kindly gave as part of this study have now been analysed, so it is no longer possible to destroy them.
- We are legally required to collect information about certain side-effects from the study treatment, if you happen to experience these in future.

Further contact about the study: "Will I be contacted again about this study?"

It is useful to be clear with participants if they will be contacted again about the study (unless the nature of their ongoing involvement in the study means it is obvious that they will be). This includes who would contact them, and what it might be about.

If the participant has clearly opted out of all further communications, this could be confirmed here. However, it may still be in participants' own interests, in some (rare) cases, to contact them about new information related to the treatments they have taken. This possibility should be made clear to them if it is not already clear in other sections of the communication.

All study participants should have the chance to receive the results of the study if they want them, regardless of how long they participated for. If there are plans to contact participants directly about this when the study results are ready, this should be mentioned, with any information already known about participants' contact preferences.

If there are other, optional ways that study updates are being shared with participants (e.g. newsletters), this could be mentioned in case any participants would like to sign up.

Example

As you have stopped taking part in the study, we will not need to contact you about the study again unless we learn anything new about the treatment you have received that you might need to know. We will also make sure you find out the results of the study, if you want to know them.

[Add anything else relevant to the study, for example if participants could still sign up to receive newsletters/updates about the study]

Please remember to tell your study doctor or nurse (or your GP) if your contact details change or if you move home. If we have your updated contact details, we can still contact you if we need to, and we can share the results of the study with you when they are ready.

Explaining why participation has stopped: "Why has my participation stopped?" (Where applicable)

Where some or all elements of participation have stopped because of a decision by someone other than the participant (e.g. their doctor), it will often be important to explain this verbally to the participant and give them a chance to ask any questions they may have. They should not hear about it first in writing unless they have lost contact with the study (see above). However, the reason for the decision should also be given in writing. It may also be helpful to give the date of the participant's last involvement in the study, if they will be stopping most or all aspects of participation.

It is important that all communication about this does not alarm the participant if their participation stopped for reasons to do with their safety. They should be given adequate reassurance that their safety and wellbeing will be looked after, in any case.

Example

Throughout your time taking part in this study, the doctors looking after your care have been regularly checking that it is still safe for you to continue taking the study treatment. They will continue to make sure all your treatments are safe for you to take after you stop participating in the study, as well.

As you will have been told by your study doctor or nurse, unfortunately it is no longer the best option for you to continue taking the study treatment. This

decision was not taken lightly, but was taken in the interests of your health and wellbeing. Do talk to your doctor or nurse about this if you have any questions or concerns.

This does not mean your involvement in the **[study]** study has to end completely, if you don't want it to. See **[below]** for more about your choices and about what aspects of your participation will continue.

Information about study payments/incentives/vouchers (may fit best with the information in this section, or in 'other' information, depending on the study)

It may be important to be clear about arrangements for any payments soon after the participant stops taking part, if it will likely be something they will wonder about. If this will be handled separately by the research sponsor or someone else, then the initial information given after the participant stops taking part could say that more information about payments will follow, and/or give details of who to contact in the meantime if they have any questions.

Clarifying participants' options in relation to their participation: "What are my choices now about my involvement in the [study] study?"

It is good to give participants clear, understandable information about what their choices are about any possible further involvement in the study, building on the summary information given above. Unless some aspects of participation have been stopped by someone else to protect the participant, or the participant has lost the ability to make their own decisions, it should be up to the participant how their participation changes (within the limits of each study's design).

Their choices around reducing or stopping their participation should be clear from the start of the study and in any discussions with study research staff around the time they stop taking part. The written information can act as a back-up to this, and help participants with the sorts of questions they might want to ask.

Exactly what choices are available will depend on the study and possibly also on each participant's circumstances. However, considerations will likely include each participant's choices regarding their participation in the study, and regarding whether they want to be updated on the study progress and the results of the study.

Participants should also get information to inform these choices, including the pros and cons of different choices both from their perspective and from that of the study. However, care must be taken not to make participants feel any pressure to change their mind about any decision they have already made. It is important to provide this sort of content in the information participants get before they agree to take part in the study. They can then be reminded of it around the time they are deciding about stopping or reducing their participation in a study.

Example

You have the right to stop taking part in any aspect of this study at any time, and without giving a reason if you don't want to give one. Any decision you make about this will not affect your standard of care.

This means you can stop all your involvement in the study if you want to, although remember that there are some limits on 'undoing' things that have already been done. We explained these to you before you agreed to take part in the study, and we have reminded you in this message, as well.

This also means that you might be able to make further contributions to the study without giving as much of your time, if you want to.

Specifically, this means:

- **[Add study-specific details about what 'reduced' participation might be possible]**

Your study doctor or nurse may have explained your options to you already, but feel free to get in touch with them using the contact details **[below]** if you want to hear more about this.

If you have already said you do not want to make any further contributions to the study, no one will ask you about this again.

Finally, it is up to you whether you want to receive updates about this study in future, including to find out the results of the study when they are available. See **[above section on future contact]** for more on this.

5.2. Important new information about post-study arrangements

Immediate arrangements after the study: "What needs to happen now that I have stopped taking part?"

It should be clear to participants if there are any specific actions required from them after ending their involvement in the study, with reasons for these if they might not be obvious.

The exact points to include will depend on the study, but may include: how to safely stop taking study treatments; information or reminders about any final study appointments that may be requested or encouraged (for example to help assess participants' health); information about returning leftover study treatment or equipment, or a reminder about picking up belongings if the study involved a stay away from home.

This information may be conveyed verbally or in more general written communications between the doctor and the participant. The most important points may also have been covered in pre-study information sheets. However, the written communication at the time of stopping participation should mention any key points and/or encourage the participant to speak to their doctor or nurse if they have any queries about what is expected of them. The participant might also be provided with a checklist of things to they might want to ask about.

Arrangements for post-study care: "What will happen to my care now? Can I still access the study treatment? Might there be more side-effects in future?"

Participants may very reasonably have questions about their future care now that they have stopped taking part in the study.

We expect the specific details of post-study care to be conveyed verbally and in general written communications between the clinical/care team and the participant. The study-specific communication might help the participant with the sorts of questions to ask and who to talk to if they do not yet feel they have had enough information. As mentioned above, this could include a checklist of things that they might want to ask about.

The clinical/care team would be best placed, for example, to give the participant details about the treatment they have had during their time on the study, the plan for their treatment after the study, whether the study treatments are or will be available outside the study, and any important information to know before trying other treatments.

Some points that could be included in the study-specific communication:

- Reassurance/reminder that the participant stopping taking part in the study early will not affect the standard of care that they will receive.
- Reassurance/reminder that stopping taking part early in this study will not in itself restrict their opportunities to take part in research studies in future, as long as they are eligible for those future studies.

- Whether or not any other healthcare professionals (especially their GP) will be notified about their stopping participation in the study.
- A reminder about any longer-term risks or potential side-effects that could occur in relation to the study treatment, how to manage these and who to tell about them.
- The possibility of updated information becoming available about the safety of the study treatment and how this would be communicated (though this might fit better in text above on future communication about the study).

Some relevant information may have been given in the pre-study written information, for example about whether the study treatment is available outside the context of the study. If so, this information can be signposted, and participants given the opportunity to have another copy of that pre-study information if they need it.

Available support: "What support is available while I end my participation in the study?"

It is important to make clear to participants throughout their time on a study (not just when they end their participation) what support is available. This may be general support such as the local Patient Advice and Liaison Service[5] or more specific support related to the participant's health condition or their participation in the research.

It is not likely to be helpful to say that there is no particular support available even if this is the case, but if there are specific mechanisms in place then these can be mentioned by the clinical/care team, and the study-specific written communication can encourage participants to ask their clinical/care team if they need more support.

Even just having the opportunity to discuss their involvement in the study with someone in confidence might be valued by a participant. This might not need to be the same individuals they talked to during their time on the study, and it might even be helpful in some cases if it is someone different.

[5] https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/

5.3. Important reminders and signposting

This section covers information that participants should have already received. Although it overlaps with some of the topics already covered above, it could be useful to provide some specific reminders to help address common questions that participants may have.

Signpost to pre-study information sheet

In general, participants should be directed back to the information sheet they were given before the study, as this will contain lots of information relevant to the situation where they stop participating early. This includes what will happen to their data and any biological samples they have given in the study. These issues (and any others considered particularly important) could be specifically mentioned in the 'signpost'.

Signposting should include clear details of who participants should contact if they have other questions about what stopping study participation will mean for them. Participants can also be directed towards any other relevant information elsewhere.

Example

You may want to look again at the information sheet you were given before you agreed to take part in this study, as it contains some important information about stopping your involvement. If you don't have a copy of that anymore, speak to your study doctor or nurse to get another one.

They will also be able to help you if you have further questions about any of the points here, or if you would like to discuss what stopping your participation in the **[study name]** study means for you.

Reminder about what will happen to data already collected: "What will happen to the information you have collected about me?"

In almost all research studies, data collected up to the point a participant withdraws consent will be retained and used in the planned analysis. It is a legal requirement to inform patients about this before they consent to take part in a study.

Participants may remember this at the time they decide to stop taking part, but if they do not, they should be directed back to the information they were given before the start of the study. Alongside the 'signpost', participants could be specifically reminded that their data will be retained, but also reassured that their data will be kept secure and confidential at all times.

Reminder about what will happen to biological samples already collected: "What will happen to the biological samples you have collected from me?"

It is important to tell patients, before they consent to take part in a study, what would happen to any biological samples if they later decide to withdraw their consent for the samples to be stored and used for the research, and their options around this. Participants may remember this at the time they decide to stop taking part, but if they do not, they should be directed back to the information they were given before the start of the study.

It is also important to establish, when a participant expresses a wish to stop or reduce their participation in a study, whether or not they are still happy for their samples to be kept and used, both for the current study and for future research. Their decision about this should be confirmed to them as part of the summary of how their participation has changed (see "Summarising exactly how the participant's participation has changed", above).

It might be helpful to remind participants what biological samples they have given. This could be practically challenging to include in a written communication for all participants, but participants could be encouraged to contact their study doctor or nurse if they would like a reminder about this.

Possibility of finding out what treatment was received: "Can I find out what treatment I have been receiving?" (For 'blinded' studies where the participant and/or doctor do not know what treatment the participant is getting)

In blinded studies, it is unlikely that participants stopping early will be able to find out what treatment they have been receiving until the end of the whole study, or at least until a certain amount of time after they joined the study. One exception is if the clinical team responsible for their subsequent care needs to know what treatment they have received in order to plan their subsequent treatment.

All of this should be made clear to participants before they agree to take part in the study in the first place, and so participants can be directed back to the pre-study information for a reminder, if they need it.

Availability of the overall study results: "When can I find out the results of the study? How can I find them out?"

The pre-study information should give some information about how participants will be able to get the study results, if they want them. The 'signpost' could remind participants of the approximate timeline for this, and provide another copy of any links to where the results will be made publicly available (e.g. study registry page, study website).

Availability of individual test results: “Can I find out my own test results from the study?”

In any studies involving medical tests or procedures, participants might be interested to find out about the results of those tests, if they have not had them already. This can include the result that the test was intended to look for, but also other, unexpected findings (including so-called ‘incidental’ findings).

Where this is relevant to a study because of the sorts of tests being carried out, the information participants were given before they agreed to take part should have made clear whether there might be any such individual test results to find out about, and how they could find out about them. This includes the potential to inform a participant’s family members about genetic test results, in cases where this is applicable. As this is a complex area, participants might be reminded of any specific measures for support or counselling that is offered alongside the notification of test results.

If the pre-study information did not cover this topic because it was not deemed necessary for the study, the information given at the time the participant stops taking part does not need to mention it either.

Complaints: “What if I have a complaint?”

In some cases, participants may have stopped taking part in a study because something went wrong for them, and they are unhappy or upset about it. The pre-study information should always include information about how to complain about any aspect of their involvement in the study, and so this should be signposted in the information given to participants when they stop taking part. The availability of a way to complain should be presented neutrally and factually, without assuming there is or is not a problem to complain about, or to either encourage or discourage a complaint.

5.4. Other information

The 'other' information mentioned here may be useful or interesting to participants, but does not necessarily need to be given so soon after the participant stops taking part (i.e. it *can* be given soon, but a delay is acceptable). We also suggest that the topics here are lower priority than those given in the sections above, so might not be prioritised for inclusion in a written communication where space is limited.

Giving feedback on the study experience: "Can I give any feedback about my experience taking part in this study?"

If there is some way for participants to give feedback on their experience taking part in the study, this can be made clear to them. Participants who have stopped taking part early might have particularly useful feedback. Research sponsors could use this to understand how to improve their studies and design them in ways that are easier or less burdensome for participants to take part in.

General feedback is slightly different to the more specific information about a 'reason for stopping' (see below) – it has a different purpose and might be collected in a different way. In the case of this feedback, participants could be reassured that any feedback they give would be treated confidentially and would not be combined with any data collected about them for the study (or *could not* be combined, if it is collected anonymously). They might also be offered a chance to give feedback verbally or discuss their experience on the study with someone, if this is a possibility.

Although an invitation to provide feedback could be given very soon after a participant stops taking part, a delay is acceptable (or even desirable). At the later point the participant will have finished the process of 'withdrawing' from the study, hopefully resolved any initial queries about what will happen next for them, and perhaps will have had time to reflect on/cognitively process their participation in the study. Inviting feedback at the later stage also means it is uncoupled from the process of stopping participation, and therefore helps remove any sense that participants might be being asked to explain or justify any decision to stop taking part.

If there is no study-specific feedback mechanism, participants could be given details of more general feedback routes such as NIHR's Participant in Research Experience Survey (https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-learn-about-research/participant-in-research-experience-survey.htm).

Reminding participants of the option to give a reason for their decisions: "Why might it be helpful to know why I wanted to stop taking part?"

Participants have the right to stop taking part in any study without giving a reason. However, if they are happy to give a reason this can help the study statisticians to better understand

the study's results. It is particularly helpful to understand whether participants' reasons for stopping participation have anything to do with their health improving or worsening, because this can inform the overall research question in a study about which treatment is better.

Participants must not be pressured into giving a reason for stopping. However, informing participants about why it can help the study if they do give a reason can allow participants to make an informed choice about whether to provide a reason. This can only be mentioned at the end of a participant's time on a study if it was already mentioned in the information they were given before they agreed to take part.

From the participant's point of view, there may not be much difference between 'giving a reason' as here versus 'giving feedback' as above. It is important they are separated from the researchers' point of view because they serve different purposes. Information on reasons for stopping mainly informs study analysis, whereas more general feedback informs the design and management of future studies (or even the current study if feedback is received in time). This distinction could also be made in the communication for participants.

Example

If you would like to give any general feedback about your experience taking part in the study, we would very much like to hear from you. Please see **[above]**.

You don't have to give anyone a reason for stopping your involvement in this study. You may already have told your doctor or nurse why you wanted to stop taking part, or you may not want to do this. Either is completely fine.

However, as mentioned in the information you were given before you agreed to take part, it can be helpful for the study if you are happy to give a reason. This is because it can help the people analysing the study to understand the results of the study better. In particular, it is helpful to know if you stopping your involvement has anything to do with changes in your health. We would not need to know any more detail than that. It is completely up to you whether you want to share this information or not.

Feel free to contact your study doctor or nurse if you would like to tell them anything else about why you have decided to stop taking part in the study. Any information you give will be treated sensitively and confidentially.

Possibility of research involvement: "Can I get involved in any other research, or help improve how research is done in future?"

It may be appropriate to give general information about other opportunities to participate in research, either through condition-specific resources, or more general resources such as NIHR's 'Be Part of Research'. It should in general be made clear to participants that stopping

their participation in one study will not have any impact on their opportunities to take part in other studies (as long as they are eligible for those future studies).

Being a participant in a research study may also have increased people's general interest in research. They might be interested to know about research involvement, where they can input into how other research is instigated, designed and run. They may also have a specific, useful experience to share as part of this, given that they have decided or had to stop taking part in the study early.

Participants can be provided with links to more information, such as condition-specific pages provided by Cancer Research UK (https://www.cancerresearchuk.org/get-involved/volunteer/patient-involvement/what-is-patient-involvement) or more general resources such as those provided by NIHR (https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-help-with-research/).

Current update on study status or other news about the study

Some participants who stop taking part in a study early may still be interested to hear about how the study is going. This information is general and therefore should not take priority over the various individualised topics mentioned above.

Updates might include how study recruitment is going, or news of any significant milestones reached. If a study or the study treatment has been mentioned in the media, this could be mentioned and reflected upon.

Participants might also be reminded about ways to stay in touch with the study progress and find out the final study results, if they want to.

Frequently asked questions

A list of frequently asked questions should only be included if there are any questions to mention. This can be a useful way for participants to quickly find answers to questions they have, including as alternative ways to get information that is already presented elsewhere. For example, although there may be a section in the communication called "How has my participation in the study changed?", a participant might wonder, slightly differently, "Has my participation in the study completely ended?" A frequently asked questions section could help them find the answer to that specific question, mainly by referring to the other sections that cover this point. A similar approach could be taken on other topics, particularly about things participants are perhaps most likely to have questions about (such as plans for their subsequent care and treatment).

Appendices

Appendix A: document author list

Liam Bishop, William Cragg (project lead), Rachael Gilberts, Michael Gregg, Mary Mancini, Terry Lowden, plus others (not named).

Appendix B: acknowledgements

We would like to thank all everyone who contributed to this work by reviewing topic lists, more generally by discussing the project and the issues it raises, and through providing support and assistance in various other ways.

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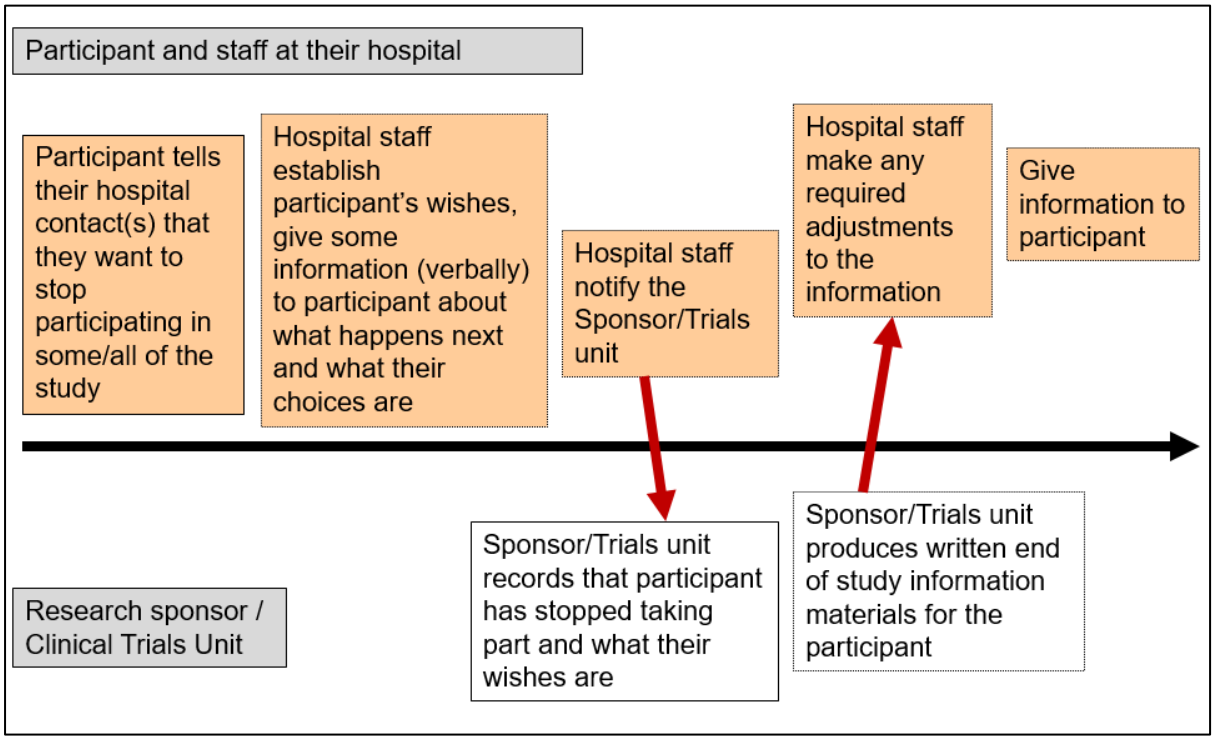
Appendix C: how this document was developed

This guidance was developed in three stages. First, we carried out a scoping literature review to find previously published reports about the process of participants stopping their participation early, or otherwise mentioning information topics to provide to research participants at the end of their time participating (whether they stop early or at the originally planned time). The results of the literature review were summarised into a single 'topic list' of information topics or items to potentially provide to research participants who stop taking part in studies early. This topic list was reviewed by a group of interested researchers and patients to help prioritise the topics, suggest any items that might be unnecessary or any that might be added.

Next, a series of discussion meetings were held for a group of patients and researchers to discuss the idea of researchers providing information to research participants who stop taking part early. This included reviewing the topic list mentioned above, discussing which information topics might be most important, how they should be communicated and by whom. The project lead amalgamated these discussions into a first draft of this guidance, and all group members were given a chance to review and feed back on this.

Finally, a separate, larger group of patients was asked to review the draft guidance, feeding back on any aspects they wanted, with some guidance questions to answer if they helped guide their review. The final guidance, incorporating this additional feedback, was agreed collectively by the main guidance development group.

Appendix D: example 'pathway' for participation ending



Appendix E: suggested items about ending participation to include in pre-study information for potential participants

The following points can be considered for inclusion in pre-study information (across both verbal and written modes) to support the information given at the time of stopping participation:

- Where applicable to the study, it should be clear that if a participant is finding it hard to continue participating in the study, **it might be possible for them to continue participating but with less commitment.** They can be advised to speak with their study doctor or nurse if they are finding participation difficult but are interested to know if a reduced 'level' of participation might be possible.
- Participants must always be made aware that they have **the right to stop taking part in the study at any time**, without giving a reason and without affecting the standard of the care they receive. They can also be made aware that it can **help the quality of research studies if as much as possible of the planned data is collected**. They can also be told **why it can be helpful to the study for them to give reasons for stopping, if they are happy to do so (or want to).** These points must be made sensitively, using wording approved by an independent research ethics committee. Informing participants of these points gives participants 'balanced' information and allows them to make informed choices about stopping or changing their participation. It is unethical for pressure to be put on participants to continue participating in a study, or to provide a reason for stopping. However, we suggest it is also not appropriate to

deny participants information about their choices, and information to guide those choices, if they may be keen to continue supporting the study as much as they can. In any case, participants should be reassured that whatever they decide is OK, and there are no 'wrong' decisions.

- Depending on the nature of the study and the treatments involved, it may be useful to confirm that doctors will keep an eye on participants' safety and **recommend they stop study treatment(s) early, if it is no longer in participants' best interests to continue receiving it/them.** This may not be useful if it could cause participants unnecessary concern or worry, but may be important if a study treatment is new and its safety is not well understood. If content about this is included, care must nonetheless be taken to do it in a balanced and sensitive way, to avoid causing unnecessary alarm or concern.
- Participants can get clear information about **what will happen if they lose contact with the researchers during the study.** For example, this might include any approaches the researchers might take to get back in touch with participants, or any plans for researchers to contact other healthcare professionals (such as GPs, with participants' consent) to find out if they have any information on how participants are doing.
- Any **limitations on participants' rights to stop or 'undo' aspects of participation** need to be mentioned up front. This includes any limitations on rights to have data about them deleted if it was collected before they decided to stop participating. It also includes limitations to have any biological samples destroyed if they have already been used. In some cases it may not be possible to stop some sorts of data collection, such as collection of data about side-effects in some clinical trials of new drugs where this data collection is a statutory requirement.
- Researchers may want to make clear **that data collection about a participant would continue until the participant says they want it to stop.** This means that if a participant says they want to stop taking a study treatment (for example) but does not say (even after having been asked) that they want to have no more data about them collected, collection of data relevant to the study would continue. If this approach is taken, it must be clear to participants how they can express a wish for data collection to stop if that is what they want. Research staff must also make reasonable efforts to find out the participant's wishes (usually through discussion with the participant at the time they are stopping or reducing their participation in the study). This approach should be applied conservatively. For example, if a participant has not specifically said they wanted data collection to stop but there are reasons why further data collection seems inappropriate (perhaps based on something the participant has said, or based on known changes to their personal circumstances), then it should stop. In our guidance below, we suggest that if researchers intend to continue collecting data about a participant after they stop participating in some elements of a study, they should make this clear at the time the participant stops taking part. This should help

ensure the approach is transparent, and ensure that participants definitely do have a choice in the matter.

- Pre-study information should include anything else relevant to the process of stopping participation in the study, or the implications of stopping on things like incentives, or access to the study treatment(s). It can also refer to the provision of information at the time of stopping (i.e. the communication suggested in this guidance), so that participants will be more likely to expect this to happen.

Appendix F: further links

Links and references given in the text:

- NIHR Research Participant Experience Survey Report 2018-19: https://www.nihr.ac.uk/documents/research-participant-experience-survey-report-2018-19/12109
- NIHR Participant in Research Experience Survey (PRES): https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-learn-about-research/participant-in-research-experience-survey.htm
- Cox K, Wilson E, Arthur A, Elkan R, & Armstrong S (2005). A randomised controlled trial of nurse-managed trial conclusion following early phase cancer trial participation. British Journal of Cancer, 93(1), 41–45. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2361479/
- Information for participants at the end of a study: Guidance for Researchers/Sponsors/ Chief Investigators/Principal Investigators: https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/hra-guidance-end-study-pis-v4-1_20-august-2015.pdf
- What is PALS (Patient Advice and Liaison Service)? https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/
- Cancer Research UK – what is patient involvement? https://www.cancerresearchuk.org/get-involved/volunteer/patient-involvement/what-is-patient-involvement
- NIHR – I want to help with research: https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-help-with-research/

Further information about ensuring information is suitably accessible:

- Coleman, E., O'Sullivan, L., Crowley, R. et al. Preparing accessible and understandable clinical research participant information leaflets and consent forms: a set of guidelines from an expert consensus conference. Res Involv Engagem 7, 31 (2021). https://doi.org/10.1186/s40900-021-00265-2
- NHS England Accessible Information Standard – Implementation Guidance: https://www.england.nhs.uk/publication/accessible-information-standard-implementation-guidance/
- British Dyslexia Association – Dyslexia-friendly style guide: https://www.bdadyslexia.org.uk/advice/employers/creating-a-dyslexia-friendly-workplace/dyslexia-friendly-style-guide
- Gov.uk – Accessible Information Formats: https://www.gov.uk/government/publications/inclusive-communication/accessible-communication-formats

- Autistica – Participant information, consent and assent forms: https://www.autistica.org.uk/our-research/research-toolkit/info-sheet