

Why?

This guide has been developed to help improve, and reduce the variability in, our consent rates between recruiting sites. We believe there are different practices happening across the country - this document aims to help standardise these. Feedback from study participants, a number of our recruiting sites and existing healthcare research have informed its development.

*The scientific basis of HORIZONS is that a **full cohort is approached**. However, it is important to remember you are approaching patients at a very difficult time – this requires communication skills, empathy and understanding.*

Value of HORIZONS

It is important that potential participants understand the value, relevance and importance of HORIZONS:

Little research has been done in relation to how people's lives are affected after they have had cancer, and how they recover from treatment. This is the first large study to look at patients' experiences and recovery of health and wellbeing over time. By following a large group of people, we can better understand the impact of cancer and its treatment, and identify how to best support people and improve care for patients in the future.

Recruitment window

Once identified, there is a narrow window to approach and consent eligible participants before they start treatment.

- If possible, it is ideal to approach patients face to face, ideally at one of their appointments prior to commencing treatment (e.g. surgical pre-assessment).
- Site teams have worked with clinical teams (clinical nurse specialists and doctors) to introduce HORIZONS at the initial appointment (often giving them HORIZONS flyers/introductory letters to aid this), therefore facilitating research teams to approach patients within the short window. Others have worked individually with the local lead consultant for each cohort to achieve best practice for their area, rather than a one size fits all approach.
- Participants themselves also suggest alerting the clinical team (nurses or doctors) present in clinic to mention the study upfront. Another approach to introducing the study is to use waiting room flyers.
- If it is not possible or inappropriate to approach face to face, HORIZONS packs can be posted to patients (after checking with the clinical team that the patient is fully aware of their diagnosis). Similarly, patients can also take packs home with them before making an informed decision.

Initial approach

Patients may find it disconcerting to be approached regarding HORIZONS immediately after their cancer diagnosis, at a very emotional time. Please remember that this may be their first appointment since diagnosis.

- Personalised communication is key in improving participant understanding about HORIZONS².
- Spending time talking to patients one-on-one is the best way of improving their understanding and helping them to understand why they are being asked to participate so soon after their diagnosis¹.
- It is important to acknowledge that this is a difficult time and you understand if they do not feel they can cope with taking part.
- Watching audio-visual information (alongside reading the PIS) can improve understanding and retention of a study's purpose². We have a series of 'talking heads' on the HORIZONS website (<http://www.horizons-hub.org.uk/index.html>) explaining how HORIZONS helps to understand the needs of people with cancer during and after their treatment. Please do signpost potential participants to watch these.
- Explaining the study in layman terms and outlining its purpose, have been described as effective. Using the wording above (the value of HORIZONS) can help with this, and a number of sites have found the A5 patient flyer particularly useful.
- Where patient packs have been taken or sent home, best practice is to conduct a follow up telephone call. Confirming receipt, reassuring the patient that the study information has come from the hospital, explaining the study in more detail, addressing any questions and if they are happy to participate in the study, explaining the completion of study documents.

Introducing the questionnaire

There is no getting away from the fact that our HORIZONS questionnaires are quite long. It helps to *acknowledge the length* of the questionnaire upfront, and share some of these facts to explain why and improve understanding:

- Our first questionnaires (baseline, 3 months, 12 months) aim to capture information about all the areas of someone's health and wellbeing before, during and following their cancer treatment. Questions will cover topics related to their general health, and their cancer diagnosis and treatment. Subsequent questionnaires will capture information regarding their recovery, and thus will be shorter in length.
- Each questionnaire is divided into sections and can be completed in multiple sittings.
- Participants say the questionnaire is clear, easy to complete and well laid out.
- Participants should not spend time pondering over choices; the first answer that comes to mind is usually the best one.

Generally, upon completing the questionnaire participants are happy with its length, acknowledging this reflects its comprehensiveness and relevance.

Introducing the content

Some questions within the questionnaire are of a *personal nature*.

- We have found that it is better to address this upfront when talking participants through the study, and explain why such questions are included, to improve their understanding.
- If they do not feel comfortable completing any of the questions, they can always strike through these and skip to the next.
- However, we have found that once participants expect these questions and understand why they are included, they can make an informed decision, and are usually happier to complete them.

It is important to inform participants that *not all questions may apply* to them.

- For example, some of the questions regarding treatment might not be applicable, or be difficult to answer, if they have not yet started their treatment.
- Please advise patients that they can always strike through these questions and move on to the next.
- Equally, explaining why they are present (so that we can explore changes in answers over time) can encourage them to complete these.

The questions used within our questionnaires are often part of standardised measures that we cannot change.

- Explaining this to participants will help them to understand why some questions appear similar or repetitive.

Everyone's experience is valued

It is important to explain that we are interested in everyone's experience even if over time, individuals feel they have moved on from cancer. We will also be able to understand the changes in people's lives (such as diet, physical activity and relationships) after a cancer diagnosis, so even if people are not undergoing treatment or experiencing problems their answers are still very important.

Benefits to taking part

Participants have provided feedback that the questionnaire itself is informative and helpful, for example in:

- Helping them to address their thoughts and feelings
- Understanding what they might expect to experience in future
- Providing reassurance that others experience similar things
- Helping to give something back and improve things for the future

Voluntary participation should be emphasised throughout the consent process.

References

- 1) Flory J, Emanuel E. Interventions to Improve Research Participants' Understanding in Informed Consent for Research A Systematic Review. *JAMA*. 2004;292(13):1593–1601. doi:10.1001/jama.292.13.1593
 - 2) Kao C.Y., Aranda S., Krishnasamy M. & Hamilton B. (2017) *European Journal of Cancer Care* 26, e12424, doi: [10.1111/ecc.12424](https://doi.org/10.1111/ecc.12424)
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