

Additional file 1

Topic guide for interviews with decision aid stakeholders.

Discussion and ensure signing of consent form

- Check the participant has read the participant information leaflet and understands what the interview entails;
- Ask if there are any questions;
- Ensure they are aware that confidentiality will be ensured at all times and their anonymity should direct quotes be used in publication;
- Request verbal consent and completion and return of paper copy of consent form in post.

Recording to commence.

- Present background to the study

Please tell me about your experience of clinical trials.

Patients

- How was the trial introduced to you?
- Did you feel you understood what was expected of you as a participant?

Research nurses, trial managers and principal investigators

- Can you tell me about where you work?
- What is your role in the clinical trials that you run ?
 - How long have you worked in clinical trials?
 - Is it an NHS or University setting?
- What kind of trials do you work on? How are they mainly funded?
- Do the trials that you run have a focus? E.g. cancer trials, paediatric trials...
- Can you tell me a little bit about who does the recruiting in your trials?

Ethics committee chairs

- What is your role at the ethics committee?
 - How long have you been the chair of this REC?
 - Does your REC focus on any particular types of research studies?

Please can you tell me about your views on existing patient information leaflets for clinical trials.

Patients not asked this question.

Research nurses, trial managers and principal investigators.

- Can you tell me a little bit about how you develop the patient information leaflets you currently use in your trials.
 - For example do you have a skeleton template that you use or do you have team discussions, who do you involve?
- How effective do you think existing patient information leaflets are at helping patients make a decision about trial participation?
- Do you think they facilitate discussion between the recruiter and the participant? Why or why not?

Ethics committee chairs

- How effective do you think existing patient information leaflets are at helping patients make a decision about trial participation? Are they fit for purpose? Why or why not?
- And do you think they facilitate discussion between the recruiter and the participant? Why or why not?
- What do you think about the NRES guidance on information leaflets and consent forms?
- Do you think researchers follow this when developing information leaflets? Why or why not?
- How does your REC review information leaflets? E.g. do you use a template? How often do they come up in the discussion?

Views about the prototype trial decision aids

Please can you tell me a little bit about what you think about using these tools to help people make a decision about trial participation?

- In general, what were your impressions of these tools?

- How do you think they compare to existing patient information leaflets?
(patients not asked this probe)

Please can you tell me what you thought were the most useful components of the tool?

- Why?

And can you tell me if you felt any aspects of the tool weren't helpful?

- Why?

What do you think about the sections on possible benefits and disadvantages of taking part and NOT taking part?

- Do you think this will influence decision making? Why or why not?

Can you tell me what you thought about the section covering experiences of others?

- Do you think this will influence decision making? Why or why not?

What do you think about the risk information that is presented?

- Do you think this will influence decision making? Why or why not?
- Do you have a preference? Why?
- More generally, do you think participants have trouble understanding risk information?
- Do you think this influences their decision to participate?

Can you tell me what you think about the worksheets at end?

- What do you think the best way to utilise these would be?
- Again, do you think they would support potential participant's decision making?
Why or why not?

Can you tell me what you thought about the length of the tool?

- If too much, how do you think we can reduce the amount of information presented?

When thinking about using these tools within recruitment consultations, how do you think they should be delivered?

- Why?

What do you think the objective of a trial participation decision aid should be?

- For example, there could be a variety of outcome researchers may want these tools to influence. What do you think is most important? Why?

Thinking about current practice, do you think the decision support tools would better support potential participants when faced with a decision about trial participation?

- Think specifically about the decision to participate and the decision to continue to participate.

Thank the participant for their contribution and ask whether they have any additional questions.

- Complete demographic data questions;
- Ask if wish to receive a summary of the results.