**Draft interview topic guides – Perspectives study**

This topic guide indicates of the sorts of questions and prompts that we anticipate asking interviewees. Interviews will be individualised to interviewees and this will be informed by a review of the specific documentation available for the particular study (e.g. protocol, participant information materials, study websites) that the interviewee has been involved with. This review will take place before each interview. The questions and their precise wording will also be adapted according to each participant’s needs and responses. As usual in qualitative research, the topic guide will be refined over the course of the study as informed by the developing analysis.

For all interviewees we will reiterate the purpose of the Perspectives study before each interview. .

**Topic guide for researchers**

***Demographic questions***

* Job title
* Role title in relation to ICU study [CI, Co-I. other - please specify]
* Do you have a clinical role? Please describe?
* Years of experience in ICU care setting
* Years of experience in ICU research
* Approximate number of ICU studies involved in as a member of research team

***Background***

* Tell me about your research project [title]. What are/were its main objectives/aims?
* Tell me about your role on the project and what that involves? Are you involved first hand in recruiting /consent participants into the project? Roughly how many patients have you approached?
* What interventions, samples and procedures does the project involve for patients?
* What stage is the research at currently?

***Study recruitment and consent process***

* Does the study involve deferred consent (sometimes called consent waiver or research without prior consent)? Could you tell me about the reasons for this?
* Would you ‘walk me through’ how patients are recruited into the study from the point when patient arrives in hospital? Prompt about who is involved, at what stage in the patient pathway, timing issues, who can provide consent?
* What would you/recruiters usually do before approaching a patient/relative to join the study? Prompt if there any steps taken to assess the timeliness of the approach for the patient/relative and if so how is this done?
* What would you/recruiters usually say to a patient/relative when first introducing the study?
* How do patients/relatives tend to respond at this point? Prompt about most recent 2-3 cases. Any discussions that stick out as particularly challenging?
* At what point is written information given? How long do patients/relatives usually have to consider joining the project? How was that time window decided?
* Would you ‘walk me through’ how consent is sought? What do you/recruiters usually say to patient/relatives when seeking consent? Prompt about who seeks consent, who it is sought from, at what point, how are the study risks and benefits explained?
* Do patients/relatives usually respond at this point? Prompt about what they understand/struggle to understand? What questions they ask
* Explore what happens in situations when a relative/surrogate has provided proxy consent and how and patient is informed of the research and their consent is sought.
* How is capacity to consent assessed and fluctuations in consent managed [prompt about repeat discussions, use of ICU patient diaries]?
* Does the project involve taking any research samples from patients before consent is obtained? Could you tell me about this?
* Explore consent rate and perceived reasons that patients/relatives a) eligible but not approached to participate b) decline?
* How would you compare the recruitment and consent process for this study to others that you’ve been involved in, in terms of its complexity or difficulty?

***Initial planning of the recruitment and consent process***

* I’d like to focus around the time you were first planning the study (before seeking funding and ethics approval). Tell me about how the recruitment and consent process took shape?
* Explore whether other studies provided a ‘model’ for the recruitment and consent process. Tell me about any models/alternatives that were considered?
* Prompt about who helped with development of recruitment and consent process, what factors were foremost in your mind in developing the process?
* Explore any compromises between what was scientifically ideal for this study and what was ethically/pragmatically possible? Awareness of any scientific questions that could not be addressed or methodological compromises made because doing so would be too challenging ethically?
* Were there any recruitment/consent issues that you discussed with colleagues/sought advice on when planning the study?
* Anyone else or any other resources that helped at this planning stage? How did these help?
* Any point at which research evidence on a) patient perspectives b) recruiter perspectives on recruitment/consent might have helped in planning recruitment/consent process? In what ways?

***Developments to recruitment and consent process: input from PPI, peer-review/funding process, and ethics committees***

* Did PPI partners/contributors comment or input on the recruitment/consent process/resources? In what ways? Prompt about any changes made?
* Did the peer-reviewers/funders comment on the recruitment/consent process? In what ways. Were any changes made as a result?
* Did you anticipate any complexities or difficulties in gaining ethics approval for the study? What were these?
* What questions did the REC have about the study in general, and the recruitment and consent process in particular? How did you address these?
* Did you make any changes as a result of the ethics review? What were these?
* Have you sought REC approvals for any amendments related to the recruitment and consent process? Tell me about these?

***Implementing the recruitment and consent process***

* Explore any training or guidance provided for staff involved in recruiting/consenting participants
* Any concerns raised by centres/staff about recruitment / consent?
* Explore site specific adaptations to recruitment and consent process.
* Any adaptations arising from implementation/feedback more broadly?

***Discussing research with relatives of deceased patients***

* Explore experience of deferred consent research where research participation is discussed and consent is sought from relatives of deceased patients, both in focal research project and in other research projects?
* Has interviewee had experience of this? What is the process in such situations, when does the conversation usually take place, who is involved, any special steps taken?
* How is the situation explained to relatives? How do relatives respond?
* What happens to study data if the relatives can’t be approached?
* Any information or guidance that would assist recruiters with this?

***Reflections***

* Are there things that you’ve learn about recruitment and consent over the course of your research project that you wished you’d known at the outset? Tell me about these?
* Are there any aspects about recruitment and consent in ICU research that you’d like feedback on from patients/relatives, from other stakeholders?
* Are there any changes to research ethics for ICU studies that would a) help scientific progress b) better serve the needs/interests of patients?
* Our study is about developing good practice guidance for ICU studies – do you have any guidance or reflections that you’d like us to take into account in developing this guidance?

***Closing***

* Are you still in touch with the patient/public partners who helped in the design of the study? Explain that we’d like to invite the partners for interview and explore willingness of interviewee to contact them on our behalf?
* Would you like access to a summary of the findings? Explore preferred route – email PDF or send link to a website
* That’s the end of my questions. Is there anything else that is important to you that we haven’t talked about today?
* Is there anything else you’d like to say?

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*Given thanks and close interview*

### Topic guide for research partners

There are different views about what to call patient/public involvement. In our study we’re using the term ‘research partner’, what term would you usually use? Would you prefer we use that in our interview?

***Demographic questions***

* Name or description of PPI role in relation to ICU study [please specify]
* Knowledge of ICU care setting as a) patient b) relative/friend c) other [please specify]
* Approximate number of studies involved in in a PPI capacity; of these how many have been ICU studies?

***Background***

* Tell me about the research project [title]. What were its main objectives/aims?
* What stage is the research at currently?
* Explore how interviewee first became involved in the research project? [prompt, when did you get involved, how did you find out about it, why you became involved/what were your goals?]
* Tell me about your role on the study? What aspects of the study have you advised on, how do you do this i.e. via formal meetings, teleconferences etc or informal discussions?
* Did you have any previous experience PPI work before this project?

***Study recruitment and consent process***

* What is your understanding of how patients are recruited into the study? Prompt about who is involved, at what stage in relation to admission, timing requirements/constraints of study.
* What would expect recruiters to say and do when first introducing the study to a patient/relative?
* Drawing on your experience, what do you think patients/relatives will be thinking when they first hear about the study? How far do will they be able to absorb information and what do you think could be done to help them?
* How do you expect recruiters go about seeking consent for the study? What things do you think they should do for/say to patient/relatives when seeking consent? What do you think could be done to help recruiters in this role?
* What questions do you think patients/relatives will have about the study? Do you think they’ll be able to voice these to recruiters, what would support them doing so?
* Roughly what proportion of patients/relatives do you think consent to the study? For those who do consent, what do you think are their reasons? For patients who decline, what do you think are their reasons?
* Sometimes in studies not all eligible patients are approached – what are your thoughts about that?

***Initial planning of the recruitment and consent process***

* I’d like to focus around the time the study was first being planned (before seeking funding and ethics approval). Were you involved at that point?
* Explore what aspects interviewee has helped/advised on related to recruitment and consent. What factors were foremost in your mind in providing advice/developing the process/resources. Were the research team receptive to your input? Were any changes made in the light of your input?
* Are you aware of any compromises or deliberations between what was scientifically ideal and what was ethically/pragmatically possible in relation to the recruitment and consent process?

***Developments to recruitment and consent process: input from PPI, peer-review/funding process, and ethics committees***

* Did the peer-reviewers/funders comment on the recruitment/consent process as far as you’re aware? In what ways. Were any changes made as a result?
* What questions did the ethics committee have about the study in general, and the recruitment and consent process in particular? How were these addressed?
* Have there been any amendments related to the recruitment and consent process that you are aware of?

***Knowledge of deferred consent and discussing research with relatives of deceased patients***

* Explore knowledge of deferred consent research, explaining as necessary and seeking opinions.
* Acknowledge that some ICU patients sadly do not survive. Where a patient has been entered into a study and later died, consent needs to be sought from relatives of deceased patients. Explore interviewee’s views on this. What the process should be in such situations, when the conversation with the family should usually take place, who should be involved, what special steps should be taken?
* Explore thoughts about how bereaved relatives would usually respond in this situation?
* What should happen regarding the research and patient data if the relatives can’t be approached?
* Any information or guidance that would assist relatives and recruiters with this?

***Reflections***

* What would you say are the key things that the team have learnt about recruitment and consent over the course of the research project?
* Are there any aspects about recruitment and consent in ICU research that you’d like feedback on from participating patients/relatives, or from other stakeholders? Questions that future research on ICU recruitment and consent processes could usefully address?
* Our study is about developing good practice guidance for ICU studies – do you have any points or reflections that you’d like us to take account of in developing this guidance?

***Closing***

* Would you like access to a summary of the findings? Explore preferred route – email PDF or send link to a website
* That’s the end of my questions.
* Is there anything else that is important to you that we haven’t talked about today?
* Is there anything else you’d like to say?

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*Give thanks and close interview*