# **Patient Topic Guide**

**Introductory questions**

* How are you today?
* [If telephone interview] Could I start by checking your address?
* Are you/were you in paid employment before you went into hospital? What is your occupation?
* What hospital were you treated at?
* How long did you stay in the ICU?  *When were you discharged? How long did you stay in the hospital?*

**IF PARTICIPANT WAS APPROACHED ABOUT RESEARCH**

1. Can you tell me about the research study you were approached about?
   * What was it aiming to do?
   * What was involved?
   * When did the study/intervention start? *As soon as you entered the ICU? After some time had passed?*

**Being approached about research**

1. Did you enter hospital as an emergency, or was this a planned visit/treatment that you knew about in advance?
2. Walk me through what happened. When did you first hear about the study?
   * Was this before or after you were enrolled in the study? *Was your family member asked to approve/assent for you to be enrolled in the study?*
   * How were you approached about the study? *Face to face? Over the phone?*
   * Who approached you? *Doctor? Nurse? Researcher?*
   * Who was with you when you were approached about the study? *Family member? Another member of staff at the hospital?*
   * How did they approach you?  *What did they say to you? How did they introduce the topic of research? How did you feel about what was happening?*
   * How did you respond? What was going through your mind?
3. Were you given any information about the study? *Written or verbal?* [SEE SURVEY RESPONSES]
   * What did you think about this information/explanation? Was it clear and informative? [SEE SURVEY RESPONSES]
   * Did you have any concerns about the study? What were they?
   * Were they addressed? If so, how were they addressed?
   * Was there anything you found unclear? Was there anything you would have like more information/explanation on? Could anything have been improved in any way?
4. Asking questions
   * Do you remember if you asked any questions? *What were they? Were they answered satisfactorily? What did you think of the timing of the approach? If not, ask why not?*

**Deciding to participate or not**

* Did you agree to be involved in the study or did you decline? *Or ask for your data to be removed* [SEE SURVEY RESPONSES]
  + When making the decision whether or not to consent, what kind of things went through your mind? *Did you have any concerns?*
  + Was there anything you found helpful when making up your mind? *Speaking to another person? Any resources you were given or looked up yourself?*
  + Did you discuss the study with anyone else before making your decision? *Who?*
  + How did you find making this decision? *What was easy/difficult about it?*
  + What would you say were the deciding factors in your decision?
  + Looking back, would you make the same decision again?

1. Were there any risks from taking part in this study from your perspective? What were these? Did you think of this study as a ‘risky’ thing to do? *Would your decision have changed if it were more/less risky?* 
   * What counts as a risky study from your perspective?
2. Were there any possible benefits from taking part in this study from your perspective? What were these?
3. *Explore* *the risks and benefits as described by the doctor/nurse?*
4. Are there any questions you would like answering about the study that have not been addressed?
5. Could anything have been improved? Was there anything good about your experience with research? Was there anything bad about your experience?
6. Would you engage in research in the future? *As a consultee? As a participant?*

**Family member’s response (if applicable)**

* You may have been rather ill at the time, but did you talk with your family member about the study when it was first mentioned to them? *If so, how did they respond when the study was first mentioned to them? If not talked, how do you think they may have responded?*
* What did they think about the decision you made? *Did they agree or disagree?*
* What decision do you think they would make on your behalf?
* Had you talked about research before this all happened? *Did you know each other’s feelings about research before making the decision?*
* Based on their response, would you make the same decision again?

**QUESTIONS REGARDLESS OF RESEARCH EXPERIENCE**

**Types of research and consent**

* What do you think about another person, like a family member or close friend, assenting on behalf of someone else in general? *For? Against? What are your reasons for this?* [SEE SURVEY RESPONSES]
* What are your thoughts about doctors, who are not involved in the study, giving consent on behalf of ICU patients? *Is this a good or bad thing?* [SEE SURVEY RESPONSES]
* Under what circumstances would this be acceptable? [SEE SURVEY RESPONSES]
  + If time is too short to contact a family member – so if an intervention needs to occur quite quickly?  *Should a patient be enrolled at all in this situation?*
  + If a patient doesn’t have any known family members, for instance if they are not known to the doctors or have no ID on them? *Should a patient be enrolled at all in this situation?*
  + If the doctors are aware of a family member who could be contacted to give consent on behalf of the patient, but they’re not available (e.g. phone switched off)? *Should a patient be enrolled at all in this situation?*
  + *What do you think are the reasons for use doctors to give agreement on behalf of patients for studies consent in situations like this?*
  + *Does it make you feel more comfortable that the doctor who gives the agreement on behalf of the patient isn’t involved in the study?*
* What are your thoughts about studies that involve a patient without consent beforehand? So when an intervention has to occur very quickly, and then afterwards someone involved in the study (doctor or research nurse) asks the patient or their family member for consent? *Given the circumstances, is this acceptable? What would be an acceptable alternative?*

***I’m going to describe different types of studies, and I’d like to ask you your thoughts on how they should be approached or introduced to a patient/their family members*** [CHECK STUDY WAS PARTICIPANT APPROACHED ABOUT if applicable]

* Some studies involve medicines. There are studies that look at the use of established medicines in a different way (e.g. if it’s been shown that paracetamol helps patients who’ve suffered a heart attack, they may want to see whether it can help patients with sepsis in the ICU). And other studies look at newer drugs that haven’t been widely tested or used before. How would you expect the consent procedures to differ for these kinds of studies?
* Other studies involve other medical care, such as equipment (e.g. catheters that deliver medication or nutrients). For instance, one study might look at the effectiveness of a different type of catheter to the one usually used, on a patient’s outcomes in ICU. How would you expect the consent procedures to differ for these kinds of studies to those involving medication, if at all?

**Thoughts about research**

* What did you think about research before? Did your opinion on research change after visiting the ICU? *How so?*
* Have you ever been involved in research before?  *What was it? What did you think? Did that influence your opinions?*
* What has influenced your opinions on researched? *Personal [academic] experience? Media?*

**Overview**

* Our study is about developing good practice guidance for ICU studies – do you have any ideas or suggestions that you’d like us to take into account in developing this guidance?
* Do you have any ideas or suggestions on the ways patients are recruited and consented?
* Is there anything you would like to add?