# **ICU Doctor and Nurse Topic Guide**

1. **Introductory questions**
* How are you today?
* [If telephone interview] Could I start by checking which hospital you work at?
* What is your role?
* Have you been involved in research [SEE SURVEY RESPONSES] *in what capacity?*

***\_\_IF PARTICIPANT WAS INVOLVED IN RESEARCH\_\_***

* Can you tell me a little about the research studies you’re involved with currently?
	+ What are their aims?
	+ What was involved?
	+ When did the study/intervention start? *As soon as the patient entered the ICU? After some time had passed?*
	+ What type of consent is used?

**2. Consent and involvement in research**

* Thinking about your most recent experience of approaching a patient or family member about research, or to obtain consent, can you ‘walk me through’ how patients are recruited into the study from the point when patient arrives in hospital. *Who is involved, at what stage in the patient pathway, timing issues, who can provide consent?*
* When is a patient or relative approached about the study? *For family members, is this at the same time they’re told your relative was in the ICU? While visiting hospital visiting? For patients, before the intervention? After? Which ward? By whom?*
	+ Was this before or after the patient was enrolled in the study? *RWPC or personal consultee?*
	+ *[If applicable]* How were patients approached about the study? *Face to face? Over the phone?*
	+ Who by? *Doctor? Nurse? Researcher?*
	+ How do they usually approach patients?  *What did they say? How did they introduce the topic of research? Do they usually feel comfortable with making the decision?*
	+ How do they respond?
	+ What’s going through your mind at this time?
	+ How typical was this of other patients?
	+ *[If applicable]* How were family members approached about the study? *Face to face? Over the phone?*
	+ Who by? *Doctor? Nurse? Researcher?*
	+ How do they usually approach patients/family members?  *What did they say? How did they introduce the topic of research? Do they usually feel comfortable with making the decision?*
	+ How do they respond?
	+ What’s going through your mind at this time?
	+ How typical was this of other family members?
* What kind of information are patients/relatives given about the study? *Written or verbal?* [SEE SURVEY RESPONSES]
	+ Do patients/family members have any comments about this? Was it clear and informative? [SEE SURVEY RESPONSES]
	+ What do you think about the information provided? [SEE SURVEY RESPONSES]
	+ Did patients/family members have any concerns about the study? What were they? How were they addressed? *Did you have any concerns about the study? What were they?*
	+ *How were they addressed?*
	+ Was there anything patients/family members found unclear? Was there anything patients/family members wanted more information on?
	+ Do you think anything could have been improved in any way?
* Did patients/family members have enough time to answer questions?
	+ Did patients/family members ask any questions? *What were they? Were they answered satisfactorily? What did you think of the timing of the approach?*
1. **Reasons for participating or not**
* Do patients/family members tend to give reasons for agreeing to consent or not agreeing to consent?
	+ Did they have any concerns*? What were they?*
	+ Do patients/family members use any resources to help them come to a decision? *Speaking to another person? Any resources* patie*nts/family members were given or looked up yourself?*
	+ Do patients/family members discuss the study with anyone else before making your decision? *Who?*
	+ Do patients/family members find this decision difficult or easy? *What was easy/difficult about it?*
	+ When making the decision, do patients/family members mention how the research might benefit other patients in the future?
	+ What decision would you make in this situation? *For this particular study [see survey responses for study names]*
* 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?
* How ‘risky’ did patients/family members consider the study to be?
	+ What counts as a risky study?
* What were the possible risks or benefits of participating? *Your perceptions of risk? The risks and benefits described by the patients/family members?*
* Could anything have been improved? *From your perspective? Did patients and family members give any feedback?*
* What was good about your experience with research?
* Would you engage in research in the future? *As a consultee? As a participant?*

***\_\_QUESTIONS REGARDLESS OF RESEARCH EXPERIENCE\_\_***

1. **Types of research and consent**
* What do you think about another person, like a family member or close friend, giving consent 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?*
	+ *Why do you think they use doctors to consent in situations like this?*
	+ *Do you think it makes patients/family members feel more comfortable that the doctor 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?*
1. ***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?
1. **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?