

Suggested questions for volunteers to ask the research team about a clinical trial

Questions	Answers
The Study	
What is the purpose of the study?	
What health conditions must I have? Are there any particular conditions that would exclude me?	
Why do you think the approach being tested may be effective? Has it been tested before?	
How will it be decided which treatment I get in the trial? Do I have a choice?	
How many volunteers will be in the trial: In Australia/NZ? In the world?	
Who is sponsoring the study?	
Who has reviewed and approved the study?	
What are the medical credentials and experience of the researchers and other study personnel?	
How will the study results and my safety be monitored?	
How long will the trial last?	
How will the results be shared?	

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Possible Risks and Benefits	
What are the possible short-term and long term benefits?	
What are the short-term risks, such as side effects, or possible long-term risks?	
What other treatment options are available?	
How do the possible risks and benefits of the trial compare with my current treatment, or other options?	
What will happen if I suffer a serious side effect as a result of the trial? Can I withdraw from the study at any time?	
Participation and Care	
What will be my responsibilities if I take part?	
What kinds of treatment, medical tests, or procedures are involved? How often will I receive the treatments, tests, or procedures?	
How often will I need to visit the researchers and what will I need to do between visits?	
Is there anything I am not allowed to do while I am in the trial? Are there any medications or supplements I shouldn't take while I am in the trial?	
Will treatments, tests, or procedures be uncomfortable or painful? If so, how can I be made more comfortable or have the pain controlled?	
How do the tests in the study compare with what I might receive outside the study?	
Will I be able to take my regular medications while in the clinical trial?	

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Where will I come for my medical care? Will I need to be hospitalised? If so, for how long?	
Who will be in charge of my care? Who should I contact if I have a problem?	
Will I be able to see my own doctors?	
How long will I need to stay in the study? Will there be follow-up visits after the study?	
Will I have access to the medicine after the trial is over?	
Personal Issues	
How might the trial affect my daily life?	
Will participating in a trial affect my life insurance and medical insurance status? Am I covered by insurance if something goes wrong because of the trial?	
Who will get to see my medical records, and how is my privacy protected?	
Do I need to tell my GP about the trial, or do you do that?	
What support is available for me and my family?	
Will I be paid to take part in the trial? Will any of my expenses for taking part in the study be covered?	
Can I talk with people already enrolled in the study?	