EVALUATING A CLINICAL TRIAL - CHECKLIST

It's OK to ask questions

Before you agree to take part in a clinical trial, the research team should provide you with a participant information sheet that will explain everything about the trial, and may talk you through that information. Afterwards, they are required to provide you with the opportunity to ask questions and have those questions answered.

Please take the opportunity to make sure you understand everything that will happen and that you will have to do. This will help make sure you make a more informed decision about whether you can, and want, to take part. No question is wrong or silly. If there is something you don't understand, or aren't sure how it will work, please ask.

The following are examples of questions that the participant information sheet and research team should be able to answer for you, else you can ask to clarify.

The Study

- ☐ What is the purpose of the study?
- ☐ What health conditions must I have? Are there any particular conditions that would make it unsafe or inappropriate for me to take part?
- ☐ 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?
- ☐ If I am not told which treatment I am getting, when will I find out what treatment I had?
- ☐ How many volunteers will be in the trial - In Australia? In the rest of the world?
- ☐ Is the research well funded?
- ☐ How many other people have already agreed to take part in *this* trial? When do you expect to complete recruitment for this trial, and finish the study?
- ☐ Who is sponsoring the study? Who is funding the study?
- ☐ Are you being paid to run this study? Will you personally benefit in any way from the study if the results are positive?
- ☐ Who has reviewed and approved the study? How do I get in touch with them if I have questions or complaints about the trial, trial researchers or its approval?
- ☐ What is the experience and medical credentials of the researchers and other study personnel?
- ☐ How will the study results and my safety be monitored?
- ☐ How long will my participation in the trial last?
- ☐ Will I get told my results or the outcome of the trial? How will the trial results be communicated?

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Possible Risks and Benefits

- ☐ What are the risks of this research to me? For example, has this intervention been researched before? How many people have tested it before me? How scientifically rigorous has preclinical testing been? Can supportive research papers be provided? If a clinical trial of a medicine, what phase of clinical trial is it?
- ☐ What are the possible short-term and long term benefits of the trial or the intervention being studied?
- ☐ What are the possible short- and long-term risks, such as side effects?
- ☐ 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 I have to do (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? What do I need to do if I visit a doctor who prescribes a new medication/treatment during the trial?
- ☐ Where will I come for my medical care? Will I need to be hospitalized? 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 continue to see my own doctors? Will you be informing my usual doctors what is happening in the trial?
- ☐ How long will I need to stay in the study? Will there be any follow-up afterwards?
- ☐ Will I have access to the medicine after the trial is over?
- ☐ If something goes wrong in the trial, how will I be cared for? Who will cover those costs?
- ☐ Who will I visit for my ongoing medical care after the trial is finished?

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Personal Issues

- ☐ I don't live in the city/state/country that you are running the trial in. Am I still able to participate? Can you support my travel costs to participate?
- ☐ Is anyone allowed to come along to the visits with me?
- ☐ How might the trial affect my daily life?
- ☐ When, where and how often are trial visits?
- ☐ Will I need to carry or use any additional technology? What if I am not comfortable or able to use that technology? What training and support to use the technology will be provided?
- ☐ Will I need to use my own devices and/or internet/data credits?
- ☐ Are you able to help me explain the time off I need to my employer, school, etc?
- ☐ Will I be paid to take part in the trial?
- ☐ What will I need to pay for?
- ☐ Will any of my expenses be covered? For example, can you help with covering flights, taxi's/transport, car parking, meal & accommodation expenses, childcare, etc in order to get to visits if needed, or data/internet costs?
- ☐ 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 have access to my medical records and trial data?
- ☐ How will my privacy be protected? How/where will the trial data be stored?
- ☐ Do I need to tell my GP about the trial, or do you do that?
- ☐ What support is available for me and my family?
- ☐ Can I talk with people already enrolled in the study?