



Guidance Document for Researchers designing Patient Information Leaflets

This guidance document has been designed by the NIHR Medicines for Children Research Network (MCRN) Young Person's Advisory Group. The group was set up in 2006 and has recently expanded to involve more children and young people across the country. To find out more about the group click on the MCRN website at www.mcrn.org.uk

The guidance is aimed at researchers to design better Patient Information Leaflets for children and young people involved in clinical studies. It's important for researchers to provide children and young people with enough comprehensible information to allow them to make a fully informed decision to take part in a study. Well designed Patient Information Leaflets may also help researchers recruit more children and young people into a study and may possibly retain children in that study.

Here are some tips for designing information leaflets for children and young people:

Tip 1

Separate the information sheet into a **part 1** and **part 2**:

Part 1 - summary of the study, which invites the child or young person to read part 2 if they are interested in the study

Part 2 - further information about the study which incorporates the five W's to make it simple:

What - what is the study about? What will happen to me in the study? What are the possible benefits and risks?

Why - why is the study being done?

Where - where will the study take place, will I need to take time off school, and if so how much time? Would it affect my social life?

When - when will the study begin and possibly finish?

Who - who will lead the study?

Tip 2

Have a separate leaflet available to children and young people explaining what research is. Try to avoid explaining everything in one leaflet. If possible you could try using different media and formats (e.g DVDs)

Tip 3

Top- tip - break the information into smaller chunks, so it's clear for children and young people to read. A long piece of writing puts children and young people off reading it! Using a good font helps also.

Tip 4

Presentation is important because it's the first thing children and young people will notice about a leaflet, the more colour the better!

Tip 5

Top tip - put pictures in because it means something, not because you feel you have to! "I still won't understand the information by adding a picture to the text".

Younger children relate to illustrations and cartoons

Young people relate more to photographs of real situations relating to clinical trials, maybe photographs of young people actually involved in trials.

Tip 6

Top-tip - Information needs to be planned (not just thrown in!)

Information needs to flow, don't repeat sentences, or put words in that don't mean anything.

Tip 7

Keep it simple and easy to understand, don't put too many scientific words in.

Tip 8

Top-tip - Seek advice from children and young people before going to an ethics committee