



A minor's (ages 10 to 14) informed consent for a clinical trial

Name of trial: _____

Doctor's name: _____

My doctor has asked me to take part in this trial. I would be suitable for this trial because _____.

This trial tries to find out if this medicine _____ will help _____ feel better. My doctor will tell me _____.
 I and _____ have been told about this trial and the treatment.

During the trial I will have _____ appointments with my doctor. At the appointments _____.
 During the trial _____.

My part of the trial ends on _____.

During this new treatment may appear _____.
 This feeling usually goes away soon _____.

■ If I feel different in some other way I should tell _____ about it right away, and _____ will tell my doctor about it.

■ I have had enough time to think if I want to take part in this trial. I have also been allowed to ask questions.

■ I and _____ have been told about this trial. If I want to take part in it _____ will sign another consent form, which gives me permission to take part in this trial.

■ It may also be that my doctor thinks I should stop taking part in the trial. In that case my doctor will decide with me and _____ that I will not take part in the trial any more. After that I will still be taken care of in the best possible way.

■ I know that I don't have to take part in this trial if I don't want to. If I say yes now and change my mind later, all I have to do is tell the adults who are working with the trial. I will still get the treatment I need.

■ Information about me and the trial can only be seen and handled by _____, the people taking care of me and working with this trial. This is because this information is confidential and should be kept a secret.

If I want to take part in this trial, I will write my name below.

My name: _____

Date: _____

Doctor's name _____

and signature: _____

Date and place: _____