



## A minor's (ages 6 to 10) 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 the trial because \_\_\_\_\_.

■ This trial helps to find out if the study medication will help children feel better.

During the trial I will have a doctor's appointment \_\_\_\_\_ times. The last appointment will be on \_\_\_\_\_.

\_\_\_\_\_

My doctor has told me about this trial. \_\_\_\_\_  
 He/she has told me what will happen during the trial. I have been able to ask questions about the trial.

The medicine may cause me \_\_\_\_\_, but usually that goes away quickly. \_\_\_\_\_.

■ If I notice I feel different, I should tell \_\_\_\_\_ about it right away and \_\_\_\_\_ will tell my doctor about it.

■ My doctor has spoken with \_\_\_\_\_ about the trial. \_\_\_\_\_ also consented to my participation in the trial.

■ I have been allowed to say if I want to take part in this trial. I know I don't have to if I don't want to.

■ If I later want to stop taking part in the trial, no one will be angry at me. In that case I should tell \_\_\_\_\_ or some other grown-up who is working with the trial. The doctors and nurses will still take care of me in the best possible way.

■ It could also happen that my doctor thinks I shouldn't continue taking part in the trial. In that case the doctor will tell \_\_\_\_\_ and me about it, and I will get another treatment that is just as good as before.

■ Only I, \_\_\_\_\_, my doctor and the grown-ups working with this trial will get to see information about me.

**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: \_\_\_\_\_