FPM-E-001-EN-A v3.0 30.3.2021

# A minor's (under 15 years) Informed Consent Form template for a Clinical Trial

**Title of the study:** _____

**Name of the study doctor:** _____

## Brief description of the study

1. _____ has asked me to take part in this study. I would be suitable for this study because _____.

2. I have been told about this study and what happens during the study. I have been told what kind of procedures are included in the study and that some of these might be a little unpleasant. I have been told how these procedures will be done and how they can be made less unpleasant.

3. I have been told that the study starts on _____ and ends on _____. During the study, I will have _____ of appointments with my doctor.

4. I have been told that I might feel different during the study. I might have _____. These can be treated and they usually go away soon. If I feel different in some other way I should tell my _____ and the doctor or nurse right away.

5. I have been told that this study might not help me or make me better, but it might help other children of the same age who have the same disease.

6. I have been told that this study might clearly help me or make me better.

7. I have been allowed to say if I want to take part in this study. I know I don't have to if I don't want to. If I don't want to take part in this study, I have been told what other options I have. The doctors and nurses will still take care of me in the best possible way.

8. If I decide to participate now, I know that I can change my mind later and stop taking part in the study. If I later want to stop taking part in the study, no one will be angry with me. In that case I should tell my _____ or some other grown-up who is working with the study. The doctors and nurses will still take care of me in the best possible way.

  

9. It could also happen that my doctor thinks I shouldn't be in the study anymore. In that case the doctor will tell me and my _____ why. I will still be taken care of in the best possible way.

10. My _____ has also been told about this study and asked if I can participate. _____ has said that I can participate.

11. I have been told that information will be collected about me for this study. This kind of information includes my name, birthday and information about my illnesses and medicines. This information is needed to treat me as well as possible. All information is kept confidential and stored in a locked place. Only people working in this study will see this information.

12. If I want, I and my _____ can ask the doctor or nurse to show us what information has been collected about me.

13. I have been allowed to ask questions. I and my _____ have been told who we can ask questions later. We both have the doctor's or nurse's name and phone number.

**If I want to take part in this study, I will write my name below.**
**If I want to take part, _____ also has to sign.**

My name: _____ Date and place: _____

**This consent was received and information about the study was given by**
(a doctor/nurse fills in):

Name: _____ Title: _____

Signature: _____ Date and place: _____

This consent form is prepared in two copies. One is given to the person participating in the study. The other is archived in a study file.

  