**INFORMED CONSENT FORM FOR THE INCLUSION IN A CLINICAL TRIAL**

**INTENDED FOR A MINOR AGED BETWEEN 12 AND 17 YEARS**

|  |
| --- |
| **Official title of the trial***(in Italian)* |
| **Official title of the trial in more understandable terms for the patient** *(use common and non-technical terms: for example, make it clear that the investigational molecule is a new drug to lower blood pressure, prevent heart attack, etc.)* |
| **Facility-context of the trial** |
| **Coordinating center** *(if different from the structure where the trial will take place)*  **and clinical trial coordinator**Coordinating center **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Clinical trial coordinator**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Register where the trial has been registered or will be registered (if applicable) and any identification code if available**Identification code \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Register\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Principal investigator** *(indicate the local Trial Manager)*Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Affiliation \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |
| **Sponsor/Financing body** |
| **Ethics Committee** |

This document consists of the following sections:

1. INTRODUCTION
2. QUESTIONS AND ANSWERS SECTION: KEY INFORMATION
3. FURTHER INFORMATION
4. CONSENT SECTION

ADDITIONAL DOCUMENTS

1. **INTRODUCTION**

*Dear Young Person,*

*your parents have been involved to inform them and ask for their consent to your participation in a clinical trial. For this purpose, we have submitted to them a detailed information sheet, which goes into detail on the various aspects of the trial. From a legal point of view, their consent is essential for you to be able to take part in the trial.*

*However, it is your right to be informed about the purpose and characteristics of the trial so that you can make an informed and free decision whether to participate or not. In relation to your age, there are the prerequisites for a reasonable maturity allowing you to form your own opinion on the subject and to evaluate the information relating to the trial, to its risks and benefits. For this reason, your explicit desire will be taken into consideration to participate or to refuse participation in the trial or to withdraw from it at any time.*

*This document aims to inform you clearly and thoroughly about the nature and purposes of the trial, and about what your participation will entail for you, including your rights and responsibilities. We have restricted ourselves to the aspects that we consider most significant for you but, if you wish, you can also consult the information sheet delivered to your parents.*

*Please read the following carefully. The researchers involved in this project, indicated at the beginning of this document, are available to answer your questions. No question that comes to your mind is trivial: don't be afraid to ask!*

*Besides us, you can discuss the proposal contained in this document with your general practitioner, your family and other trusted persons. Take your time to decide. You can take home an unsigned copy of this document to think about it or to discuss it with others before making a decision.*

*Should you decide not to participate in the trial, you will still receive the best possible care for patients with your condition/disease. In no way will your refusal be interpreted as a lack of trust.*

*If appropriate:*  *To facilitate the understanding of this document, the Trial Center* (others: indicate) *makes available a cultural mediator in order to transfer the contents in the manner and language most suitable for you.*

*If appropriate: If you are unable to sign the informed consent, the consent can be provided and recorded using specific alternative means, such as audio or video recordings, in the presence of at least one impartial witness.*

*Once you have read this form, received answers to any questions and decided to participate in the trial, you will be asked to sign a consent form, of which you will receive a hard copy.*

*The first section will answer the following questions:*

* *What is the aim of this clinical trial?*
* *What are the objectives of the trial? Who else will participate? How long will it last?*
* *Is it my free choice to decide whether to participate or not?*
* *What if at some point I want to withdraw from the trial?*
* *What happens if I decide to participate in the trial? How long will it last?*
* *Are there any rules to respect?*
* *What benefits can I expect?*
* *Will I take risks if I participate in the trial?*
* *Who can I ask for further explanations? Who will my contact point be?*
* *What happens if I come of age during the trial?*

*In the next section, we will provided you with additional relevant information.*

 The Principal Investigator

1. **QUESTIONS AND ANSWERS: KEY INFORMATION**
* ***What is the aim of this clinical trial?***

*We are asking you to participate in a clinical trial funded by ................ because you have......*

Provide a clear, concise and phase-specific explanation of why the research is conducted.

E.g., *you suffer from..../you have a high risk of ................/the treatments to date available have many side effects/we want to verify if the investigational therapy could be more effective than those in use*

* ***What are the objectives of the trial? Who else will participate? How long will it last?***

*The trial is performed to answer this question* *“………………….“ (*insert a short question summarizing the primary objective of the trial in simple and understandable words):

For instance, *“Is it possible to reduce the probability of xxx cancer growth by adding a new drug to those currently used? We are carrying out this trial to understand if the new approach is better, equal or worse than the usual one. The usual approach is the one used in most patients with ......... (insert the patient's condition/disease)*

Or, *“the drug is already in use for other diseases and the trial we propose that you join aims to verify if it is also effective in your disease and to define the best dosage”.*

*The trial is expected to take place ....(*briefly indicate the number of countries and centers) *and xxx patients with your same condition will be included.*

*The trial is expected to last ....* (indicate)

* ***Is it my free choice to decide whether to participate or not?***

*In relation to your age, there are the prerequisites for a reasonable maturity allowing you to form your own opinion on the subject (discussing it with your parents, with trial staff or with whomever you deem appropriate) and to evaluate the information relating to the trial, to its risks and benefits. For this reason, your explicit desire will be taken into consideration to participate or to refuse participation in the trial or to withdraw from it at any time.*

*If you decide not to join the trial, you can still be followed by the clinical center that is treating you and you will be treated using the best approved (non-experimental) therapeutic methods for your disease.*

*In addition, you can participate in another trial that may be in progress.*

* ***What if at some point I want to withdraw from the trial?***

*You can decide to withdraw from the trial at any time and for any reason, without having to justify your decision.*

*Should you decide not to participate anymore, please inform one of the investigating doctors as soon as possible: it is important to suspend treatment safely. The doctor may consider a final check-up test/examination.*

*Your doctor will keep you informed of any changes in the trial that may affect your willingness to participate.*

*Please note that the investigating physician may decide to terminate your participation in the trial if:*

* *Your health conditions were to change and participation in the trial proved potentially harmful*
* *New information is available and the trial is no longer in your best interest*
* *You do not follow the agreed rules for participation in the trial: in particular, for girls, if you happen to get pregnant during the trial*
* ***What happens if I decide to participate in the trial? How long will it last?***

*Before taking part in the trial, your doctor will ask you to perform some tests and check if you have the characteristics required to join it. Only then will the trial begin, which will be followed by a follow-up period, i.e. verification of the results deriving from it.*

Indicate the period of time during which the patient will receive the treatment or the intervention or be followed up.

For example, *“If you decide to participate in the trial you will be treated with the investigational drug or the comparative treatment/placebo for a maximum of XX weeks/months. Once the treatment is complete, you will be followed for a maximum of XX weeks/months/years. The entire duration of your participation can be up to XX months/years.”*

*In addition to routine checks, you will undergo a series of tests aimed at evaluating the drug, according to the scheme summarizing the phases and times of the trial, which was given to your parents. In principle ...* (Describe in a simple way the tests and evaluations required by the trial)

E.g.,*“You will be required to undergo an examination X times a month as you usually do, with the addition of a check-up after X days from taking the investigational drug and the examinations will not last more than one day. Should you decide to participate in the trial, you will be provided with a schedule containing the tests and examinations to undergo, which will be booked directly by the center.*

*The evaluations of the drug effects will include:*

*• a general examination and record of the medications you are taking;*

*• blood samples - each time xxx ml;*

*• urine collection;*

*• questionnaires on quality of life, etc.;*

*• further examinations and procedures* (Specify). If the trial includes invasive maneuvers, please specify. Clarify if invasive maneuvers would be necessary even if the patient does not participate in the trial or if they are required by the type of trial. Also specify the procedures envisaged during the invasive maneuvers to avoid pain (local anesthesia, sedation, general anesthesia).

* ***Are there any rules to respect?***

*In order to provide useful information, a clinical trial must be conducted in strict compliance with the prescriptions you will be given by the investigating doctor. In particular, it will be essential ....*

report information on the participant's responsibilities, in particular:

* *Scrupulously observe the indications and requests from the health personnel following the trial and ensure attendance at appointments.*
* *Please inform the clinical trial doctor on:*

*o any medications you are taking including non-conventional medicine,*

*o any side effects that may arise during the trial,*

*o any exam or hospitalisation in facilities other than the trial center,*

*In all this you will be advised and supported by your parents.*

*Moreover, it will be mandatory to:*

* *For boys, avoid having a child during the trial.*
* *For girls, avoid pregnancy or breastfeeding during the trial.*

E.g., specify: *“We remind you that the treatment envisaged by the trial could harm a possible fetus. It is therefore envisaged that you first carry out a pregnancy test and subsequently undertake not to get pregnant. If you agree to participate in this trial, you must therefore use a safe method of contraception during the trial period and for ....... months after the last dose of the drug. You should evaluate with the doctor who proposed this trial the best contraceptive method for your case”.*

* ***What benefits can I expect?***

*Taking part in this trial may or may not improve your health. Doctors think that this experimental treatment is more useful against your disease than the treatments known to date, but at the moment there is not yet evidence of this.*

Describe the expected benefits (according to the type of trial) in a clear and concise way, by referring to: 1) benefits for the patient 2) benefits for other sufferers.

E.g.

Benefits for the patient: “*by joining the trial, you will have the opportunity to be treated with a drug that could be better than those currently marketed*";

Benefits for other sufferers: "*By joining the trial you will make a contribution to the development of new drugs for your disease. In the future you could benefit yourself as well as other people suffering from your disease"*.

Describe the benefits according to the trial stage.

E.g.

Phase I studies. *There is experimental laboratory evidence (in animals, cells etc.) that the treatment in question can (stabilize/improve/heal) your disease, but we do not know if this also occurs in humans. Furthermore, the possible side effects of the treatment are not known. This will help doctors to gain knowledge that is potentially useful for you and other patients in the future.*

Phase II studies. *Experimental laboratory evidence (in animals, cells etc.) has suggested that the new drug/treatment/intervention may prove useful in your disease. Furthermore, administration to a few healthy subjects or to patients with your disease has shown that it is free from serious side effects.* (If appropriate: *there is preliminary evidence that some of the patients who have taken the drug have benefited from it)*. *It is therefore possible, but not proven, that treatment will improve your disease. However, your participation in the trial will allow doctors to acquire useful knowledge to treat future patients.*

Phase III studies. *Clinical studies in patients with your disease have shown that this treatment is effective in controlling/improving/healing your disease. The trial we propose that you join aims to accurately measure the effects of the new treatment by comparing them with those of treatments already in use. To achieve this, you may be drawn to take the investigational treatment or the best non-investigational treatment currently available.*

**or (randomized trial with placebo)** *comparing them with the effects of a preparation not containing any active ingredient (placebo). It is therefore not certain that by accepting to participate in the trial you will receive the new treatment. However, please consider that if you are drawn to receive the placebo, your disease will continue to be treated with the best treatments currently available.*

* ***Will I take risks if I participate in the trial?***

*In a study like this, every adolescent can react differently after taking the investigational drug and could have side effects or ailments, even serious ones, that the trial doctor cannot predict at the moment. For this reason you will be carefully monitored.*

*Many of these reactions disappear immediately after stopping the therapies. In some cases, adverse reactions may instead become more serious, long-lasting, or never go away; they may require hospitalization and even (rarely) be fatal.*

*For this reason, if side effects occur during the study, you must immediately report them to your parents and to the investigating doctor, so they may decide to suspend the administration of the drug and give you any necessary treatment.*

*In addition, you and your parents will be notified promptly if information becomes available during the trial that could influence the decision to participate in the study.*

*With reference to this trial, ...* Describe all reasonably foreseeable risks, including those associated with the drug under trial, agent, and/or treatment, as well as the risks associated with tests intended as mandatory in the trial, such as biomarkers, tests, invasive procedures, and other tests. If appropriate, the risks shall include:

* Lack of efficacy of the investigational treatment (*“even if we believe that the new treatment can act on your disease better than those already available, we cannot exclude that it may be ineffective for you”)*
* Possible reduction or abolition of fertility: “*it is proven - it is possible - we cannot exclude that the treatment you will undergo makes future conception more difficult or even impossible. If you wish, we can discuss together the opportunity of collecting and freezing your eggs/sperm before starting the therapy".*
* Other possible negative impacts. If appropriate, inform the patient that the treatment could have a negative impact on school, work, social life: *it is proven - it is possible - we cannot exclude that the treatment you will undergo reduces attention/sex drive, etc.).*

*The investigational drug will also be associated with other products already marketed, which may cause* (brief description) .......................................................................

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Clarify what risks may change or be different than what would happen if the person did not participate in the trial.

* ***Who can I ask for further explanations? Who will my contact point be?***

*For any doubt and unforeseeable or unscheduled event during the trial (doubts relating to the treatment in progress, side effects, decision to abandon the trial, etc.), you or your parents (guardian) can contact:*

Indicate Names and references of the trial center staff that the participant can contact (Dr. [specify name], [specify telephone number, e-mail]).

Indicate who can be contacted on holidays and possible contacts on call

* ***What happens if I come of age during the trial?***

*As already indicated, if you aggree to participate in the trial you will be asked to sign a consent form, whereby you confirm that you have been sufficiently clarified every aspect of the trial, that you express your willingness to participate but that it has no legal value, unlike the consent given by your parents, who exercise the so-called parental authority. Should you come of age, you will become legally autonomous in your choices. Consequently, you will be submitted a new informed consent.*

1. **FURTHER INFORMATION**
2. **Trial Authorization**

*The trial protocol proposed to you has been examined and approved by the Ethics Committee ......................... Among other things, the Ethics Committee has verified the compliance of the trial with the standards of Good Clinical Practice and with the ethical principles expressed in the Declaration of Helsinki and that your safety, rights and well-being have been protected.*

1. **Processing of personal, health and clinical data**

*Your data, in particular personal and health data, will be processed only to the extent that they are indispensable to the objective of the trial and for pharmacovigilance purposes, in compliance with EU Regulation 2016/679, known as GDPR (General Data Protection Regulation) and with Legislative Decree 10 August 2018, no. 101, that is, the rules governing privacy. In practical terms, the documents concerning you will be kept in a safe place and will not report your name in clear text (only known to the researchers), but an identification code.*

*The data, made anonymous, may be subject to control by regulatory bodies and used for scientific publications (journals, conferences).*

*Your clinical data collected for the purposes of the trial, as well as the results of the tests carried out, will be stored for the time required by the regulations and subsequently destroyed. They will not be destroyed only if a) it is no longer possible to trace them back to your identity, because they have been anonymised during the trial itself; b) in the presence of your specific informed consent.*

*If the personal data are transferred to a third country or to an international organization, all the guarantees will be adopted which are provided for by Article 46 of the GDPR 679/2016.*

1. **Treatment of biological samples**

*For the purpose of experimentation, you may be asked for taking of biological samples such as blood or tissue samples.*

*As for health data, also biological samples will be used for the purposes of the trial in a pseudonymised way (technique allowing to change and mask personal and sensitive data of a natural person, in order not to make them directly and easily attributable to him/her).*

 *Once the trial is over, your samples will be destroyed. They will not be destroyed only if: a) it is no longer possible to trace them back to your identity, because they have been anonymised during the trial itself, or b) in the presence of your specific informed consent and agreement with the biobank for sample storage.*

1. **Access to the results of the trial?**

*Once the trial is over and all the resulting data have been collected, they will be analyzed to draw conclusions. The investigators undertake to make them available to the scientific community.*

*The law provides for the possibility that participants have access to the results of the trial. Therefore, you and your parents can ask the investigating physician to communicate the general results of the trial (or indicate where and how to access the trial results).*

1. **Unexpected results following analysis**

in the case of experiments involving analyses (genetic, X-ray, etc.), the patient must be informed that unexpected results could emerge. In the case of genetic analysis, for example, s/he must be informed that the it may highlight the predisposition to the future development of other diseases or his/her state of carrier of a genetic disease, which could lead to the generation of affected children, if the other parent also carries the same alteration. The patient must also be adequately informed about the practical consequences of these unexpected results (e.g., identification of predisposition to preventable /non-preventable diseases) and of his/her right "not to know". Please refer to what discussed in the attached guidelines about this topic in order to be able, when requested, to provide the patient with complete information about the possible limits to his/her "right not to know".

E.g., *Analyses (genetic, X-ray, etc.) performed during the trial may give unexpected results (e.g. relating to the possibility of developing other diseases in the future). This information will only be provided to you upon your indication. You may also choose to receive only information that may be useful for the care of your health and/or your potentially affected family members and/or to allow you to make an informed reproductive choice.*

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Full name of the doctor Date Time Signature

who delivered the note

**Additional documents:**

* Consent for use of biological data/samples for future studies
* Consent for genetic testing
* Consent for any sub-studies (additional studies that are not an integral part of the main study protocol)
1. **INFORMED CONSENT BY A MINOR AGED BETWEEN 12 AND 17 YEARS**

(Notes: 1 copy for the participant, 1 copy for the trial manager)

Title of the trial:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol code, version and date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Promoter of the trial/sponsor funding body: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator (Name, Affiliation, references): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I, the undersigned \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

born in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on \_\_\_/\_\_\_/\_\_\_\_\_\_

**DECLARE THAT**

▢ Dr \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has provided me/us with exhaustive explanations regarding the request for participation in the research in question, as reported in the information section contained in this consent, of which I was/we were given a copy on \_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*indicate date and time of delivery*);

▢ I have been clearly explained and I have understood the nature, the purposes, the procedures, the expected benefits, the possible risks and inconveniences and the alternative treatment methods with respect to the proposed clinical trial;

▢ I had the opportunity to ask any question to the trial investigator and I received satisfactory answers;

▢ I had sufficient time to reflect on the information received and to discuss it with my parents or with whomever I deemed appropriate;

▢ I have been informed that the trial protocol and all the forms used have received the favorable opinion by the competent Ethics Committee;

▢ I have been informed that I can decide not to take part in the study or to leave it at any time, without providing justification, and that such decisions will in no way change the relationship with the treating doctors and with the facility where I am being treated;

▢ I am aware that the research can be interrupted at any time, by decision of the trial manager;

▢ I have been informed that I will be made aware of any new data that could jeopardise the safety of the research and that, for any problem or further questions, I may contact the doctors where I am being treated;

▢ I have been informed that the results of the trial will be made known to the scientific community, protecting my identity according to the current legislation on privacy;

▢ I am aware that any choice expressed in this consent form may be revoked at any time and without any justification;

▢ I have received a copy of this consent form.

 **I HEREBY DECLARE THAT**

 ▢ I am willing to participate in the trial

 ▢I am willing ▢ NOT willing to be informed of all unexpected news relating to my present or future health that may accidentally emerge from the investigations envisaged by the trial, including genetic ones

 ▢I am willing ▢ NOT willing to be informed of all unexpected news relating to my present or future health only if it can be useful for my health care or to allow me to make informed reproductive choices

 ▢ I am willing ▢ NOT willing to be contacted after the end of the trial to provide information on my state of health (this only applies to contacts that the study protocol does not envisage as follow-up)

*If applicable:*

 ▢ I ACCEPT ▢ I DO NOT ACCEPT to use contraceptive drugs

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_/\_\_\_/\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Place and date Time

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Full name of the minor patient Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Full name of the legal representative Signature

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Full name of the doctor who provided Signature

information and who obtained the consent

**STATEMENT OF THE DOCTOR WHO OBTAINED THE CONSENT BY A MINOR AGED BETWEEN 12 AND 17 YEARS**

(Name of the minor patient, place and date of birth)

Title of the trial:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol code, version and date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Promoter/sponsor of the trial\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator (Name, Affiliation, references): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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I, the undersigned Prof./Dr. ………………………………… ……………………..… in my capacity as Principal investigator

 Surname Name

(or as delegate of the Principal investigator)

Hereby declare that

the minor mature patient has voluntarily consented to his/her participation in the trial

I also declare, compatibly with his/her age, that:

 ▢ I have provided the minor patient with full explanations relating to the purpose of the trial, the procedures, the possible risks and benefits and to possible alternatives;

 ▢ I have verified that the minor patient sufficiently understood the information provided

 ▢ I have given the minor patient the necessary time and the opportunity to ask questions about the trial

 ▢ I have clearly described the possibility of withdrawing from the trial at any time or of changing the choices made

 ▢ I have not exerted any coercion or undue influence in requesting this consent

 ▢ I have provided the patient with information on how the results of the trial will be disclosed to him/her

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_

Place and date Time

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name Surname (block letters) of the doctor who provided the Signature (and stamp)

Information and who obtained the consent

This form is an integral part and must be kept together

with the information sheet for informed consent