**INFORMATION SHEET AND INFORMED CONSENT FORM FOR THE PARTICIPATION OF PATIENTS IN A CLINICAL TRIAL**

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| --- |
| **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. INFORMATION SECTION. SUMMARY OF THE TRIAL: KEY INFORMATION
3. INFORMATION SECTION. FURTHER INFORMATION
4. INFORMED CONSENT SECTION

ATTACHMENTS

ADDITIONAL DOCUMENTS

*Dear Sir/Madam, the information contained in the following information sheet is very detailed. We kindly ask you to accept to participate in the trial ONLY after having carefully read this information sheet and having had a FULL INTERVIEW with a member of the clinical trial group who shall dedicate the NECESSARY TIME to fully understand what is proposed to you.*

1. **INTRODUCTION**

*Dear Sir/Madam,*

*We propose that you participate in the clinical trial outlined below.*

*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.*

*This document aims to inform you about the nature and purposes of the trial, and about what your participation will entail for you, including your rights and responsibilities.*

*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 Principal Investigator

1. **INFORMATION SECTION.**

**SUMMARY OF THE TRIAL: KEY INFORMATION** *(****no more than 1-2 pages****)*

*This section aims to briefly present the key aspects of the trial which we propose that you join. The following sections will provide more details in order to give you the opportunity to express or not a fully informed consent to your participation in the trial.*

***- Why am I being asked to participate in this trial?***

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

*You are being asked to participate in this trial because you show some clinical characteristics that will be better specified in section C.*

***- What are the aims of the trial? How many centers and patients will participate?***

*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”.*

Indicate the secondary objective/s (if applicable)

*The trial is expected to take place in approximately xxx centers in xxx countries and xxx patients will be included.*

***- What is the routine care approach for treating the disease*** (indicate the disease)***?***

IF APPROPRIATE (CONTROLLED STUDIES) Describe clearly and briefly the standard care approach that the experimental treatment/approach will be compared to.

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

*You can freely choose whether or not to participate in the trial. Even after accepting, you can change your mind at any time.*

***- If I decide not to give my consent to participate in the trial, what choices do I have?***

*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 happens if I decide to participate in the trial?***

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 his/her participation can be up to XX months/years.”*

*Before taking part in the trial, your doctor asked you to perform some tests and checked if you have the characteristics required to join it. During the trial, invasive procedures (e.g. biopsies, bone marrow sampling, etc.) are planned, which are better detailed below.*

*The entire program of tests and examinations provided for during the trial is reported in the next section "What examinations, tests and procedures are provided for in the trial?"*

***- What are the risks and benefits if I participate in the trial?***

*Participation in this trial may result in both risks and benefits. It is important to evaluate them carefully before making a decision.*

***Expected benefits***

Describe the expected benefits (according to the type of trial) in a clear and concise way, by referring to: 1) benefits for the patient who will participate in the trial; 2) benefits for future patients and for the acquisition of more knowledge.

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 patients: "*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 patients with 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) his/her 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.*

***Potential risks***

*We want to make sure that you immediately understand some possible risks: additional information can be found in the next section* “What risks can I face if I participate in this trial”?

Describe the risks in general terms.

E.g.*, Should you decide to take part in this trial, there is a risk that the investigational drug/treatment is less effective than the usual drug/treatment. There is also a risk that more severe adverse reactions may occur with the investigational treatment than with the usual treatment.*

*You will be closely monitored for each of these reactions. However, not all adverse reactions that can occur are known.*

*(*where applicable due to the type of trial*) 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.*

*Important adverse reactions known for the investigational treatment are: .............................................*

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

***- Is the consent final? Can I decide to withdraw from the clinical trial (voluntary exit)?***

*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.*

***- Are there any reasons why the trial could be stopped not by my will (early termination)?***

*Yes, 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*
* *For women: you get pregnant during the trial*
* *The trial is stopped by the competent authorities or by the promoter.*

In any case, please clarify the need/opportunity to continue the scheduled follow-up exams in the event of withdrawal of consent, suspension of trial, pregnancy or otherwise.

1. **INFORMATION SECTION.****FURTHER INFORMATION**
2. **What is the purpose of the trial?(no more than ½ page)**

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

E.g. Phase I drug trial. *“The purpose of this trial is to study the safety of (\*insert drug name\*) when administered in different doses. By “dose" it is meant the amount of drug that will be administered to you, (\*enter the prescribed dosage in \_\_mg or \_\_mL\*) About (\*insert number\*) people will participate in the trial”.*

1. **What are the patient groups compared? What is the intervention being tested?**  (no more than 1 page if no framework is provided, otherwise 1 page + 1 page for the framework)

* Provide a clear, concise and phase-specific description of the study groups
* provide a description of the inclusion/exclusion criteria
* Clearly identify the intervention under study. Enter the name and type of the drug/product/intervention under study and the administration route, dosage, treatment form (frequency, duration of the infusion ...).
* clearly identify which treatment is to be considered investigational and which is already used in clinical practice
* clearly explain whether the experimental treatment will or not be available to the patient at the end of the trial. *“If you have completed the trial and benefited from the new treatment, you will have the option of receiving additional administrations even if the drug/device is not available on the market in your country. If further investigations with that particular product are abandoned due to your illness, your family doctor will re-assess your treatment options."* This is a very important issue for the patient, so highlight it appropriately.
* For studies with multiple groups, indicate the expected number of participants for each group.
* For randomized studies, indicate the probability of being allocated to one or another group. If randomization is not in a 1:1 ratio, briefly describe the allocation.
* Describe the type of trial in terms of randomization and control(e.g., *“you will be drawn to receive the new drug or the most effective drug currently marketed. You will have a xxx% probability of receiving the investigational drug“).* If placebo randomization is provided, please specify that currently no effective drug exists for the patient's disease and explain that placebo is a preparation not containing the active ingredient. If blind treatment is provided, explain what it consists of and provide information that this is the best methodology to verify the real effectiveness of a treatment.

***Clinical trial design***

The use is strongly recommended of a schematic graphic representation of the trial. If exhaustive, this can replace all or part of the written text. The scheme must not be a duplication of the trial protocol, but should provide the most relevant information to potential participants, using a simple and easily understandable language.

1. **What examinations, tests and procedures are provided for if I participate in the trial? (section no longer than ¾ page, unless many tests/procedures are provided for)**

In this section it is important to highlight to potential participants what will change in the care provided if they decide to participate in the trial.

* Indicate the frequency and duration of each examination, enter short and simple description of the types of examinations provided for by the trial protocol.
* Do not list examinations, tests or procedures under the usual care approach.
* Please focus on examinations, tests and procedures intended as mandatory for the main trial.
* Indicate if specific examinations, tests or procedures will be performed only in some of the patient groups.

Make sure that what described in this section is coherent with what reported in the trial protocol and in other sections of the consent form.

*For each single invasive examination or intervention provided for in the trial, a specific consent shall be required.*

In order to facilitate patients’ participation, it is recommended adding a calendar, attached to the consent form.

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 examinations to undergo, which will be booked directly by the center.*

*The evaluations of the drug effects will include:*

*• a general examination (with measurement of blood pressure and heart rate, etc.) and record of the medications s/he is 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).

Also make clear any examinations and procedures provided for by the study protocol in the follow-up phase.

1. **What risks can I face if I participate in the trial?** (section no longer than 4 pages)

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, etc. 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 risks to the fetus in case of pregnancy. If applicable, report that the investigational drug taken by either partner could harm the product of an eventual conception. If necessary, specify that a pregnancy test will be carried out before taking the drug and participants able to conceive will be required, subsequently and for the entire duration of drug intake, to adopt effective contraceptive methods.
* 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 (decrease in attention, reduced sex drive, etc.).

Frequency categories of risks.

Report the frequency, when known, expressing it in percentage or using the terminology proposed by the EU [: Very common (≥1/10), Common (≥1/100 to <1/10), Not common (≥1/1000 to <1/100), Rare (≥1/10000 to <1/1000), Very rare (<1/10000)].

1. **How will I be notified of any unexpected results following diagnostic tests?**

if the trials provide for analyses (genetic, X-ray, etc.), the patient must be informed that unexpected results may come out. 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.*

1. **Is it useful/necessary to inform my family doctor?**

It is important that the family doctor be informed of participation in the trial (e.g., allowed and not allowed concomitant drugs/therapies, surveillance of possible side effects): explain the reasons to potential participants.

E.g., “*If you decide to participate in the trial, it is important to inform your general practitioner. To this end, we have prepared (or will give you) a letter that you can deliver to him/her, which explains the trial procedures".*

1. **What will my commitment be and what are my responsibilities if I decide to participate? (section no longer than ½ page)**

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 hospitalization in facilities other than the trial center,*

*o current or previous participation in other clinical trials.*

*•* (If appropriate) *record on a diary each time the investigational drug is taken at home.*

*•* (For women, if appropriate): *avoid pregnancy or breastfeeding during the trial.*

*•* (For men, if appropriate): *avoid having children during the trial.*

*•* (For anyone, if appropriate)*: promptly inform the doctor if you or your partner think about pregnancy during the trial or within (insert the period in months/years) after the last dose of the investigational drug (indicate).*

E.g., for a female patient: *“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”.*

1. **Will I have to bear costs for participating in the trial? Will I be reimbursed for any expenses? Will I receive a compensation?**

Clarify that participation in the trial does not involve expenses and the person will not be rewarded in any way (the law explicitly prohibits it); if travel/accommodation reimbursement are provided for, they shall be duly specified.

*You will not bear costs for participation in the trial as these are fully covered by the trial center (or by the sponsor, if any).*

*Moreover, no financial compensation is envisaged for participation in the trial.*

(if applicable) *The clinical trial provides for reimbursement of the costs incurred to allow you to take part in the trial (e.g., travel expenses, accommodation also for an accompanying person, etc.). In this case, specific agreements must be made with the investigating doctor or with a person acting on his/her behalf.*

1. **What happens if I suffer damage as a result of participating in the trial?**

*Participation in a clinical trial may involve drawbacks and risks that cannot be determined a priori. For this reason, the clinical trial provides insurance coverage to protect your participation.*

*Pursuant to applicable law, insurance is provided to cover any damage suffered due to participation in the trial, for the entire period of the same, to cover the civil liability of the investigator and the promoter.*

Indicate the insurance company, the policy number, the limit of liability per participant, the aggregate limit of liability *Please find the details in attachment*

*It is worth noting that, according to the Ministerial Decree of 14 July 2009, the insurance policy does not cover the value exceeding the ceiling and is effective exclusively for damages whose compensation request has been submitted no later than the period provided for in the policy (*indicate the number of months*). However, this limitation does not affect your right to obtain compensation from the person liable for any damage* (to protect the trial participant).

1. **Who will have access to my health data, including personal data, and how will they be treated during the trial?**

*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. In practical terms, the documents relating to the participant will be kept in a safe place and will not report his/her 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.*

*Further information is included in the attached data processing authorization form.*

1. **How will my biological samples taken for trial purposes be treated and who will have access to them?**

*As for your health data, also your 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. **How will I have 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 and the promoter 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 can ask the investigating physician to communicate the general results of the trial (or indicate where and how to access the trial results).*

1. **Was the trial approved by the Ethics Committee?**

*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. **Who can I refer to for more information on the clinical trial I am invited to participate in?**

Indicate the names and references of the persons who can be contacted for further information.

1. **If I join the trial, who can I contact in case of need?**

*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 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

*Shoud you deem it appropriate to report events or facts relating to the trial you have joined to subjects not directly involved in the trial itself, you can refer to the Ethics Committee that approved the trial (INDICATE), to the Health Department of the Trial Center (INDICATE), to the competent authority (AIFA).*

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Full name of the doctor Date Time Signature

who delivered the note

**Attachments**

* Insurance policy
* Consent form for processing of personal data

**Additional documents:**

* Letter to family doctor/pediatrician
* Consent for use of biological data/samples for future studies (if not entered directly in the text of the information note and in the main consent form)
* 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 SECTION**

(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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

**DECLARE THAT**

▢ Dr \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ provided me 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 given a copy on \_\_\_\_\_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*indicate date and time of delivery*);

▢ I was 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

▢ I had sufficient time to discuss it with third parties;

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

▢ 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;

▢ for the best protection of my health I am aware of the importance (and of my responsibility) of informing the general practitioner of the trial in which I agree to participate. I am aware of the importance of providing the investigator with all information (drugs, side effects, etc.) concerning me;

▢ 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, if this may entail possible benefits

▢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

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Full name of the adult patient Date Time Signature

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

Full name of the legal representative Date Time Signature

**STATEMENT OF THE DOCTOR WHO OBTAINED THE CONSENT**

(Patient name, place and date of birth)

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

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

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

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

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

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

Surname Name

(or as delegate of the Principal investigator)

Hereby declare that

the Patient has voluntarily consented to his/her participation in the trial

I also declare that:

▢ I have provided the 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 Patient sufficiently understood the information provided

▢ I have given the 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

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Place and date Time

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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