**Guidance for users of the Template Subject Information**

*Also referred to as SIS: Subject Information Sheet*

**Model for any type of study**

This template information sheet can be used for any type of study. The template was designed for both interventional and observational research. All sections of the information sheet also apply to observational research although the latter often requires less text (see guidance for each individual section).

*Examples of interventions*: medicinal product (authorised/not authorised), medical device, nutritional product, physiotherapy, medical procedure/surgical technique, behavioural therapy, psychosocial intervention.

**Purpose of the Subject information sheet**

Participation in medical research requires informed consent from the study subject. Part of this process of obtaining informed consent is making the information available in the written form. Verbal information and discussion as well as question-and-answer sessions are also part of the process. The purpose of the process and the written information is to give potential subjects sufficient information to enable them to make an informed decision on whether or not to participate in the study. The purpose of the Information Sheet is not to hedge against possible claims against the sponsor or to include as many subjects into the study.

**Guidance on typography**: from the next page the template should be completed for any specific study as follows:

1. Use ordinary text as standard and amend only if incorrect for the study concerned;
2. Replace [description/options] with the actual information OR select the most suitable term for the nature of the study
3. Use text marked with EXAMPLE PASSAGE as and when desired. Please note: this text often does not cover the content of the *entire* section.
4. Example text in table format: copy/move the desired text and then delete the table.
5. Ensure that *all* aspects in each comment are covered per section (in as far as applicable)
6. Finally, delete: - this page (guidance for users)

 - top line of the header

 - the comments

 - text between <*guidance*> and subsequent text

 - unused example passages

 - texts for special situations that do not apply

**Section numbers:** Any topics in the template that are not applicable can be deleted (please remember to change the section numbers).

**Subject information versus Ministry General Medical Research Brochure**
The patient information refers to the Ministry General Medical Researchbrochure for further explanation of or elaboration on some concepts. Key concepts, such as voluntary participation, withdrawal, data handling and insurance should all be covered in the information sheet (see this template).

**Point of view, length and language level**

Point of view, length and language level should be consistent with the objective of the PIS: write from the point of view of the study subject (not the investigator). Make sure that the information sheet is concise and easy to read. This may require specialist input from e.g. a professional editor, instructor or communication specialist. Ask a lay person preferably educated to no more than basic secondary education level to proofread your text.

The subject information sheet must **not be longer than 4000-5000 words**. This word count does not include the consent form(s) and the following appendices: contact details, insurance text, schematic overview of study procedures and, for example, more information about side effects or mechanism of action of the product or treatment under investigation. **The appendices, like the rest of the PIS, should be concise and easy to read.**

The language level of the information sheet should be no higher than **basic secondary education level**.The standard and example passages in this template meet this requirement (tested by Readability Foundation [Stichting Makkelijk Lezen]). Exceptions include a target audience very different from the ordinary Dutch population (e.g. children under 12 or students in further education).

*This template was supported by and developed in collaboration with 'Vereniging Innovatieve Geneesmiddelen, NFU, STZ, V&VN Research Professionals, ACRON, de Hart&Vaatgroep, Insurance Alliance, NVMETC and the Ministry of Health, Welfare and Sport. Please use the feedback form on the DCRF website to report any inconsistencies or give other feedback. The general brochure on medical research can be found on the CCMO website or you can order one free of charge from the government, call 1400 or visit* [*www.rijksoverheid.nl*](http://www.rijksoverheid.nl/documenten-en-publicaties/publicaties-pb51?keyword=&form-period-from=&form-period-to=&form-department=&form-information-type=publicaties-pb51)*.*

**Subject information for participation
in a medical-scientific study**

**[Study title]**

*Official title:*

**Introduction**

Dear Sir/Madam,

<Always> You are being asked to take part in a medical-scientific study.

Participation is voluntary. In order to participate your written consent is required. <*if you were approached due to illness or surgery or recent diagnosis of disease*> You are receiving this letter because you have [disorder]/ have been diagnosed with [disease profile] / you will soon be undergoing [intervention].
*<if relevant indicate here how you came across the person’s data – this text instead of comment 5*>

<Always>Before you decide whether you want to take part in this study, you will be given an explanation about what the study involves. Please take your time to read this information and ask the investigator if you have any questions. You can also ask the independent expert mentioned at the end of this letter for additional information. You can also discuss it with your partner, friends or family.

Further information about participating in such a study is found in the enclosed brochure ‘Medical scientific research’.

1. **General information**

|  |  |
| --- | --- |
| **Situation** | **Example paragraph** |
| Investigator-initiated- mono-centre | This study is being conducted by [name of institution] |
| Investigator-initiated- multi-centre | This study was designed by [name of institution] and is being conducted by [doctors/therapists/investigators] in various [hospitals/general practitioners offices/…] |
| - Company is the sponsor | This study was designed by [name of company] and is being conducted by [doctors/ …] in various [hospitals/general practitioners offices/…]. [name of company] will cover the costs of this study. |

*<if a commercial party pays (part of) the study, you must mention that in section>*

EXAMPLE PARAGRAPH For this study, [X subjects] from various countries are required. In the Netherlands, [X subjects] are expected to participate. END OF EXAMPLE PARAGRAPH

The Medical Ethics Review Committee [X] has approved this study. General information about the assessment of research can be found in the brochure ‘Medical scientific research’.

1. **Purpose of the study**

<*description of purpose: select an example from the table, or describe it yourself*>

|  |  |
| --- | --- |
| **Situation** | **Example text** |
| **Intervention drug research** |
|  | Safety/Phase-I | The purpose of this study is to find out how safe the new drug [X] is, when it is given to [healthy subjects/patients with [disorder]].<*if it is administered for the first time to human subjects, add*>[X] has not previously been used in humans. It has however been tested in the laboratory and also on animals. |
|  | Dose-ranging | The purpose of this study is to find out how safe (and effective <*if applicable*>) the new drug [X] is. [X] is tested in different strengths in [healthy subjects/patients with [disorder]]. |
|  | Efficacy and safety - With placebo - With comparator | The purpose of this study is to find out how safe and effective the new drug [X] is for the treatment of [disorder]. [X] may not yet be prescribed by [doctors] (outside of the study).We compare the effects of [drug] with the effects of a placebo. A placebo is a substance without active substance, a ‘fake drug’.ORWe compare the effect and safety of [drug] with the effect and safety of [comparator]. [comparator] is already being used for the treatment of [disorder]. |
| **Intervention with a product other than a drug (for example, nutritional supplement/ingredient, medical device, etc.)** |
|  | Medical device | See examples above for drug research studies, but also:- The purpose of this study is to find out how trustworthy [the] new [MD] is/how often [it] displays the correct value. - The purpose of this study is to find out whether subjects are able to use [the] new [MD] correctly.- The purpose of this study is to find out whether the [doctor/other practitioner] can work correctly with [the] new [MD].*<if it is not yet CE marked, add>* [X] may not yet be used by [doctors] outside of study. |
|  | Effectiveness nutritional ingredient/product | The purpose of this study is to find out whether the daily [eating/using] of [product/ingredient] can reduce [the cholesterol/the blood pressure/sensation of hunger/…] in [healthy subjects/overweight people /slightly elevated …]. |
| **Other type of study (examples)** |
|  | Surgical procedure | - There are two different techniques for [surgery]. In this study we compare these two techniques./The purpose of the study is to find out with which technique [subjects recover quickest/are able to go home/have the least pain/…]- With [disorder] we sometimes perform surgery and sometimes give [physical therapy/…]. The purpose of this study is to find out what treatment gives the best results after […six months…].  |
|  | Physical therapy | In this study, two different physical therapy treatments are compared with each other. |
|  | Behavioural therapy | Find out if treatment [x] [reduces/minimizes/increases/…] [anxiety disorder]. |
|  | Brain function (in children) | In this study, we compare the brain function in children with and without behavioural problems. |
|  | Lung problems/function/stress test (in children) | The purpose of this study is to compare the endurance of [children with and without asthma]. |
|  |  | (for example, after RS-virus infection)The purpose of this study is to find out what the effect of the infection is on the lung function, one year later. We also look whether there are differences between children who were and were not ventilated during the infection. |
|  | Malaria parasites | In this study we infect subjects using an anti-malaria drug with malaria. The purpose is to find out whether this approach can protect people against malaria. |
|  | Measurement methods | The purpose of this study is to find out whether the [x-test] can also be used to measure the effects of stimulating drugs. |
|  |  | The purpose of this study is to find out if a blood test renders the same information as a food provocation test. [explain test in section 4, for example: With a food provocation test, you will receive the food that causes symptoms in you. You get more and more of the food while we keep a close eye on you.] |
|  |  | During exertion, the adrenal glands secrete the hormone cortisol. This can be measured in saliva. The purpose of the study is to find out whether the amount of cortisol after an exercise test is elevated in the saliva. |
|  |  | The purpose of this study is to find out whether two MRI scans give the same results in one person. |
|  | Infections | The purpose of this study is to compare the immune systems response to an infection/contamination with Q fever, with the response to immunisation against Q fever. |

1. **Background of the study**

<*background description*>

1. **What participation involves**

If you participate, your participation will last a total of approximately [X weeks/months].

**[Screening]**

EXAMPLE PARAGRAPH

First we determine whether you can participate. The investigator [performs a physical examination/performs an electrocardiogram (ECG)/measures your weight, height, blood pressure and heart rate/performs a blood test]. The investigator will also ask about your [medical history/ethnicity/…]. *<and, if applicable:>*You will also be tested for [hiv/hepatitis B/…]. If you have one of these diseases, we will inform you. If you do not want to know this, you cannot participate in this study.

END OF EXAMPLE PARAGRAPH

EXAMPLE PARAGRAPH (if applicable) Sometimes we find something during [the examination/the screening] that requires further medical investigation. We will always tell you. Further investigation is carried out by the primary care physician or specialist. The cost of this will be borne by your own insurance. <*in healthy subjects*: >It may also occur that you are healthy, but not eligible to participate. END OF ADDITIONAL EXAMPLE PARAGRAPH

**[Treatment/surgery/use products/…]**

EXAMPLE PARAGRAPH We will treat you [x weeks] with study drugs/you will use [product] for [x weeks]. One [half] of the subjects will receive [treatment], the [other half] [treatment]. Randomisation will determine which [treatment] you receive. <*as blinded study*> Neither you, nor the investigator will know which group you are in. If it is important for your health, it may be revealed.
General information about this can be found in the brochure ‘Medical scientific research’.

END OF EXAMPLE PARAGRAPH

**Visits and tests**

EXAMPLE PARAGRAPH For the study, you have to visit [the investigator/study site/hospital/…] [X] times in [X weeks/months]. A visit will take [X minutes/hours/X to approximately X hours].

The following will then take place:

* We will perform a physical examination - at two visits
* We will perform an electrocardiogram (ECG) - at one visit
* We will collect blood - at every visit, two tubes at a time + for (do not state all analysis, but for example: This is to see if […] is absorbed well in your blood/We measure […]/to check for [side effects/…]).
* We will have you complete a questionnaire about […] - at each visit

Appendix C states which [treatments/measurements] take place at each of these visits.

OR In total, you will be called [X] times at home. You will be asked questions about […]. A phone call will take approximately […]. OR a questionnaire will be sent to you [X] times. The questions will be about […]. It will take you approximately [X minutes] to complete. END OF EXAMPLE PARAGRAPH

EXAMPLE PARAGRAPH

**Other than standard care**

Normally you may visit your doctor once every two months to monitor your [disorder]. Your doctor [then collects 1 tube of blood/examines your … /performs …]. The visits that are involved in this study, replace the regular visits to your doctor/are additional. END OF EXAMPLE PARAGRAPH

1. **What will be expected of you**

For the study to run smoothly [<*if applicable*> and for your own safety], it is important that you follow the following agreements.

 The agreements are that you:<*delete that which is not applicable and possibly supplement, if necessary, see explanation in the comment*>:

* [take the investigational product/perform the exercises] as explained.
* do no participate in another medical-scientific study.
* follow appointments for visits.
* carry the participant’s study card with you at all times. It explains that you are taking part in this study. It also states who should be warned in the event of an emergency. Please show this card when you see a[nother] doctor.

It is important that you contact the investigator: <*delete that which is not applicable*>

* before you use another medicine. Even if these are homeopathic medicines, natural medicines, vitamins and/or over the counter medicines.
* if you are hospitalised or treated in a hospital.
* if you suddenly experience health symptoms.
* if you no longer wish to participate in the study.
* if your contact details change.

EXAMPLE PARAGRAPH **Pregnancy**<*Include if applicable - possibly split into text for women and text for men:*>

**Your or your partner’s pregnancy**

Women who are pregnant or breastfeeding, may not take part in this study. Women may also not get pregnant during the study. For men, their partner must not become pregnant during the study. Inform your partner about this.

This study may have consequences for an unborn child. [*if known, state which*] OR It is not known what these consequences are. It is important that you tell this to your partner. The investigator will speak to you about a suitable birth control method.

What if you do become pregnant during the study? Inform the investigator of this right away. If your partner does become pregnant during the study, ask her to consent to inform the investigator of this. The pregnancy can then be monitored more closely [and reported to the sponsor of this study]. Consent will be requested separately for the additional checks (and for requesting information about the progress and outcome of the pregnancy from other practitioners). END OF EXAMPLE PARAGRAPH

1. **Possible [side effects/complications and other/adverse effects/discomforts]**

[the study drug/the procedure/therapy to be investigated] may have [side effects/adverse effects].

EXAMPLE PARAGRAPH *<if hazardous/urgent side effects can be expected*>

You should immediately contact the investigator if you experience:

-

-

-

END OF EXAMPLE PARAGRAPH

These [adverse effects/discomforts/side effects] are common (occurs in 1 in 10 people or more):

* + …
	+ …

*< if there is advice with a side effect, list this directly below the side effect, for example: it may help to… >*

These [adverse effects/discomforts/side effects] occur, but not often:

* + …
	+ …

*< if there is advice with a side effect, list this directly below the side effect, for example: it may help to… >*

[the study drug/the procedure/therapy to investigate] may also cause [adverse effects/side effects] that are unknown.

*<if it is a registered product, add>* Learn more about [drug] in the package leaflet, see Appendix [X] OR Are you participating in the study? Then you will receive the package leaflet with the drug.

<*optional, if many side effects must be described, or many explanations are necessary or possibly with very rare side effects*>

….you can read more about this in Appendix [X]

**[Comparator]**<*if applicable*>

[Comparator] can also cause side effects. The most important ones are:

<*list most important/most likely side effects >*More information about the [comparator] can be found in the package leaflet, see Appendix [X]OR Are you participating in the study? Then you will receive the package leaflet with the drug

**Tests**

<*Describe possible adverse effects and discomforts of invasive procedures to be applied in the study – also think about, for example, radiation burden* >

EXAMPLE PARAGRAPH Blood collections may cause pain or bruising.

*<if quite a lot of blood is collected, add:>* In total, we will collect [XX mL] blood from you. This amount should not cause any problems in [adults]. In comparison: at the blood bank, 500 mL of blood is collected at one time.
END OF EXAMPLE PARAGRAPH

EXAMPLE PARAGRAPH

**Radiation burden**

With a [indicate test CT, PET, ..] we use [X-ray radiation and/or radioactive substances]. The total radiation burden in this study is [XX] mSv. In comparison: the background radiation in the Netherlands is ~2.5 mSv, per year.

If you often participate in scientific research with a radiation burden, you should discuss with the investigator whether participation at this time is sensible.

The radiation used during the study may cause damage to your health. This risk, however, is small. We nevertheless advise you not to participate in another scientific study with a radiation burden in the near future. There is no objection to research or treatment with radiation for medical reasons. END OF EXAMPLE PARAGRAPH

1. **Possible advantages and disadvantages**

<Always>It is important that you properly consider the possible advantages and disadvantages before you decide to participate.

|  |  |
| --- | --- |
| **Situation** | **Example text (advantage)** |
| No advantage healthy subject | You will not personally receive any advantage from taking part in this study. Your participation may contribute to more knowledge about [the treatment of [disease/disorder]/the effect of/…].  |
| No patient advantage | If you participate in this study it does not mean [your disease will be cured/you will experience less hinder from your disease/…]. You will, however, contribute to more knowledge about [the treatment of [disease/disorder]/the effect of/…]. |
| Possible advantage for the patient | [the study drug/study product/the study device/the therapy/..] may lead to [list concrete advantageous effect, such as a decrease in blood pressure/abdominal discomfort/etcetera], but this is not certain.*<Possibly supplement with:>*Your [disease/your symptoms] may return or get worse at any time during this study. |

Disadvantages of participation in the study may be <*delete that which is not applicable*>

* + possible [side effects/complications of [the intervention]];
	+ possible [adverse effects/discomforts] of the measurements in the study.

Participation in the study also means: <*as far as applicable*>

* + that you lose additional time;
	+ an additional or an extended hospitalisation;
	+ (additional) testing;
	+ that you have appointments that you have to attend;

All of these things are described below under point 4, 5 and 6.

1. **If you do not want to participate, or would like to stop participating in the study**

You decide for yourself whether you want to participate in the study. Participation is voluntary.

<*if it involves a study in patients, also add:*>If you do not want to take part, you will be treated as usual for your [disease/disorder]. <*if there is a clear standard of care, state this here, otherwise*: > The investigator can tell you more about the treatment options that exist and the advantages and disadvantages of each.

If you do participate, you can always change your mind and stop, even during the study. *<*if it involves a study in patients, also add:>You will be treated as usual for your [disease/disorder]. You do not have to state why you are stopping. However, you should immediately inform the investigator.

The data obtained thus far will be used for the study.

*<OR, if applicable>* If you like, the bodily material that was collected can be destroyed.

If there is any new information about the study that is important for you, the investigator will inform you of this. You will then be asked if you wish to continue your participation.

1. **End of the study**

Your participation in the study ends when

* all visits [according to the schedule/such as described under point 4] have been completed
* you personally choose to stop
* you become pregnant <*if applicable*>

< *and if applicable*:>

* the end of the study has been reached <*if applicable, so if the study continues until the outcome has been reached, explain this here, for example, as many cases of X* >
* the investigator finds that it is better for you to stop
* [name sponsor], the government or the assessing Medical Ethics Review Committee, decide to stop the study.

The entire study ends when all participants are finished.

<*if participants are patients and the study involves drugs:*>The drugs you used during the study, [will/will not] be available at the end of the study. The investigator will talk to you about the options for further medical care.

After processing all the data, the investigator will inform you about the most important outcomes of the study. <*if known and it can be generally indicated*> This will happen about [term] after your participation.

The investigator will also tell you [which treatment you had/in which group you were, <*if applicable*> ]. If you do not want this, you can tell the investigator. He may then not tell you.

1. **Use and storage of your data [and body material]**

For this study, your personal data *<if applicable>* and body material will be collected, used and stored. It involves information such as your name, address, date of birth and data about your health. <*if* > applicable For this study [type of body material] is required. The collection, use and storage of your data <*> if applicable* and your body material is required in order to answer the questions asked in this study and to be able to publish the results. <*> if applicable* It is also necessary to introduce the investigated drug into the market. We ask your consent for the use of your data *<if applicable>* and body material.

**Confidentiality of your data** *<if applicable>* **and body material**

To protect your privacy, your data <*if applicable*> and your body material will receive a code. Your name and other information that could directly identify you are therefore omitted. This information can only identify you with the key. The key to the code will be stored securely in the local research facility. The data <*> if applicable* and body material that is sent to the sponsor [and any other parties involved] only contain a code, but not your name or other data that can identify you. In reports or publications about the study, the data will also not be identifiable.

**Access to your data for review**

Some individuals may have full access to your data at the study site. Also to the data without a code. This is needed in order to check whether the study is performed properly and reliably. Individuals who have access to your data for review are <*full list, select that which is applicable*>: the committee monitoring the safety of the study, a controller/monitor that works for the [investigator/sponsor of the study] OR hired by the [investigator/sponsor of the study], national and international regulatory authorities, for example, the Health Care Inspectorate and Youth and […others…]. They will keep your data confidential. We ask your consent for this access.

**Retention period of data** *<if applicable>* **and body material**

Your data must be stored for [….] years at the study site <*if applicable*> and [....] years at the sponsor.

<*if applicable*> Your body material will be destroyed immediately after use. <*if applicable*> Your body material will not be destroyed immediately after use. It is stored in order to perform new assessments in the course of this study, related to this study.

*<if applicable*> **Storage and use of data <***if applicable***> and body material for other studies**

Your data <*if applicable*> and body material may still be of interest after the end of this study for other clinical research in the area of [your disorder and/or for the further development of the product/treatment method]. For this your data <*if applicable*> and body material will be stored for [….] years. You can indicate on the consent form if you do or do not agree with this. If you do not consent to this, you can still participate in the current study.

<*if applicable*> **Information about incidental findings**

During this study, there may be incidental findings that are not relevant for the study, but are for you. If this is important for your health, you will be notified [by the general practitioner, specialist, others]. You can then discuss with your general practitioner or specialist what needs to be done. You will also consent to this.

**Withdrawal of consent**

You can always withdraw your consent for the use of your personal data. This applies to this study and <if applicable> also for the storage and use for the future research. The study data that has been collected until the time you withdraw your consent will still be used in the study. <if applicable> Your body material will be destroyed after withdrawal of your consent. If measurements have already been taken with that body material, then that data will still be used.

*<if applicable*> **Transfer to countries outside the European Union (EU)**

In this study your coded data *<if applicable>* and body material will also be sent to countries outside the EU. [please indicate why this is required, i.e client is located outside the EU, institutions are located outside the EU]. In those countries, the rules of the EU to protect your personal data, do not apply. Your privacy will, however, be protected in an equivalent manner.

**More information about your rights concerning the processing of data**

For general information about your rights concerning the processing of your personal data, please consult the website of the Dutch Data Protection Authority.

If you have any questions about your rights, please contact the person responsible for the processing of your personal data. For this study it is:

*<with investigator initiated study*> [Name of institution] Refer to Appendix A for contact information, *<if applicable>* and website.

*<with sponsor-initiated study*> [Name of sponsor and institution]Refer to Appendix A for contact information, *<if applicable>* and website.

*<if applicable>* Because the sponsor is located outside the EU, [Name of representative] has been assigned to act as representative. For contact details, refer to Appendix A.

If you have any questions or complaints regarding the processing of your personal information, we recommend that you contact the study site. You can also contact the Data Protection Officer for the institution [refer to contact details in Appendix A] or the Dutch Data Protection Authority.

**Registration of the study**

Information about this study is also included in a summary of medical research i.e. (state website). No data that can be traced back to you is included. After the study, the website may contain a summary of the results of this study. You can find this study under [study indication].

1. **Insurance for subjects**

|  |  |
| --- | --- |
| **Situation** | **Standard text** |
| Insurance taken out | Insurance has been taken out for everyone who participates in this study. The insurance covers damage resulting from the study. Not all damage is covered. In **Appendix B** you can find more information about the insurance and the exceptions. It also states who you should report damages to. |
| The sponsor is a government agency without insurance obligation | [name of sponsor] covers damage due to the study. Not all damage is covered. In **Appendix B,** you can find more information about the insurance and the exceptions. It also states who you should report damages to. |
| When comparing two standard treatments and obtained exemption from an insurance obligation | If you participate in the study, you are at the same risk as with the usual treatment for your [disease/disorder]. The [sponsor/investigator], therefore, is not required by the [regulatory committee ] to take out additional insurance. |
| With no risk and acquired exemption of the insurance obligation | If you take part in the study, you will not incur any additional risks. The [sponsor/investigator], therefore, is not required by the [regulatory committee ] to take out additional insurance. |

1. **Informing [general practitioner and/or treating specialist and/or pharmacist]**

We will always send your [general practitioner and/or treating specialist and/or pharmacist] a [letter/e-mail] to let them know that you are taking part in the study. This is for your own safety. If you do not agree to this, you cannot participate in this study. <*If applicable – ad hoc-situations*> [situation] we may contact your [ (GP) doctor], for example about [your medical history or your medication use].

<*If applicable,*>You cannot take part in the study if you do not have a general practitioner.

<Other information exchange, if applicable>

1. **[No] Compensation for participation**

EXAMPLE PASSAGE

The [study medication, additional testing and treatment] for the study costs[s] you nothing. You will not be paid for participation in this study. However, you will be reimbursed for your (additional) travel expenses. OR You will receive an expense allowance (including travel related costs) of € [xx/xx per visit]. This is indicated to the Dutch tax administration as income, <*if applicable>*. If you stop before the study ends, you will receive a lower reimbursement.

END OF EXAMPLE PARAGRAPH

1. **Do you have any questions?**

If you have any questions, please contact [the investigator/investigational team]. If you would like independent advice about participation in this study, please get in touch with the independent [doctor/…/expert/person]. [He/she] knows a lot about the study, but has nothing to do with this study.

If you have any complaints about the study, you can discuss this with the investigator or your regular doctor. If you would rather not do that, you can contact the [complaints’ officer/complaints committee at your hospital/institution/others]. All data can be found in **Appendix A**: Contact information.

1. **Signing of informed consent form**

EXAMPLE PARAGRAPH

When you have had a sufficient reflection period, you will be asked to decide about participation in this study. If you consent, you will be asked to confirm this on the corresponding consent form, in writing. With your written consent, you indicate that you have understood the information and agree to participate in the study.

Both you and the investigator will receive a signed version of this consent form.

END OF EXAMPLE PARAGRAPH

Thank you for your attention.

**Text for special situations**

|  |  |  |
| --- | --- | --- |
| **Situation** | **Insertion location** | **Example paragraph** |
| Participation of children and/or legally incapable subjects | After point 7, as separate section(adjust numbering of follow-up sections) | **Resistance of [your child/the person you are representing]** It may be that [your child/the person you are representing] resists during the study (does not cooperate). The investigator must then immediately stop the study. It is difficult to precisely describe what resistance is. Before the study is started, you will be consulted about what is seen as resistance. The investigator will comply with the Code of Conduct resistance [minor/mentally impaired/geriatric patients]. |
| Studies in healthy subjects | End of introduction | <In the event of a VIP-check>:You may participate in a (medicinal)drug study up to four times a year. Only one study at a time. We check this in a central system to which other research institutions are also connected. This system stores secure data about participation in studies. |
| Research in emergency situations |  |  |
|  |  |  |
| Study falling under 21 CFR (Code of Federal Regulations Title 21)/for which FDA (Food and Drug Administration) requirements should be followed | Proposal: under section 10, as the last item, instead of the text it currently holds about register | <Compulsory text:> A description of this clinical study can be found on <http://www.ClinicalTrials.gov>, as required by U.S. law. This website will not include information that is traceable to you as an individual. The website can, however, show a summary of the outcomes. You have access to this website. <*Please complete with:*> You can find this study under [study indication]. |

1. **Appendices with this information**

A. Contact details <*per participating site*>

B. Information about the insurance <*compulsory, unless a waiver has been obtained*>

C. Schedule of study treatments/description of study activities <*if available*>

[D and further]. <*other, for example more information on the effect of an intervention, or other possible treatment options, or information about side effects*>

[X]. Consent form(s) <*select correct model(s)*>

[X] Brochure “Medical Scientific Research General information for the subject” (version [number and/or date]) <*required, to be given separately*>

[X]. <other, for example an existing brochure on a measurement to be taken/invasive surgery (with version indication)> <*to be given separately*>

**Appendix A: contact details for [name of participating site]**

[Investigator]: [for principal investigator of site: name, contact details and availability]

< if applicable>

[Study nurse/study doctor]: [for a possible 2nd point of contact: name, contact details and availability]

Independent [doctor/expert]: [insert name, type of doctor/expert, contact details and availability]

Complaints: [department or person with contact details and availability]

Data Protection Office of the institution:

For more information about your rights: [Contact information [including website] of the person(s) responsible for the processing of personal data]:

<*if applicable, to be supplemented with, for example, coordinating investigator and/or an emergency number/24 hour availability*>

**Appendix B: information about the insurance**

The [sponsor/other] has taken out insurance for everyone participating in this study. The insurance covers damage resulting from participation in the study. This applies to damage incurred during the study or within four years after the end of your participation in the study. You must have reported damage to the insurer within these four years.

The insurance does not cover all damage. The bottom of this text explains briefly what damage is not covered.

These provisions are in the Medical Research Involving Human Subjects Act. This decree is on [www.ccmo.nl](http://www.ccmo.nl), the website of the Central Committee on Research Involving Human Subjects (see ‘Library’ and then ‘Laws and regulations’).

In case of damage, you can contact the insurance company [or claims representative] directly.

*<here also indicate how the subject must act with/report damage: via telephone/mail/post, other instructions?>*

The insurer of the study is:

Name:

Address:

Telephone number:

E-mail

(Policy number: …)

(Contact: …)

<*only include if there is a claims representative – this is mandatory if the insurer is located outside of the Netherlands*>

The claims representative of the study is:

Name:

Address:

Email:

Telephone number:

The insurance offers a coverage of <copy the amount of the policy, this must be at least € 650,000> per subject and <copy the amount of the policy, this must be at least € 5,000,000> for the entire study (and <copy the amount of the policy, this must be at least € 7,500,000> per year for all the studies of the same sponsor).

The insurance will **not** cover the following damage:

* damage due to a risk about which you were informed in the written information. This does not apply if the risk is more serious than anticipated or if the risk was very unlikely;
* damage to your health that would also have occurred if you had not taken part in the study;
* damage due to not (completely) following directions or instructions;
* damage to your offspring, due to a negative effect of the study on you or your offspring;
* damage due to an existing treatment method when studying existing treatment methods.

**Appendix [X] – Overview of measurements** *<optional*>

**Appendix [Y] – Side effects/risks** <*optional*>

**Appendix [Z]: consent form subject**

[Short title of the study as listed on page 1 of the information letter]

<*required:*>

* I have read the information letter. I was also able to ask questions. My questions have been answered sufficiently. I have had enough time to decide whether or not to participate.
* I understand that participation is voluntary. I also know that I may decide at any time to not participate or to stop participating in the study. Without having to provide any reason.
* I give consent for my [general practitioner/specialist(s) treating me/pharmacist/...] to be informed of my participation in this study <*if applicable*: > and to inform about […]
* <*If applicable*>: I give consent to information being requested from my [general practitioner/specialist(s) treating me/..] about […].
* I give consent to collect and use my [data/blood samples/body material] for answering the research question in this study <*if applicable*> and for registration of the study drug.
* I know that for study monitoring purposes some individuals could have access to all my data. Those people are listed in this information letter. I consent to that access by these persons.

<*insofar as applicable:*>

* I give consent for my general practitioner and/or treating specialist to be informed of unexpected findings which are (may be) of interest for my health.
* I know that I [may not become pregnant/impregnate my partner] [during the study and up to xx after xx].
* The investigator has discussed the most suitable contraceptives for [me and/or my partner] with me.
* I □ **give**

□ **do not give**
consent for the further storage of my personal data and retention for future research into the area of [my disorder and/or the method of treatment].

* I □ **give**

□ **do not give**
consent for my body material to be stored after this study and for later use of this for [other/more] study, such as stated in the information letter.

* I □ **give**

□ **do not give**consent to being contacted again after this study for a follow-up study.

* I □ **would like**

□ **would not** **like**
to be informed about the treatment I have had/in which group I was.

<*required*:>

* I want to participate in this study.

Name of subject: ……………………………………………………………………………..

Signature: Date : \_\_ / \_\_ / \_\_

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I certify that I have fully informed this subject about the said study.

If information becomes known during the study that could influence the consent of the subject, I will inform him/her of this on time.

Name of investigator (or his/her representative):…………………………………………

Signature: Date: \_\_ / \_\_ / \_\_

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<*if applicable*>

Additional information was provided by:

Name:…………………………………………………………………………

Function:……………………………………………………………………..

Signature: Date: \_\_ / \_\_ / \_\_

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\* Delete that which is not applicable.

*The subject will receive a complete information letter, together with a signed version of the informed consent form.*

**Appendix [Z]: Informed Consent Form parents or guardian**

[Short title of the study as listed on page 1 of the information letter]

I have been asked to consent to the participation of the following person/my child in this medical research study:

Name of subject (child): ……………………………………. Date of birth: \_\_ / \_\_ / \_\_

<*required*>

* I have read the information letter for parents/caregivers. I was also able to ask questions. My questions have been answered sufficiently. I have had enough time to decide whether I want my child to participate in the study.
* I understand that participation is voluntary. I also know that I can decide at any time that my child would rather not participate. Without having to provide any reason.
* I give consent for my [general practitioner/specialist(s) treating my child/pharmacist/...] to be informed of my child's participation in this study <*if applicable*:> and to being informed about […]
* <*If applicable*>: I give consent to request information from the [general practitioner/specialist(s) treating my child/..] about […].
* I give consent to collect and use my child's [data/blood samples/body material] for answering the research question in this study <*if applicable*> and for registration of the study drug.
* I know that for study monitoring purposes some individuals could have access to all the data for this person. Those people are listed in this information letter. I consent to that access by these persons.

<*insofar as applicable:*>

* I consent to my general practitioner and/or treating specialist being informed of unexpected findings which are (may be) of interest for my child's health.
* I know that my child [may not become pregnant/impregnate his partner] during the study [and up to xx after xx]. The investigator has discussed the most suitable contraceptives for [my child and/or his/her partner] with me.
* I □ **give**

□ **do not** **give**
consent for the further storage of my child's personal data and retention for future research into the field of [my [*sic:* my child’s] disorder and/or the method of treatment].

* I □ **give**

□ **do not give**
consent for my child's body material to be stored after this study and to the later use of this for [other/more] study, such as in the information letter.

* I □ **give**

□ **do not give**consent for my child to be contacted again after this study for a follow-up study.

* I □ **would like**

□ **would not like**
to be informed about the treatment that my child had/in which group my child was.

<*required*:>

* I agree that this person/my child participates in this study.

Name of parent/guardian\*\*:……………………………………………………..

Signature: Date: \_\_ / \_\_ / \_\_

Name of parent/guardian\*\*:……………………………………………………..

Signature: Date: \_\_ / \_\_ / \_\_

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I hereby certify that I have informed the above person/persons fully about the said study.

If information becomes known during the study that could influence the consent of the parent or guardian, I will inform him/her of this on time.

Name of investigator (or his/her representative): …………………………………….

Signature: Date: \_\_ / \_\_ / \_\_

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<*if applicable*>

Additional information was provided by: ……………………………………………….

Name:

Function:

Signature Date: \_\_ / \_\_ / \_\_

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\* Delete that which is not applicable.

\*\* If the child is under the age of 16 years, the parents who have custody or the guardian signs this form. Children aged 12 at 15 years who are able to make decisions independently (legally capable), must also sign a form <according to model A>.

*The parent/guardian will receive a complete information letter, together with a signed version of the informed consent form.*

**Appendix [Z]: Informed Consent Form representative**

[Short title of the study as listed on page 1 of the information letter]

I have been asked to consent to the participation of the following person in this medical research study:

Name of subject: ………………………………………. Date of birth: \_\_ / \_\_ / \_\_

<*required*>

* I have read the information letter for the [subject/representative]. I was also able to ask questions. My questions have been answered sufficiently. I have had enough time to decide whether I want this person to participate in the study.
* I understand that participation is voluntary. I also know that I can decide at any time that this person would rather not participate. Without having to provide any reason.
* I give consent to inform the [general practitioner/specialist(s) treating the person concerned/pharmacist/...] that this person is participating in this study <*if applicable*:> and to being informed about […]
* <*If applicable*>: I give consent to requesting information from the [general practitioner/specialist(s) treating the person concerned/..] about […].
* I give consent to collecting and using the [data/blood samples/body material] of this person to answer the research question in this study <*if applicable*> and for registration of the study drug.
* I know that for study monitoring purposes some individuals could have access to all the data for this person. These individuals are listed in this information letter. I give consent to that access by these individuals.

 <*insofar as applicable:*>

* I give consent for informing this person’s general practitioner and/or treating specialist of unexpected findings which are (may be) of interest for this person health.
* I know that this person [may not become pregnant/impregnate his partner] [during the study and up to xx after xx]. The investigator has discussed the most suitable contraceptives for [this person and/or his/her partner] with me.
* I □ **give**

□ **do not give**
consent to the further storage of this person’s personal data and retention for future research into the field of [my [*sic:* this person’s] disorder and/or the investigated method of treatment].

* I □ **give**

□ **do not give**
consent for this person’s body material to be stored after this study and to the later use of this for [other/more] study, such as in the information letter.

* I □ **give**

□ **do not give**consent for this person to be contacted again after this study for a follow-up study.

* I □ **would like**

□ **would not like**
to be informed about the treatment that this person had/in which group this person was.

<*required*:>

* I agree that this person participates in this study.

Name of legal representative:……………………………………….

Relationship to the subject:…………….. ………………………………………..

Signature: Date: \_\_ / \_\_ / \_\_

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I hereby certify that I have informed the above person/persons fully about the said study.

If information becomes known during the study that could influence the consent of the legal representative, I will inform him/her of this on time.

Name of investigator (or his/her representative):……………………………………….

Signature: Date: \_\_ / \_\_ / \_\_

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<*If applicable*>

Additional information was provided by (if applicable):

Name:…………………………………………………………………………

Function:………………………………………………………………………

Signature: Date: \_\_ / \_\_ / \_\_

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\* Delete that which is not applicable.

*The representative will receive a complete information letter, along with a signed version of the informed consent form.*