**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 medical scientific research**

**[Title of the study]**

*Official title:*

**Introduction**

Dear Sir/Madam,

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

Participation is voluntary. Participation requires your written consent. <*if the patient was invited because of a specific disease or procedure or recent diagnosis*>You have received this letter because you have [disorder]/have been diagnosed with [syndrome]/you will shortly undergo [procedure].
*<if relevant this section should state how the personal details of the potential study subject were obtained - this text can replace comment 5*>

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

Additional information about participating in a study can be found in the enclosed general brochure on medical research.

1. **General information**

|  |  |
| --- | --- |
| **Situation** | **Example passage** |
| Investigator-initiated- single centre | This study is being carried out by [name of institution] |
| Investigator-initiated- multi-centre | This study has been designed by [name of institution] and is being carried out by [doctors/therapists/investigators] at various [hospitals/GP surgeries/...] |
| - Industry-initiated | This study has been designed by [name of company] and is being carried out by [doctors/...] at various [hospitals/GP surgeries/...]. [name of company] is paying for the costs of this study. |

*<If the study is sponsored (in part) by a commercial party, this must be stated in this section>*

EXAMPLE PASSAGE For this study [X study subjects] from different countries are required. [X study subjects] are expected to participate in the Netherlands. END OF EXAMPLE PASSAGE

[Medical Research](http://www.ccmo.nl/en/accredited-mrecs?51d2da84-cef8-490b-907c-4846525ed690) Ethics Committee [X] has approved this study. General information about the assessment of research can be found in the general brochure on medical research.

1. **Purpose of the study**

<*describe the purpose: select an example from the table or write your own description>*

|  |  |
| --- | --- |
| **Situation** | **Example text** |
| **Interventional medicinal product study** |
|  | Safety/Phase I | The purpose of this study is to investigate how safe the new medicine [X] is when it is administered to [healthy subjects/patients with [disorder]].<*if this is the first time it has ever been given to humans, add*>[X] has not been administered to humans before. It has been previously tested in the laboratory and on animals. |
|  | Dose-ranging | The purpose of this study is to investigate how safe (and effective <*if applicable*>) the new medicine [X] is. [X] will be tested at various strengths in [healthy subjects/patients with [disorder]]. |
|  | Efficacy and safety  - Placebo-controlled  - Comparative | The purpose of this study is to investigate how safe and effective the new medicine [X] is for the treatment of [disorder]. Doctors cannot prescribe [X] yet (outside a study).The efficacy of [medicine] will be compared to the efficacy of a placebo. A placebo is a medicine without any active ingredient. It is a ‘fake’ medicine.ORThe efficacy and safety of [medicine] will be compared to the efficacy and safety of [comparator]. [comparator] is already being used in the treatment of [disorder]. |
| **Intervention with a product other than a medicinal product (e.g. nutritional product/ingredient, medical device, etc.)** |
|  | Medical device | See examples for medicinal product studies above, but also:- The purpose of this study is to investigate how reliable [the] new [MD] is/how often [the device] gives the correct value. - The purpose of this study is to investigate how easy it is for subjects to use [the] new [MD].- The purpose of this study is to investigate whether the [doctor/other healthcare professional] can easily work with the new [MD].*<if the MD does not have the CE marking yet, then add>*Doctors cannot use [X] outside a clinical study yet. |
|  | Efficacy of nutritional ingredient/product | The purpose of this study is to investigate whether [eating/using] [product/ingredient] on a daily basis can help reduce [cholesterol/blood pressure/appetite/...] in [healthy subjects/overweight people/mildly elevated ...]. |
| **Other types of studies (examples)** |
|  | Surgical procedure | - There are two different techniques for [procedure]. This study compares these two techniques. The purpose of this study is to investigate which technique will help subjects [recover/go home most quickly/have the least amount of pain/...]- [Disorder] is sometimes treated with surgery and sometimes with [physiotherapy/...]. The purpose of this study is to investigate which treatment gives the best results at [...six months...].  |
|  | Physiotherapy | In this study two different physiotherapy treatments are compared. |
|  | Behavioural therapy | Investigating whether [x] [improves/reduces/worsens/ …] [anxiety disorder]. |
|  | Brain function (in children) | This study compares brain activity of children with and without behavioural problems. |
|  | Lung problems/function/stress test (in children) | The purpose of this study is to compare the exercise capacity of [children with and without asthma]. |
|  |  | (e.g. after RS virus infection).The purpose of this study is to investigate what the effect of the infection is on lung function after one year. We will also investigate whether there are any differences between children who were ventilated during the infection and those who were not. |
|  | Malaria parasites | This study involves infecting subjects who are using an antimalarial medicine with malaria. The purpose of the study is to investigate whether this approach protects people against malaria. |
|  | Diagnostic tests | The purpose of this study is to investigate whether the [x test] can also be used to evaluate the effects of stimulants in children. |
|  |  | The purpose of this study is to investigate whether a blood test gives the same information as a food challenge test. [explain the test in section 4, e.g.: A food challenge test involves giving you the type of food you are having problems with. You will be given more and more of the food over time while we closely monitor you.] |
|  |  | Your adrenal glands produce a hormone called cortisol when you exercise. This can be measured in saliva. The purpose of this study is to investigate whether cortisol levels in saliva are increased after an exercise test. |
|  |  | The purpose of this study is to investigate whether performing an MRI in the same person twice gives the same results. |
|  | Infections | The purpose of this study is to compare the immune response to a Q-fever infection to that to a Q-fever vaccination. |

1. **Background of the study**

<*Description of the background*>

**4. What participation involves**

Your participation will last about [X weeks/months].

**Screening**

EXAMPLE PASSAGE

We will first evaluate whether you may participate. The investigator will do a [physical examination/make a heart tracing (ECG)/measure your weight, height, blood pressure and heartbeat/will do a blood test]. The investigator will also ask you about your [medical history/ethnic origin/…]. *<and if applicable:>*You will also be tested for [HIV/hepatitis B/…]. If you have any of these diseases, we will tell you. If you do not want to know, you cannot participate in this study.

END OF EXAMPLE PASSAGE

EXAMPLE PASSAGE (if applicable) The screening sometimes reveals findings that require further medical examination. We will always tell you about these findings. Further medical examination will be done by your own GP or specialist. The costs of this will be charged to your own insurance. <for healthy subjects:>You may also be healthy but may still not be eligible for participation. END OF EXAMPLE PASSAGE

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

EXAMPLE PASSAGE We will treat you with study medicines for [x weeks]/You need to use [product] for [x weeks]. [Half] of the subjects will receive [treatment], and the [other half] [treatment]. It will be determined by drawing lots which [treatment] you will receive. <*for double-blind studies*> Neither you nor the investigator will know which group you are in. This can be found out if important for your health.
General information about this can be found in the general brochure on medical research.

END OF EXAMPLE PASSAGE

**Visits and tests**

EXAMPLE PASSAGE This study requires that you will visit the [investigator/study centre/hospital/…] [X] times over a period of [X weeks/months]. A visit will take [X minutes/hours/X to about X hours].

The following will take place:

* We will do a physical examination - at two visits
* We will make a heart tracing (ECG) - at one visit
* We will draw blood - at each visit, two tubes each time + what it is for (do not list all analyses, but, for example. This is to see how well […] is absorbed in your blood/We will measure […]/to check for [side effects/…]).
* We will ask you to complete a questionnaire about […] - at each visit

Appendix C describes what [procedures/tests] will take place during each visit.

OR You will be telephoned at home [X] times. You will then be asked about […]. A telephone call will take [...]. OR You will be sent a questionnaire [X] times. The questions are about […]. Completing the questionnaire will take you about [X minutes]. END OF EXAMPLE PASSAGE

EXAMPLE PASSAGE

**Other than standard care**

Usually you may perhaps only visit your doctor for follow-up for [disorder] once every two months. Your doctor [will then take 1 tube of blood/will examine your … /will make …]. The study-related visits will replace these regular visits to your doctor/are additional. END OF EXAMPLE PASSAGE

1. **What is expected of you**

In order to carry out the study properly [<*if applicable*> and for your own safety], it is important that you follow the study instructions.

 The study instructions require that you: <*delete or supplement as appropriate, see guidance in the comment*>:

* [take the study product/do the exercises] as directed.
* do not participate in another medical study.
* keep appointments for visits.
* carry your participant card for the study with you. This card states that you are participating in this study. It also states whom to contact in the event of an emergency. Show this card if you visit any [other] doctor.

It is important that you contact the investigator: <*delete as appropriate*>

* before you start using other medicines. Even if they are homeopathic or natural remedies, vitamins and/or over-the-counter medicines.
* if you are admitted to hospital or are going for treatment there.
* if you suddenly develop any health problems.
* if you no longer want to participate in the study.
* if your contact details change.

EXAMPLE PASSAGE **Pregnancy***<Include as appropriate - split into text for women and text for men if appropriate*>

**Your or your partner’s pregnancy**

Women who are pregnant or breast-feeding cannot participate in this study. Women must not become pregnant during the study. Men should keep in mind that their partner must not become pregnant during the study. Inform your partner about this.

It is because this study may have consequences for an unborn child. [*if known, state which consequences*] OR The consequences are not known. It is important for you to tell your partner about it. The investigator will talk to you about the most suitable contraceptives.

If you still become pregnant during the study, you should immediately tell the investigator. If your partner becomes pregnant during the course of the study, please ask her for permission to inform the investigator. The pregnancy can then be monitored more closely [and reported to the sponsor of this study]. Separate consent will be asked for monitoring of the pregnancy (and for collecting of information from other health providers on the clinical course and the outcome of pregnancy). END OF EXAMPLE PASSAGE

1. **Possible [side effects/complications (and other)/undesirable effects/discomforts]**

[the study medicine/the procedure under investigation/therapy] may cause [side effects/undesirable effects].

EXAMPLE PASSAGE <*if there are any hazardous/urgent side effects*>

You should immediately contact the investigator if you develop:

-

-

-

END OF EXAMPLE PASSAGE

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

* + …
	+ …

*<if there is any particular advice for any of the side effects, state this immediately under the side effect, e.g.: it may help to…>*

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

* + …
	+ …

*<if there is any particular advice for any of the side effects, state this immediately under the side effect, e.g.: it may help to…>*

[the study medicine/the procedure under investigation/therapy] may also have [adverse effects/side effects] that are still unknown.

<*if this concerns an authorised product*> More information about [medicine] can be found in the package leaflet, see appendix [X]OR Are you participating in the study? You will then receive the package leaflet with the medicine.

<*optional, if there are many side effects, or if this requires a significant amount of explanation or possibly with very rare side effects*>

…..You can find more information in Appendix [X]

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

The [comparator] may also cause side effects. The most important ones are:

<*list the 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? You will then receive the package leaflet with the medicine.

**Tests**

<*Describe the possible adverse effects and discomforts of the invasive procedures that will be performed as part of the study - also remember exposure to radiation, for example>*

EXAMPLE PASSAGE Drawing blood may be painful or cause some bruising.

*<if a rather large amount of blood is being taken:>* In total, we will take [XX ml] of blood from you. This amount does not cause any problems in [adults]. To compare: a blood donation involves 500 ml of blood being taken each time.
END OF EXAMPLE PASSAGE

EXAMPLE PASSAGE **Exposure to radiation**

[Select test: CT scan, PET, ...] involves using [X-rays and/or radioactive markers]. The total amount of radiation you will be exposed to in this study is [XX] mSv. To compare: the background radiation in the Netherlands is ~2.5 mSv per year.

If you participate in scientific research involving exposure to radiation more often, you should discuss with the investigator whether participation at this moment would be safe.

The radiation used during the study may lead to damage to your health. However, this risk is small. We nevertheless advise you not to participate in another scientific study involving exposure to radiation in the near future. Examinations or procedures involving radiation for medical reasons are not a problem. END OF EXAMPLE PASSAGE

1. **Possible advantages and disadvantages**

<Always>It is important that you properly weigh up the possible benefits and disadvantages before you decide to join.

|  |  |
| --- | --- |
| **Situation** | **Example text (benefit)** |
| No benefit to healthy subject | You will not personally benefit from participation in this study. Your participation may contribute to increased knowledge about [the treatment of [disease/disorder]/the activity of/...].  |
| No benefit to patient | If you participate in this study, it will not mean that [your disease will be cured/you will suffer less from your disease/...]. But you will contribute to increased knowledge about [the treatment of [disease/disorder]/the activity of/...]. |
| Possible benefit to patient | [the study medication/study product/the study device/the therapy/...] may [state actual positive effect, such as lower your blood pressure/relieve abdominal pain/etc.], but this is not certain.*<Optional addition:*>[Your disease/symptoms] may return or worsen at any time during this study. |

Disadvantages of participation in the study may be <*delete as appropriate*>

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

Participation in the study also means: <as applicable> ..

* + additional time;
	+ additional or longer hospital stays;
	+ additional tests;
	+ instructions you need to follow;

All these aspects have been described above under points 4, 5 and 6.

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

It is up to you to decide whether or not to participate in the study. Participation is voluntary.

<*if this is a study in patients, also add:*>If you do not want to participate, you will be treated as usual for your [disease/disorder]. <*if there is a clear standard, state it here, otherwise*:> The investigator can tell you more about the various treatment options that exist and the benefits and risks associated with them.

If you do participate in the study, you can always change your mind and decide to stop, at any time during the study. [*if this is a study in patients, also add:*] You will then be treated as usual for your [disease/disorder]. You do not have to say why you are stopping, but you do need to tell the investigator immediately.

The data collected until that time will still be used for the study.

*<OR, if applicable>* If you want, any bodily material collected can be destroyed.

If there is any new information about the study that is important for you, the investigator will let you know. You will then be asked whether you still want to continue your participation.

1. **End of the study**

Your participation in the study stops when

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

<*and if applicable:*>

* the end of the entire study has been reached <*if applicable; if the study continues until an endpoint has been reached, this should be explained here, for example, a specific number of cases of X>*
* the investigator considers it best for you to stop
* [name of company], the government or Medical Research Ethics Committee, decides to stop the study.

The study is concluded once all the participants have completed the study.

<*if the participants are patients and this concerns a medicinal product study:*>The medication you have used during the study [will/will not] be available once the study has ended. The investigator will discuss the options for further medical care with you.

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

The investigator will also tell you [which treatment you had/which group you were in, <*if applicable*>]. If you do not want this to happen, please tell the investigator. He/she will then not be permitted to tell you.

1. **Usage and storage of your data [and bodily material]**

Your personal data *<if applicable>* and bodily material will be collected, used and stored for this study. This concerns data such as your name, address, date of birth and data about your health. <if applicable> [characterization of bodily material] is required for this study. The collection, use and storage of your data <*if applicable)>* and your bodily material is required to answer the questions asked in this study and to publish the results. <*if applicable)>* It is also required to put the investigated product on the market. We ask your permission for the use of your data *<if applicable>* and bodily material.

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

To protect your privacy, your data <*if applicable)*> and your bodily material will be given a code. Your name and other information that can directly identify you, will be omitted. Data can only be traced back to you with the encryption key. The encryption key remains safely stored in the local research institute. The data <*if applicable)>* and bodily material that is sent to the sponsor [and any other interested parties] will only contain the code, not your name or other data with which you can be identified. The data cannot be traced back to you in reports and publications about the study.

**Access to your data for verification**

Some people can access all your data at the research location. Including the data without a code. This is necessary to check whether the study is being conducted in a good and reliable manner. Persons who have access to your data for review are <*provide complete list, select what applies*>: the committee that monitors the safety of the study, a controller / monitor working for the [investigator / sponsor of the study] OR which has been hired by the [investigator / sponsor of the study], national and international supervisory authorities, for example, the Healthcare and Youth Inspectorate and […other…]. They will keep your data confidential. We ask you to consent to this access.

**Retention period of your data** *<if applicable>* **and bodily material**

Your data must be kept for [….] years at the research location <*if applicable)*> and [....] years at the sponsor.

<*if applicable)*> Your bodily material will be destroyed immediately after use. <*if applicable)*> Your bodily material will not be destroyed immediately after use. It will be kept in order to be able to perform new assessments in connection with this study, in the course of this study.

*<*if applicable)> **Storage and use of data <***if applicable)***> and bodily material for other research**

Your data <if applicable)> and bodily material may also be of importance for other scientific research in the field of [your condition and / or the further development of the product / treatment method]. To this end, your data <*if applicable)*> and bodily material will be stored for [….] years. You can indicate on the consent form whether or not you agree with this. If you do not agree with this, you can still participate in the current study.

<if applicable)> **Information about unexpected findings**

During this study, something may be found by chance that is not important to the study, but may be important to you. If this is important for your health, you will be informed [by the GP, specialist, other]. You can then discuss with your doctor or specialist what needs to be done. You also consent to this.

**Withdrawing consent**

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

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

In this study, your encoded data *<if applicable>* and bodily material will also be sent to countries outside the EU. [indicate why this is necessary, e.g. sponsor is located outside the EU, facility institutions are located outside the EU]. In those countries, the EU rules on the protection of your personal data do not apply. However, your privacy will be protected at an equal level.

**More information about your rights when processing data**

For general information about your rights when processing your personal data, you can consult the website of the Dutch Data Protection Authority.

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

*<for investigator initiated study*> [Name of institution] See Appendix A for contact details, *<if applicable>* and website.

*<for sponsor initiated study>* [Name of sponsor and name of institution] See Appendix A for contact details *<if applicable>* and website.

*<if applicable>* Because the sponsor is based outside the EU, [Name of representative] has been appointed to act as its representative. See contact details in Appendix A.

If you have questions or complaints about the processing of your personal data, we advise you to first contact the research location. You can also contact the Data Protection Officer of the institution [refer to contact details in Appendix A] or the Dutch Data Protection Authority.

**Registration of the study**

Information about this study is included in a list of medical-scientific studies namely (website). It does not contain any information that can be traced to you. After the study, the website may display a summary of the results of this study. You can find this study under [study indication].

1. **Study subject insurance**

|  |  |
| --- | --- |
| **Situation** | **Standard text** |
| Insurance in place | Insurance has been taken out for everyone participating in this study. This insurance covers damage caused by the study. The insurance does not cover all damages. **Appendix B** contains more information about the insurance and the exclusions. It also tells you who to report damage to. |
| Sponsor is a government body exempt from duty to insure | [name of sponsor] covers damage caused by the study. The insurance does not cover all damages. **Appendix B** contains more information about the cover and the exclusions. It also tells you who to report damage to. |
| Exempt from duty to insure due to comparison of 2 standard treatments | If you participate in the study, the risks will be no different from those of your usual treatment for your [disease/disorder]. The [reviewing committee] has therefore decided that the [sponsor/investigator] does not need to take out additional insurance. |
| Exempt from duty to insure due to no risks | This study is not associated with any risks for you. The [reviewing committee] has therefore decided that the [sponsor/investigator] does not need to take out additional insurance.  |

1. **Will my [GP and/or treating specialist and/or pharmacist] be informed if I participate?**

We will always send your [GP and/or treating specialist and/or pharmacist] a [letter/email] to let them know that you are participating 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*>In the event of [situation], we may contact your [GP/other doctor], for example about [your medical history or about the medicines you use].

<*If applicable*>You cannot participate in the study if you do not have a GP.

<Other sharing of information, if applicable>

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

EXAMPLE PASSAGE

The [study medication, additional tests and treatment] for the study [is/are] free of charge for you. You will not be paid for your participation in this study. You will be reimbursed for your travel costs. OR You will receive an expense allowance (including travel costs) of € [xx/xx per visit] for your participation in this study. This reimbursement should be communicated to the Tax Authorities as income <if applicable>. If you stop before the study is over, you will receive a smaller amount.

END OF EXAMPLE PASSAGE

1. **Any questions?**

If you have any questions, please contact [the investigator/the study team]. If you would like any independent advice about participation in this study, you may contact an [doctor/.../expert/person]. [He/she] knows about the study but is not involved in it.

If you have any complaints about the study, you can discuss this with the investigator or your treating specialist. If you prefer not to do this, you may contact the [complaints’ officer/committee at your hospital/institution/other]. All the relevant details can be found in **Appendix A**: Contact details.

1. **Signing the consent form**

EXAMPLE PASSAGE

When you have had sufficient time for reflection, you will be asked to decide on participation in this study. If you give permission, we will ask you to confirm this in writing on the appended consent form. By your written permission you indicate that you have understood the information and consent to participation in the study. Both yourself and the investigator will receive a signed copy of the consent form. .

END OF EXAMPLE PASSAGE

Thank you for your attention.

**Texts for special situations**

|  |  |  |
| --- | --- | --- |
| **Situation** | **Passage placement** | **Example passage** |
| Participation of children and/or mentally incompetent subjects | After point 7, as a separate section(change subsequent section numbers) | **Resistance of [your child/the person you represent]** [Your child or the person you represent] may resist (refuse to cooperate) during the study. The investigator will then have to stop the study immediately. It is difficult to describe what exactly resistance is. Before the start of the study you will be given an explanation of what is considered resistance. The investigator will follow the Code of Conduct on resistance of [minors/mentally incompetent people/geriatric patients]. |
| Studies including healthy subjects | End of the introduction | <In the event of a VIP check>:You may only participate in four medicine studies every year. And only in a single study at a specific time. We will check this in a central system that includes other research institutes. Information about participation in research is stored confidentially in this system. |
| Research in emergency situations |  |  |
|  |  |  |
| Studies falling under 21 CFR/which need to comply with FDA requirements | Proposal: under section 10, as the last item replacing the text about the registry | <Compulsory text:> A description of this clinical study will be available on <http://www.ClinicalTrials.gov>, as required by US Law. This website does not contain any information that can identify you. A summary of the results may be placed on the website. You will have access to this website. <*Please supplement with:*> You will find this study under[study reference]. |

1. **Appendices to this information**

A. Contact details <*adapt per participating centre*>

B. Insurance information <*compulsory, unless exempted*>

C. Overview/description of study procedures<*if available*>

[D and onwards]. <*other, for example more information about the efficacy of the intervention or alternative treatment options, or more information about side effects*>

[X]. Informed Consent Form(s) <*select the correct template(s)*>

[X] Medical Scientific Research Brochure. General Information for Study Subjects (version [number and/or date]) <*compulsory, to be handed out separately*>

[X]. <other, for example an existing brochure about any evaluations/invasive procedures to be performed (including the version number)> <*to be handed out separately*>

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

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

<if applicable>

[Study nurse/study doctor]: [optional for a second person to contact: name, contact details and times of availability]

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

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

Data Protection Officer of the institution:

For more information about your rights: [contact details [and website] of the person responsible for the processing of personal data].

<*if applicable, add the contact details of e.g. coordinating investigator and/or emergency number/24-hour number*>

**Appendix B: Insurance Information**

Insurance has been taken out by [sponsor/other] for everyone participating in this study. The insurance covers damage due to participation in the study. This applies to damage manifesting during the study or within four years of the end of your participation in the study. You must notify the insurance company about the damage within those four years.

The insurance does not cover all damages. The damages that are not covered are listed briefly at the end of this text.

This is set out in the Medical Research (Human Subjects) Compulsory Insurance Decree. This decree is listed on the website of the Central Committee on Research Involving Human Subjects [www.ccmo.nl](http://www.ccmo.nl) (see “Library” and then “Legislation and regulations”).

In the event of damage please contact the insurance company [or claims adjustor] directly.

*<also indicate here how the study subject must act/report damage: by telephone/e-mail/post, other instructions?>*

The insurance company for the study is:

Name: …

Address: …

Telephone number: …

E-mail: …

(Policy number: ...)

(Contact person: …)

<*include only if there is a claims adjustor - this is compulsory if the insurance company is located outside of the Netherlands*>

The claims adjustor for the study is:

Name: …

Address: …

E-mail:

Telephone number: …

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

The insurance policy does **not** cover the following damage:

* damage as a result of a risk that you were informed about in the written information. This does not apply if the risk occurs in a more severe form than envisaged, or if the risk was very unlikely to occur;
* damage to your health that would also have occurred if you had not participated in the study;
* damage resulting from not or not entirely following directions or instructions;
* damage to descendants as a result of a negative effect of the study on you or your descendants;
* damage as a result of an existing treatment method for research into existing methods of treatment.

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

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

**Appendix [Z]: Subject Consent Form**

[Brief title of the study as stated on page 1 of the information sheet]

<*compulsory:*>

* I have read the subject information form. I was also able to ask questions. My questions have been answered to my satisfaction. I had enough time to decide whether to participate.
* I know that participation is voluntary. I know that I may decide at any time not to participate after all or to withdraw from the study. I do not need to give a reason for this.
* I give permission for my [GP / treating specialist(s / pharmacist/...] to be informed that I am participating in this study <*if applicable*:> and to inform them about […].
* <*If applicable*>: I give permission for information to be requested from my [GP / treating specialist (s / ] about […].
* I give permission for the collection and use of my [data / blood samples / body material] to answer the research question in this study <*if applicable)*> and for the registration of the study product.
* I know that some people may have access to all my data to verify the study. These people are listed in this information sheet. I consent to the inspection by them.

<*in as far as applicable:*>

* I agree that my GP and / or treating specialist will be informed of coincidental findings that (may) be of interest for my health.
* I know that I [should not become pregnant / avoid pregnancy of my partner] during the study [and up to xx after xx].
* The investigator has discussed with me the most suitable contraception for [me and / or my partner].
* I □ **do**

□ **do not**
consent to keeping my personal data longer and to use it for future research in the field of [my condition and / or the studied treatment method].

* I □ **do**

□ **do not**
consent to keeping my bodily material after this study and to use this later for [other / more] research, as indicated in the information sheet.

* I □ **do**

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

* I □ **do**

□ **do not**
want to be informed about what treatment I have received / in which group I was.

<*compulsory:*>

* I want to participate in this study.

Name of study subject:

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

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I hereby declare that I have fully informed this study subject about this study.

If information comes to light during the course of the study that could affect the study subject's consent, I will inform him/her of this in a timely fashion.

Name of investigator (or his/her representative):

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

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*<If applicable>*

Additional information was given by:

Name:

Job title:

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

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\* Delete as appropriate.

*The study subject will receive the full information sheet, together with a signed copy of the consent form.*

**Appendix [Z]:** **Parent or Guardian Informed Consent Form**

[Brief title of the study as stated on page 1 of the information sheet]

I have been asked to consent to the following person/my child participating in this medical-scientific study:

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

<*compulsory*>

* I have read the subject information form for the [study subject/parents/guardians. I was also able to ask questions. My questions have been answered to my satisfaction. I had enough time to decide whether I want my child to participate.
* I know that participation is voluntary. I know that I may decide at any time that I do not want my child to participate after all or to withdraw from the study. I do not need to give a reason for this.
* I give permission for my child’s [GP / treating specialist(s / pharmacist/...] to be informed about my child’s participation in this study <*if applicable*:> and to inform them about […].
* <*If applicable*>: I give permission for information to be requested from my child’s [GP / treating specialist (s / ] about […].
* I give permission for the collection and use of my child’s [data / blood samples / body material] to answer the research question in this study <*if applicable)*> and for the registration of the study product.
* I know that some people may have access to all data of my child to verify the study. These people are listed in this information sheet. I consent to the inspection by them.

<*in as far as applicable:*>

* I agree that my child’s GP and / or treating specialist will be informed of coincidental findings that (may) be of interest for my child’s health.
* I know that my child [should not become pregnant / avoid pregnancy of my child’s partner] during the study [and up to xx after xx].
* The investigator has discussed with me the most suitable contraception for [my child and / or my child’s partner].
* I □ **do**

□ **do not**
consent to keeping my child’s personal data longer and to use it for future research in the field of [my child’s condition and / or the studied treatment method].

* I □ **do**

□ **do not**
consent to keeping my child’s bodily material after this study and to use this later for [other / more] research, as indicated in the information sheet.

* I □ **do**

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

* I □ **do**

□ **do not**
want to be informed about what treatment my child has received / in which group my child was.

*compulsory:*>

* I agree to this person’s/my child’s participation in this study.

Parent/guardian name\*\*:

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

Parent/guardian name\*\*:

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

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I declare that I have fully informed the abovementioned person(s) about the study referred to.

If information becomes available during the study that could affect the parent’s or guardian’s consent, I will notify him/her about this in good time.

Name of investigator (or his/her representative):

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

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*<If applicable>*

Additional information was given by:

Name:

Job title:

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

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\* Delete as appropriate.

\*\* If the child is under 16, the parents who have custody or the guardian must sign this form. Children aged 12 and 15 years able to make independent decisions (mentally competent) must also sign their own form <according to template A>.

*The parent or Guardian**will receive the full information sheet, together with a signed copy of the consent form.*

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

[Brief title of the study as stated on page 1 of the information sheet]

I have been asked to consent to the following person participating in this medical-scientific study:

Name of study subject: Date of birth: \_\_ / \_\_ / \_\_

<*compulsory*>

* I have read the subject information form for the [study subject/representative]. I was also able to ask questions. My questions have been answered to my satisfaction. I had enough time to decide whether I want this person to participate.
* I know that participation is voluntary. I know that I may decide at any time that I do not want this person to participate after all or to withdraw from the study. I do not need to give a reason for this.
* I give permission for this person’s [GP / treating specialist(s / pharmacist/...] to be informed about this person’s participation in this study <*if applicable*:> and to inform them about […].
* <*If applicable*>: I give permission for information to be requested from this person’s [GP / treating specialist (s / ] about […].
* I give permission for the collection and use of this person’s [data / blood samples / body material] to answer the research question in this study <*if applicable)*> and for the registration of the study product.
* I know that some people may have access to all data of this person to verify the study. These people are listed in this information sheet. I consent to the inspection by them.

<*in as far as applicable:*>

* I agree that this person’s GP and / or treating specialist will be informed of coincidental findings that (may) be of interest for this person’s health.
* I know that this person [should not become pregnant / avoid pregnancy of this person’s partner] during the study [and up to xx after xx].
* The investigator has discussed with me the most suitable contraception for [this person and / or this person’s partner].
* I □ **do**

□ **do not**
consent to keeping this person’s personal data longer and to use it for future research in the field of [this person’s condition and / or the studied treatment method].

* I □ **do**

□ **do not**
consent to keeping this person’s bodily material after this study and to use this later for [other / more] research, as indicated in the information sheet.

* I □ **do**

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

* I □ **do**

□ **do not**
want to be informed about what treatment this person has received / in which group this person was.

<*compulsory:*>

* I agree to this person’s participation in this study.

Name of legal representative:

Relationship with the study subject:

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

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I declare that I have fully informed this/these person(s) about this study.

If information comes to light during the course of the study that could affect the legal representative's consent, I will inform him/her of this in a timely fashion.

Name of investigator (or his/her representative):

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

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*<If applicable>*

Additional information was given by (if applicable):

Name:

Job title:

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

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\* Delete as appropriate.

*The representative will receive the full information sheet, together with a signed copy of the signed form.*