**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 non-Interventional research.

**Aim of the Subject information sheet**

The participation in medical research requires informed consent from the study subject. This is a process during which oral information, exchanging views and asking questions are very important. The written information is also part of this. The aim of the process and the written information is to give potential subjects sufficient information to enable them to take an informed decision on whether or not to participate in the study. To this end, the subject should be informed about the study and the interventions to be carried out. Nevertheless, this document is not intended as a detailed (day-to-day) guidance of the study protocol. The aim of the information sheet is not to safeguard the investigator from possible claims.

**Guidance on typography:** complete the template starting from the next page as follows for a specific study:

1. Plain text should be used by default and should only be amended if it is incorrect for the study concerned.
2. Replace [description/options] with the factual information OR choose the term most suitable to the nature of the study.
3. Text marked EXAMPLE PASSAGE can be used as desired. Please note: this text often does not cover the content of the *entire* section.
4. Sample text in table format: copy/move the desired text and then delete the table.
5. Make sure that *all* aspects mentioned in the remark per section are addressed (if applicable))
6. Finally, delete: - this page (explanation for users)

 - top line of the header

 - the comments

 - text between <*guidance*> and subsequent text

 - - any example passages that have not been used

 - any texts for special situations that has not been used

**Subject information versus online medical research information**For an explanation or elaboration of terms, reference is sometimes made to the Central Government's website: [www.rijksoverheid.nl/mensenonderzoek](http://www.rijksoverheid.nl/mensenonderzoek). Key issues such as voluntary participation, termination of participation, data handling and insurance should also be addressed in the subject information (see this template).

**Perspective, length and language level**

Perspective, length and language level must be in line with the purpose of the SIS: write from the subject's perspective (not the investigator's). Make sure the information sheet is concise and easy to read. Writing in this way is a profession in its own right. Use the expertise of a professional editor, information officer or communications officer where possible. Have your text proofread by a layperson who is not a content expert and preferably with a prevocational secondary education level (VMBO level).

The information sheet for the study subject **should not exceed 4000 words**. This does not include the consent statement(s) and the following appendices: contact details, insurance text, schedule of study activities and, for example, additional information about the side effects or mode of action of the product or treatment to be investigated. **The appendices should also be concise and easy to read.**

The basic principle is that the letter is written at **VMBO level**. The standard and sample texts in this model comply with this requirement (tested by Bureau Taal). Exceptions are possible if the target group differs significantly from the 'average' Dutch population (for example, children under the age of 12 or higher professional education (HBO) or university students).

***This model is a shorter version especially for observational studies based on the template for all WMO studies developed in collaboration with and is supported by the 'Vereniging Innovatieve Geneesmiddelen' ('Association of Innovative Medicines'), NFU, STZ, V&VN Research Professionals, ACRON, the Hart&Vaatgroep, the association of insurers, NVMETC and VWS. General information about medical scientific research can be found on the website of the Dutch government at*** [***www.rijksoverheid.nl/mensenonderzoek***](http://www.rijksoverheid.nl/mensenonderzoek)***.***

**Subject information for participation**
**in medical research**

**[Title of the study]**

*Official title:*

**Introduction**

Dear Sir/Madam,

With this letter, we would like to ask you to take part in a medical study. Participation is voluntary. You have received this letter because you are prescribed [medication X] for *(disease)*

You can read about the medical study in this information sheet, what it means for you, and what the pros and cons are. It is a lot of information. Can you please read the information and decide if you want to take part? If you want to take part, complete the form in Appendix [X].

**Ask your questions**

You can take your decision based on the information in this information sheet. We also suggest that you do this:

- Put your questions to the investigator who gave you this information.

- Talk to your partner, family or friends about this study.

- Ask questions to the independent expert, [name].

- Read the information on [www.rijksoverheid.nl/mensenonderzoek](http://www.rijksoverheid.nl/mensenonderzoek)

1. **General information**

|  |  |
| --- | --- |
|  | **Example passage** |
| Company is sponsor |  [name of company] has set up this study. Below, we always call [company name] the 'sponsor'. Investigators, these can be [Doctors/therapists/investigators/research nurses], conduct the study in different [hospitals/doctor's practices/…]. [Company name] pays for this research. |

*<if a commercial party (also) pays for this study, you should mention this in this section>*

EXAMPLE PASSAGE This study needs [X subjects] from different countries . In the Netherlands it is expected that [X study subjects] will take part. END OF EXAMPLE PASSAGE

This research has been assessed by the ethics advisory committee UMC Groningen / ethics advisory committee Martiniziekenhuis Groningen / nWMO advice committee MEC-U commissioned by the Dutch Clinical Research Foundation.

1. **Purpose of the study**

As part of your treatment, you will receive (name of the medication being researched). We would like to learn what the experiences of patients are with this medical product and if you notice any changes. *<maybe more specific, the goal can also be to collect more information about your disease>*.

You have been prescribed (name brand) by your doctor, because it is necessary for your treatment and not in the context of this investigation. That means that you can collect the medical product at your own pharmacy and possibly have to pay the normal personal contribution.

1. **What participation involves**

You will be treated in the usual way for your [illness / condition]. During your regular visits to the hospital / general practice, the following will happen:

- data is collected about ............

- we will let you complete a questionnaire about ...... .

EXAMPLE PASSAGE

Appendix B 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

1. **What agreements do we make with you?**

We want the study to go well. That is why we want to make the following agreements with you <*use if applicable*>:

* You take the medicine/ in the way the investigator explained to you.
* You do not take part in any other medical research during this study.
* You go to every appointment.

You should contact the investigator: <*delete as appropriate*>

* You want to start taking other medication. Also, if these are homoeopathic remedies, natural remedies, vitamins or over-the-counter medicines.
* You are hospitalised or get treatment in a hospital.
* You suddenly have problems with your health.
* You no longer want to take part in the study.
* Your telephone number, address or email address changes. .

EXAMPLE PASSAGE <*split up into text for women and text for men if necessary >*

*Paragraph 4A Is it OK for you or your partner to get pregnant during the study?*

Women who are pregnant or breastfeeding cannot take part in this study. Women should also not get pregnant during the study. Are you male and do you have a female partner? Then you need to make sure that she cannot become pregnant with your child.

This study can have consequences for an unborn child. [*if known, state consequences*] OR The consequences are not known.

The investigator will tell you how best to prevent pregnancy. Talk to your partner about this.

*Pregnant after all?*

If you do become pregnant during the study, inform the investigator immediately. In this case, you should stop participating in the study as soon as possible in consultation with the investigator. OR Did your partner become pregnant with your child during the study? Ask her permission to let the investigator know. Then the pregnancy can be monitored more closely and information about the course and outcome of the pregnancy can be requested from other healthcare providers. But only if you/your pregnant partner give permission for this. [Finally, we report the pregnancy to the sponsor of this research].

<If applicable> There is limited information from the use of [drug x] in pregnant women. <describe in appropriate terms what is known about the effect in pregnant women>. [Treatment X] is not recommended during pregnancy and in women of childbearing potential who are not using contraception. If you / your partner becomes pregnant, please contact the investigator. The investigator will ask you to read and sign a separate pregnancy consent form so that the investigator can ask about the outcome of your pregnancy, the birth and the health of your baby.

<If applicable> ‘ *Pregnant after the study*?’

EXAMPLE PASSAGE The investigator will discuss with you whether taking part in the study may have consequences if you want to become pregnant later.

1. **When does the study end?**

It is up to you to decide if you wish to participate in the study. You do not wish to participate? <if applicable> Then you will receive the standard treatment for [illness/disorder].

If you participate, the study will stop for you when:

* All checks according to the schedule are finished.
* The end of the whole study has been reached <*if applicable, so if the study continues until an end point has been reached, do explain this here, for example: so many cases of Y*>
* You have become pregnant.
* You want to stop participating in the study yourself. You can stop at any time. Report this to the investigator immediately. You do not have to explain why you want to stop. You will then get the standard treatment for [illness/disorder] again.
* One of the following authorities decides that the study should stop:
	+ [sponsor name],
	+ the government, or
	+ the nWMO advisory committee assessing the study
1. **What will be done with your data <if applicable> and body material?**

Are you taking part in the study? Then you also give your consent to collect, use and store your data <if applicable> and body material.

*What data do we store?*

We store these data <*use if applicable and complete if necessary*>:

- your name

- your gender

- your ethnic background

- your address

- your date of birth

- information about your health

- (medical) information that we collect during the study

*<if applicable> What body material do we store?*

We store [tubes of blood/tissue samples (biopsies)/other].

*Why do we collect, use and store your data <if applicable> and body material?*

We collect, use and store your data <*if applicable>* and your body material to answer the questions of this study. And to be able to publish the results. <*if applicable>* We also need these data to be able to market the investigated medicinal product.

*How do we protect your privacy?*

To protect your privacy, we give a code to your data <if applicable> and your body material. We only put this code on your data . We keep the key to the code in a safe place in [the hospital/doctor's practice/research centre]. When we process your data , we always use only that code. Even in reports and publications about the study, nobody will be able to see that it was about you.

*Who can see your data?*

Some people can see your name and other personal information without a code. These are people checking whether the investigators are carrying out the study properly and reliably. These persons can access your data:

* Members of the committee that keeps an eye on the safety of the study.
* An auditor who is hired by the [investigator/sponsor]. OR An auditor who works for the [investigator/sponsor].
* National and international supervisory authorities. For example, the Healthcare and Youth Inspectorate.
* [other]

These people will keep your information confidential. We ask you to give permission for this access.

*For how long do we store your data?*

We store your data [in the hospital/doctor's practice/research centre] for […] years. <*if applicable*> And for […] years with the sponsor.

*<if applicable> Can we use your data for other research?*

Your data <*if applicable*> may also be important after this study for other medical research on [your condition and/or the further development of the product/treatment method]. For this purpose, your data will be stored [in the hospital/research centre/...] for [...] years. Please indicate in the consent form whether you agree with this. Do you not want to give your consent? Then you can still take part in this study. You will get the same healthcare.

*Can you take back your consent for the use of your data?*

You can take back your consent for the use of your data at any time. <*in case of other research* This applies both to the use in this study and to the use in other medical research>. But please note: if you take back your consent, and the investigators have already collected data for research, they are still allowed to use this information.

<*If applicable*> *We send your data to countries outside the European Union*

In this study, we will send your coded data also to countries outside the European Union. The privacy rules of the European Union do not apply in those countries. But your privacy will be protected at a similar level.

*Do you want to know more about your privacy?*

* Do you want to know more about your rights when processing personal data? Visit [www.autoriteitpersoonsgegevens.nl](http://www.autoriteitpersoonsgegevens.nl).
* Do you have questions about your rights? Or do you have a complaint about the processing of your personal data? Please contact the person who is responsible for processing your personal data. For the present, this is:
	+ <*For investigator-initiated research*> [Institution name] See Appendix A for contact details, and website.
	+ *<In case of sponsor-initiated research>* [Name of sponsor and institution] See Appendix A for contact details and website.
	+ *<if applicable>* Because the sponsor is located outside the EU, [name of representative] has been appointed to act as its representative. For contact details, see Appendix A.
* If you have any complaints about the processing of your personal data, we recommend that you first discuss them with the research team. You can also contact the Data Protection Officer of [the institution]. Or you can submit a complaint to the Dutch Data Protection Authority.

*Where can you find more information about the study?*

You can find more information about the study on the following website (s). EXAMPLE www.ClinicalTrials.gov and/or [www.clinicaltrialsregister.eu](file:///C%3A%5CUsers%5CBOURICIUSJFD%5CAnouk%5CDCRF%20werkgroep%20PIF%5Cwww.clinicaltrialsregister.eu). <if applicable> After the study, the website may show a summary of the results of this study. You can find the study by searching for '....' (number: XXX)

1. **We will inform your doctor or your attending specialist and /or pharmacist**

The investigator will send your [doctor and/or attending specialist and/or pharmacist] a [letter/email] to let them know that you are taking part in the study. This is for your own safety. <*If applicable– ad-hoc situations*> [situation] we may contact your doctor, for example, about [your medical history or the medication you are taking].

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

You can ask questions about the study of [the investigator/research team]. Do you have a complaint? Discuss it with the investigator or the doctor who is treating you. If you prefer not to do so, please visit [complaints officer/complaints committee of your hospital/institute/Dutch Data Protection Authority/other]. Appendix A tells you where to find this.

1. **How do you give consent for the study?**

You can first think carefully about this study. Then you tell the investigator if you understand the information and if you want to take part or not. If you want to take part, complete the consent form that you can find with this information sheet. You and the investigator will both get a signed version of this consent form.

Thank you for your attention.

1. **Appendices to this information**

A. Contact details <*to be adjusted per participating centre*>

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

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

*<note: all appendices should be listed here; appendices specifically for this nWMO research should be included in the information part of this document.>*

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

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

<if applicable>

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

Complaints: [service or person with contact details and accessibility]

Data Protection Officer of the institution:

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

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

**Appendix B: Diagram of study activities and/or overview of measurements/description of study interventions <optional>**

If necessary, in addition to the main text, a simple (time) schedule or a point-by-point description of measurements/interventions in **layman's terms**.

(If there is a standard treatment for which the subject is eligible, add a comparative table for the experimental therapy and the standard treatment (with probability of success, side effects, risks and burden) if necessary**.**

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

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

<*compulsory:*>

* I have read the information sheet. I was able to ask questions. My questions have been answered sufficiently. I had enough time to decide if I wanted to take part.
* I know that taking part is voluntary. I also know that at any time I can decide not to take part in the study. Or to stop taking part. I do not have to explain why.
* I give the investigator consent to inform my [doctor/specialist (s) who treats me/pharmacist/...] that I am taking part in this study.
* <if applicable>: I give consent to request information
* I give consent to collect from my [doctor/specialist (s) treating me/...] about [...]. and use my data . The investigators only do this to answer the question of this study. <if applicable> and to register the medicinal product.
* I know that some people will be able to see all my data to review the study. These people are mentioned in this information sheet. I give consent to let them see my data for this review.
* <if applicable> I know that I [cannot get pregnant/cannot get my partner pregnant] during the study [and until xx after xx].
* Please tick yes or no in the table below.

|  |  |  |
| --- | --- | --- |
| <if applicable> I give consent to store my data to use for other research, as stated in the information sheet.  | Yes ☐ | No☐ |
| <if applicable> I give consent to ask me after this study if I want to participate in a follow-up study. | Yes ☐ | No☐ |

<*compulsory*>

I want to take part in this study.

My name is (subject): ……………………………….

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

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

If any information becomes known during the study that could influence the decision to take part, I will let the subject know 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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\* line through what is not applicable

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

**Appendix [Z]:** **Informed consent form - Parent or Guardian Informed**

[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 information sheet. I was able to ask questions. My questions have been answered sufficiently. I had enough time to decide if I wanted to take part.
* I know that taking part is voluntary. I also know that at any time I can decide not to take part in the study. Or to stop taking part. I do not have to explain why.
* I give the investigator consent to inform my [doctor/specialist (s) who treats me/pharmacist/...] that I am taking part in this study.
* <if applicable> I give consent to request information from my [doctor/specialist (s) treating me/...] about [...].
* I give consent to collect and use my data. The investigators only do this to answer the question of this study. <if applicable> And to register the medicinal product.
* I know that some people will be able to see all of my data to review the study. These people are mentioned in this information sheet. I give consent to let them see my data for this review.
* <if applicable> I know that my child [cannot get pregnant/cannot get my partner pregnant] during the study [and until xx after xx].
* Please tick yes or no in the table below.

|  |  |  |
| --- | --- | --- |
| <if applicable> I give consent to store my data to use for other research, as stated in the information sheet.  | Yes ☐ | No☐ |
| <if applicable> I give consent to ask me after this study if I want to participate in a follow-up study. | Yes ☐ | No☐ |

I agree that my child takes part in this study.

Parent/guardian name\*\*: ………………………………

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

Other parent/guardian name\*\*: …………………….

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

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I declare that I have fully informed the person(s) mentioned above about the said study.

If any information becomes known during the study that could influence the parent/guardian's consent, I will let them know in good time.

Investigator name (or their representative): …………………………

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

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<*if applicable*>

Additional information was given by:

Name: ………………………………………..

Job title: ………………………………………

Signature: ………………………………. Date: \_\_/\_\_/\_\_

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\* Delete what is not applicable.

\*\* If the child is younger than 16, the parents who exercise custody or the guardian will sign this form. Children between the ages of 12 and 15 who are able to make independent decisions (are able to give informed consent) must also sign a form themselves.

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

**Appendix [Z]: Informed consent form - Representative**

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

I have been asked to give consent for the following person to take part in this medical study:

Subject’s name: …………………….. Date of birth: \_\_/\_\_/\_\_

* I have read the information sheet for subjects/representatives. I was able to ask questions. My questions have been answered sufficiently. I had enough time to decide if I wanted this person to take part.
* I know that taking part is voluntary. I also know that at any time I can decide at any time that this person will not take part after all. I do not have to explain why.
* I give the investigator consent to inform the [doctor/specialist (s) treating this person/pharmacist/...] that this person is taking part in this study.
* <if applicable> I give consent to request information from the [doctor/specialist (s) treating this person...] about [...].
* I give consent to collect and use this persons data. The investigators only do this to answer the question of this study <if applicable> and to register the medicinal product.
* I know that some people will be able to see all of this person’s data to review the study. These people are mentioned in this information sheet. I give consent to let them see this persons data for this review.
* <if applicable> I know that this person [cannot get pregnant/cannot get their partner pregnant] during the study [and until xx after xx]. The investigator has discussed with me how this person can best prevent pregnancy
* Please tick yes or no in the table below.

|  |  |  |
| --- | --- | --- |
| <if applicable> I give consent to store this persons data to use for other research, as stated in the information sheet.  | Yes ☐ | No☐ |
| <if applicable> I give consent to ask me after this study if I want this person to participate in a follow-up study. | Yes ☐ | No☐ |

I agree that this person takes part in this study.

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

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

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

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I declare that I have fully informed the person(s) mentioned above about the said study.

If any information becomes known during the study that could influence the representative's consent, I will let them know in good time.

Investigator name (or their representative): ........................

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

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<*if applicable*>

Additional information was given by:

Name:……………………………………..

Job title:……………………………………

Signature:……………………………. Date: \_\_/\_\_/\_\_

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\* Delete what is not applicable.

*The representative will receive a complete information sheet, together with a signed version of the consent form.*