**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.

**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).

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

Point of view, length and language level should be consistent with the objective of the SIS: 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 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 SIS, 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).

**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 are prescribed [medication X] for *(disease)*

<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 may also discuss it with your partner, friends or family.

1. **General information**

|  |  |
| --- | --- |
| **Situation** | **Example passage** |
| - 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

This research has been assessed by the ethics advisory committee UMC Groningen / ethics advisory committee Martiniziekenhuis Groningen / ethics advisory committee Twente, 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 with this drug are. That is the purpose of this research *<maybe more specific>*.

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 fill in 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 is expected of you**

In order to carry out the study properly [<*if applicable*> it is important that you follow the study instructions.

<*delete or supplement as appropriate, see guidance in the comment*>:

* follow the instructions of your physician
* do not participate in another medical study.
* keep appointments for visits.

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.

END EXAMPLE PASSAGE

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 you do not want to participate, you will be treated as usual for your [disease/disorder].

If you do participate in the study, you can always change your mind and decide to stop, at any time during the study. 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.

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 choose to stop

<*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 *<when the patient turns out not to follow the agreements of the study* >
* [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.

1. **Usage and storage of your data**

Your personal data 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. The collection, use and storage of your data is required to answer the questions asked in this study and to publish the results. We ask your permission for the use of your data

**Confidentiality of your data** To protect your privacy, your data 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 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**

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

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

Your data 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 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.

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

In this study, your encoded data 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. **Any questions?**

If you have any questions, please contact [the investigator/the study team].

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. The signature sheet is kept by the investigator. Both the Investigator and yourself receive a signed version of this consent form.

END OF EXAMPLE PASSAGE

Thank you for your attention.

1. **Appendices to this information**

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

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

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

*<note: all appendices should be listed; appendices specifically for this nWMO research should be listed 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 times of availability]

<if applicable>

[Study nurse/study doctor]: [optional for a second person to contact: name, 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 [Z]: Subject Consent Form *(****for adults and participants in the age of 12 - 15 years, who can decide independently (mentally competent)*

[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.
* <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 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.

<*as far as applicable:*>

* 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 being contacted again after this study for a follow-up study.

<*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 an original of the signed consent form.*

**Appendix [Z]:** **Parent or Guardian Informed Consent Form for children up to 15 years of age**

[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 form (for the study subject/parents/guardians). I was also able to ask questions. My questions have been answered to my satisfaction. I have had enough time to decide whether I want my child to participate.
* I know that participation is voluntary. I also know that I can decide at any time that I do not want my child to participate after all. I do not need to give a reason for this decision.
* <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 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 □ **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 being contacted again after this study for a follow-up study.

<*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 an original of the signed consent form.*