The SIDCER Informed Consent Form Template for Clinical Trials

Instructions for investigators

The SIDCER informed consent form (ICF) template is designed to address all the required elements of the mandatory ICF content, as specified in the International Conference on Harmonisation for Good Clinical Practice, the Code of Federal Regulations (45 CFR 46), and the Declaration of Helsinki (2013), in a concise and easy-to-read format and to assist investigators in developing an ICF. Pertinent information related to research is organised with the help of boxes, colours and illustrations to enhance visualisation and explain what the research will entail.

Some phrases in the template are in brackets and are underlined in three different colours, ie [Gray], [Blue], and [Orange]. Here, the investigators are required to fill in study-specific information according to the individual study protocol. Each colour represents a different kind of information, as described below.

- As for the underlined gray phrases, ie [title of the study] and [subject eligibility], investigators are required to fill in the blanks with specific information according to the protocol.
- As for the underlined blue phrases, ie [short summary of background and rationale of the study] and [explanation of the study design in brief], investigators have to provide brief, detailed explanations of protocol information, relevant to the subject's decision-making. The explanations should be in simple non-technical language, and should take into account the local context and culture.
- As for the underlined orange phrases, ie [illustration of the study design] and [illustration of the schedule of the study], investigators are required to illustrate information, if possible, in a figure, flow chart, diagram or table to enhance visualisation and comprehension.

In this template, certain types of information may not be necessary for some clinical studies (eg the [alternative procedure(s) or course(s) of treatment] element may not be necessary for a phase I clinical trial involving healthy subjects). On the other hand, additional information, such as extra elements required by the local or national laws and regulations, may be necessary in some settings. A consent form may require modifications according to the type of study (eg the signature of a legally acceptable representative may be needed in a study involving vulnerable subjects). Therefore, investigators need to consider which information is required for their study and then modify the SIDCER ICF template to suit each study's individual requirements.

Suggestions

To enhance the readability and understandability of the SIDCER ICF you have developed from this template, a pilot test in a small group of laypersons is highly recommended. Additional information on other facets of your clinical study can be provided in attachments, if deemed necessary.

Informed Consent Form

[Title of the study]

Investigator(s): [name of the investigator(s)]
Organisation: [name of the organisation]
Sponsor: [name of the sponsor]

You are being invited to take part in this **research** because you [subject eligibility]. There will be [number of subjects required] individuals taking part in this research.

Before you decide, it is important for you to understand why the research is being done and what it will involve. Please read through the following information carefully and feel free to ask if it is not clear or to discuss it with anyone you wish.

Please take time to decide whether or not you want to take part in this research. We would like to stress that taking part in this study is **entirely voluntary** (**Box 1**). If you decide not to participate in the study, you will receive [alternative procedure(s) or course(s) of treatment] (**Box 2**).

Box 1. Taking part in this research is voluntary

- You **can refuse** to take part in this study.
- You **can withdraw** your participation from the study at any time.

Box 2. Alternative procedure(s) or course(s) of treatment

- [Alternative procedure or course of treatment, if any]	[Brief explanation of advantages and disadvantages of that procedure or course of treatment]
- [Alternative procedure or course of treatment, if any]	[Brief explanation of advantages and disadvantages of that procedure or course of treatment]

Information related to the study

[Short summary of background and rationale of the study]

[Brief information of the investigational drug(s)/intervention(s)]

Box 3. The expected possible adverse effects of [the investigational drug/intervention]

- [Common or important expected adverse effect(s) of the drug/intervention, if any]
- [Common or important expected adverse effect(s) of the drug/intervention, if any]

The objective of this research is to [purpose of the study].

[Explanation of the study design in brief]

Box 4. Study design
[Illustration of the study design]

The study will last around [duration of the subject's participation] in total. If you decide to take part in this study, you will be asked to follow the schedule shown in **Box 5**. You should ensure that you are available to comply with the schedule.

Box 5. The schedule of the study
[Illustration of the schedule of the study]

[Identification of any experimental procedures]

We have summarised the foreseeable risks and expected benefits arising from participation in the study in **Box 6**.

Box 6. Foreseeable risks and expected benefits arising from participation in the study

Foreseeable risks	Expected benefits
- [Foreseeable risk, if any]	- [Expected direct/indirect benefit, if any]
- [Foreseeable risk, if any]	- [Expected direct/indirect benefit, if any]

Certain occurrences may take place during the course of the study. We have summarised these in **Box 7** and described how to manage them.

Box 7. Occurrences that may take place during the study period

Occurrences	How to manage
Withdrawal of volunteers from the study	[Explanation of how to deal with the participant]
Availability of new information that may affect your decision	Such information will be provided to you in a timely manner. You can change your mind about whether to continue participating in this research.
[Criteria for the termination of participation, if any]	[Explanation of how to manage such an event]

At the end of the study, you will [description of post-trial benefits, if any].

All data collected from the study will be kept **confidential**. [Explanation of how to manage, store and/or reuse the participant's sample(s), if any]. Presentations of the study's results at meetings/conferences or their publication in a scientific journal will not include your name. However, **the national authority for drug use, ethics committees and sponsor's representatives will have access to the data for verification**.

[Explanation of how much will be paid as remuneration in total and for each visit; if none, state that there is no payment for participation in the study]. [Clarification of anticipated expenses, if any]. In case of any injury or illness resulting directly from participation in the study, [explanation of how to deal with the situation].

If you have any questions related to the study or you experience any adverse event before/during participation in the study, you can consult the contact persons listed in **Box 8**.

Box 8. The contact persons
1. [name of the contact person]
Tel. [telephone number] E-mail: [e-mail address]
2. [name of the contact person]
Tel. [telephone number] E-mail: [e-mail address]

If you have any questions related to your rights, you can contact [name of the ethics committee and contact number].

[Declaration of conflicts of interest, if any].

Certificate of Consent

I have read the foregoing information. I have had an opportunity to ask questions and all my questions have been answered to my satisfaction. I voluntarily consent to participate in this research study.	I confirm that the participant was given an opportunity to ask questions about the study and all the questions have been answered correctly. I confirm that the consent has been given voluntarily.
_____ Printed name of the participant	_____ Printed name of the person taking the consent
_____ Signature of the participant Date _____ day/month/year	_____ Signature of the person taking the consent Date _____ day/month/year