The SIDCER Informed Consent Form Template for Clinical Trials

Instructions for Investigators:

The SIDCER Informed Consent Form (ICF) template is designed to address all required elements of the mandatory ICF content, as specified in the International Conference on Harmonization (ICH) for Good Clinical Practice (GCP), the Code of Federal Regulations (45 CFR 46.116), and the Declaration of Helsinki (2013), in a concise and easy-to-read format and to assist investigators in developing an ICF. It is arranged to organize pertinent information related to research with boxes, colors and illustrations to enhance visualization and explanation of what the research will entail.

There are some parts of the template (in brackets with underlined phrases, "[__]", in three different colors, *i.e.* [title of the study], [brief information of investigational drug(s)/intervention(s)], or [illustration of study design]) that require investigators to fill in study specific information according to the individual study protocol. Each color represents a different kind of information required as described below:

- The underlined gray phrases in brackets (*i.e.* [title of the study], or [subject eligibility]) require investigators to fill in the blanks with specific information according to the protocol.
- The underlined blue phrases in brackets (*i.e.* [short summary of background and rationale of the study], or [explanation of the study design in brief]) require investigators to provide brief, detailed explanations of protocol information, relevant to the subject's decision making, in simple non-technical language with particular consideration for local context and culture.
- The underlined orange phrases in brackets (*i.e.* [illustration of the study design], or [illustration of the schedule of the study]) require investigators to illustrate information, if possible, in a figure, flow chart, diagram, or table form to enhance visualization and understanding for the reader.

In this template, certain information may not be necessary for some clinical studies (*e.g.*, 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 local or national laws and regulations, may be necessary in some settings. A consent form may require modifications according to the study type (*e.g.* 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 your SIDCER ICF developed from this template, a pilot test in a small group of laypersons is highly recommended. Additional information about other facets related to 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)]
Organization: [name of the organization]
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 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 to not participate in this 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 of the drug/intervention, if any]
- [Common or important expected adverse effect of the drug/intervention, if any]

The objective of this research is to [objective 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 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, if any]

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

Box 6. The foreseeable risks and expected benefits from study participation

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

There are some situations that may occur during the course of the study. We have concluded those situations in **Box 7** and described how to manage them.

Box 7. Situations during study period

Situations	**How to manage**
Withdrawal of volunteers from the study	[Explanation on how to deal with the participant]
Availability of new information that may affect your decision	We will timely provide such information to you. You can change your decision to continue in this research.
[Participant termination criteria, if any]	[Explanation on how to manage such an event]

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

All data collected from the study will be kept **confidential**. [Explanation on how to manage, storage and/or reuse of the participant's sample(s), if any]. Presentation of this study's results at meetings/conferences or publishment in 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 in each visit; if none, state that there is no payment for study participation]. [Clarification of any anticipated expenses, if any]. In case of any injury or illness directly resulting from participation in the study, [explanation on how to deal with this situation].

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

Box 8. The contact persons

1. [name of the contact person]
   Tel. [telephone number] Email: [email address]
2. [name of the contact person]
   Tel. [telephone number] Email: [email address]

If you have any questions related to your rights, you can contact [name of Ethics Committee and contact number].

[Declaration of possible conflicts of interest, if any].

Certificate of Consent

I have read the foregoing information. I have had an opportunity to ask questions and all of 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 voluntarily given.
_____ Printed Name of the Participant	_____ Printed Name of Researcher/person taking the consent
_____ Signature of the Participant Date _____ day/month/year	_____ Signature of Researcher/person taking the consent Date _____ day/month/year