SIDCER informed consent form: principles and a developmental guideline

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Abstract

The quality of informed consent forms (ICFs) remains an issue in clinical research. The lengthy and complicated ICFs currently being used lower research participants' ability to read and understand the information provided therein. In collaboration with the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), we have developed the SIDCER ICF, which could be of value in improving the quality of the ICFs. The three principles underlying the SIDCER ICF were: (i) an ICF contains all the required regulatory elements; (ii) an ICF provides only such information as is relevant for the subject's decision-making; and (iii) an ICF presents information in a simple format that conveys relevant information to the target population. The SIDCER ICF template, with its instructions, was then structured to assist an investigator in developing an enhanced ICF according to the three principles. The applicability of the SIDCER ICF was tested using a phase I study protocol, and a variety of experts with a special interest in ethics and clinical research were invited to evaluate the comprehensiveness of the three-page ICF for the phase I study. The SIDCER ICF template was refined and finalised in accordance with the results and comments from the experts.

Introduction

An informed consent form (ICF) is an essential document used in the informed consent process of most clinical studies, as it provides the potential subjects with the necessary information on the study in which they have been invited to take part. Although ICFs have been refined over the decades, there are still certain issues that need to be given attention regarding their quality. The length of ICFs has been gradually increasing to fulfil regulatory ethical requirements (1–3). Evidence demonstrates that the median length of the ICFs currently being used in clinical trials is over 20 pages (4,5). The increasing complexity of the language used in ICFs has also been documented (6). These two factors make it difficult for potential research subjects to thoroughly read and comprehend the information provided in an ICF. Many subjects who consent to participate in a clinical study do so without even reading the ICF given to them. They enter the study unaware of the foreseeable risks and of the fact that they are being involved in research (7–9). An ICF has gradually been transformed into a document that provides protection to investigators and research institutes rather than one that protects potential research subjects (10,11).

There is a need to improve the quality of an ICF. Two systematic reviews of informed consent have indicated that an enhanced ICF can improve the research subject's comprehension (12,13). However, neither a specific definition of an enhanced ICF, nor guidelines on how to develop it has been provided. Recently, an Advanced Notice of Proposed Rule-making, issued by the Office of the Secretary of the Department of Health and Human Services, in coordination with the Office of Science and Technology Policy, has proposed the development of a standardised ICF template that would restrict ICFs to the appropriate contents and an acceptable length (14). Despite this proposal, there are still a limited number of standardised ICF templates for various types of clinical research.

To address these issues, we, in collaboration with the Strategic Initiative for Developing Capacity for Ethical Review (SIDCER), developed the SIDCER ICF principles and ICF template for clinical trials. This could be of value in improving the quality of ICFs in clinical research.

The SIDCER ICF: the principles and the ICF template

In collaboration with the SIDCER, three basic principles were defined for the SIDCER ICF to provide guidance to investigators in developing an enhanced ICF. These are as follows.

1. An ICF contains all the required elements specified in relevant international ethics guidelines and regulations.
2. An ICF provides only such information as is relevant for a subject's decision-making on whether to participate in a clinical study.
3. An ICF presents information in a simple format that can convey relevant information to the target population.

For ease of application of the first SIDCER ICF principle, 25 elements required in an ICF by the three major regulatory ethical guidelines – the International Conference on Harmonisation (ICH) for Good Clinical Practice (GCP) (15), the Code of Federal Regulations (45 CFR 46) (16), and the Declaration of Helsinki (DoH, 2013) (17) – were identified and arranged in a comprehensive table (Table 1). The 25 elements were organised into four broad categories: general items,

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rights of the participant, scientific aspects and ethical aspects. The "general items" category contains five elements that are generally required for any clinical research: recognition that the study involves research (participants must recognise that they are being invited to take part in research, not a routine medical treatment); participants' responsibility (participants should realise their responsibility to strictly adhere to the protocol during participation in the research); the confidentiality of records and the limitations of confidentiality (who else can access the data apart from the investigators' team); and the person(s) among the researchers or the responsible body who should be contacted should the participant require further information related to the study or to the participants' rights. The "rights of the participant" category contains four elements relating to the participant's voluntariness to participate in the study: the right to refuse to participate in the study; the right to withdraw from participation in the study; the consequences of withdrawing from the study; and the right to receive new information which may become available and may be relevant for the participant's decision on whether to continue to participate in the study. The "scientific aspects" category contains eight elements pertaining to the logistics of the study: the subject's eligibility; number of subjects required; purpose of the study; trial treatment; trial procedures; identification of any experimental procedures; duration of the subject's participation; and data collection, storage and/or the reuse of human material. The "ethical aspects" category contains eight elements related to the ethical considerations in designing and conducting a clinical study: alternative procedure(s) or course(s) of treatment (other options that participants have if they decide not to participate in the study), the foreseeable risks, expected direct and/or indirect benefits, post-trial benefits, criteria for the termination of participation (when the risk–benefit ratio to the participant is unfavourable), prorated payment for participation, anticipated expenses for participation in the study, and compensation for injury directly resulting from participation in the study, if any.

To limit the contents and length of an enhanced ICF in compliance with the second SIDCER ICF principle, the ideas proposed in the European Textbook on Ethics in Research (2010) concerning the extent of the provision of information were adopted: not all but relevant information should be included (18). Only such information as is relevant to a prospective subject's decision-making on whether to take part in a particular research study is considered adequate and relevant information. In other words, it may not be necessary to disclose everything about the research that is not relevant for decision-making, and what is required is to give only such information that a reasonable person would need to know on each element (Table 1) to decide whether to participate in a particular study. It is the responsibility of an investigator or the ICF developer of an individual clinical study to carefully analyse, synthesise and summarise the "relevant information" from the study protocol for the development of the ICF.

A three-page SIDCER ICF template with a one-page instructional sheet (Appendix 1*) was created for investigators to aid in the application of the third SIDCER ICF principle in conjunction with Table 1. The template made use of four innovative presentational means:

- The use of a narrative format to relay relevant information (rather than questions, which are often used) to build the context and interlink the events;
- The placement of core summarised information into boxes (rather than prolonged running texts) so that the information is easily noticeable;
- Highlighting of important key words in colour (rather than all in black) to attract attention; and
- The use of illustrations (rather than text only), where necessary, to enhance the subject's visualisation, comprehension and retention.

The instructional sheet describes in detail how to properly use the template for developing an enhanced ICF in compliance with the SIDCER ICF principles. It is the responsibility of an investigator or ICF developer to narrate and illustrate the relevant information regarding the study in the SIDCER ICF template, using the local lay language and with reference to the local context.

Table 1
Elements required in an informed consent form classified into four categories*

General items	*Rights of the participant*
- Recognition that this is research	- Right to refuse
- Participants' responsibility	- Right to withdraw
- Confidentiality of records	- Consequences of withdrawal
- Who can access the data	- Right to receive new relevant information
- Research contact person(s)	
Scientific aspects	*Ethical aspects*
- Eligibility of the subject	- Alternative procedure(s) or course(s) of treatment
- Number of subjects required	- Foreseeable risks
- Purpose of the study	- Expected direct and/or indirect benefits
- Trial treatment	- Post-trial benefits
- Trial procedures	- Criteria for the termination of participation
- Identification of any experimental procedures	- Prorated payment for participation
- Duration of the subject's participation	- Anticipated expenses
- Data collection, storage and/or the reuse of human material	- Compensation for injury

* *Limited to the three major regulatory ethical guidelines—the International Conference on Harmonisation for Good Clinical Practice (ICH GCP) (15), the Code of Federal Regulations (45 CFR 46) (16), and the Declaration of Helsinki (2013) (17).*

Proof of concept and application of the SIDCER ICF

An enhanced ICF of a simulated phase I randomised, controlled, dose-escalation study protocol was developed following the SIDCER ICF principles and the developmental guideline. In close adherence to the first principle, Table 1 was used as a framework to ensure that the core information required

by the regulations was presented in and selected from the study protocol. The information, refined according to the second principle, was then transformed into a narrative and illustrative format and appropriately inserted into the SIDCER ICF template in compliance with the third principle. Various experts and lay persons from multidisciplinary sectors who are regularly involved in clinical research, mostly from the Forum for Ethical Review Committees in the Asian and Western Pacific region (FERCAP), participated in reviewing the resulting three-page ICF for phase I to check its accuracy and readability. The vocabulary and text structure were scrutinised extensively to ensure that the simplest terms were used.

The readability and understandability of the enhanced ICF for phase I was tested at two workshops on ICFs, which were attended by a variety of experts with a special interest in ethics and clinical research, mainly from the Asia Pacific and African regions. This process was a collaboration between ethics committee members and researchers to improve the SIDCER ICF and the template. The participants were informed that their contribution would be part of developing and improving the SIDCER ICF, and voluntary consent was taken by action (feedback or comments) in an anonymous manner. The first group consisted of participants of the 7th International Diploma Course of Research and Development of Products to Meet Public Health Needs at Nagasaki University (2013), and the second of participants of the 13th FERCAP International Conference in Bali, Indonesia (2013). A post-test questionnaire (21 short case stories, followed by a question with four possible answers for each case story, for the 21 elements identified in an ICF for the simulated phase I) was used as an assessment tool to evaluate the participants' comprehension level of the information provided. After the pilot test in the first group (participants in the Product Development Course at Nagasaki University), the enhanced ICF and post-test questionnaire were modified according to the comments. The second test was completed by 65 respondents who attended the 13th FERCAP International Conference. A quarter of the respondents (23.1%) who read the three-page ICF achieved a perfect score on the post-test questionnaire, while most participants understood most of the information provided in the ICF, the median score being 19 (out of 21). The SIDCER ICF template was refined and finalised, taking into account the results and comments from the post-test questionnaire.

Discussion

Not only was the development of the SIDCER ICF principles and template able to limit the length of the enhanced ICF for phase I to three pages while complying with all regulatory requirements, it was also able to present the information in an easily comprehensible format.

Concerning the specifics of the SIDCER ICF, the first principle mandates that each ICF must include all the required regulatory elements. To cover most types of clinical studies, the SIDCER ICF template was designed to use the three major international ethical guidelines and regulations – the ICH GCP (15), the Code of Federal Regulations (16), and the DoH (2013) (17). As previous literature has demonstrated, many ICFs being used in clinical trials, despite their extensive length, lack the information required for decision-making on the subject's part (2). Thus, the first principle of the SIDCER ICF could address these issues. By following the SIDCER ICF template when developing an ICF, investigators can ensure the validity of their ICF with respect to compliance with internationally recognised regulatory requirements. However, since the SIDCER ICF template adheres to only the three major ethics guidelines and regulations, it may be necessary for investigators to include additional information, such as extra elements required by local or national laws and regulations, in some settings.

The second principle of the SIDCER ICF emphasises the importance of limiting the extent of information provided in an ICF: only relevant information should be included. Excessive information, in contrast, may prove detrimental since the potential research subjects are less likely to digest and comprehend it. "Excessive information" or "information overload" may become equal to "no information" (18). Systematic reviews have demonstrated the effectiveness of an enhanced or simplified ICF in improving subjects' understanding (12,13), while some groups of researchers have raised concerns about the potential threat of a lengthy ICF to potential research subjects (1,4). A shorter form has also been demonstrated to be effective in helping the subjects retain more information (19) and proven to be highly satisfying for the subjects (20). In addition, the validity of a short form, with regard both to ethical and scientific aspects, has been demonstrated to be no less than that of a standard form (21). Taking all these factors into consideration, a short ICF that provides clear, concise, correct, coherent and complete relevant information would be preferable for use in clinical research. However, the application of this principle to all settings, without taking the contexts into consideration, may not be appropriate as some studies have shown that more information may be needed in an ICF for more sensitive groups, such as parents of children with cancer (22,23).

The third principle of the SIDCER ICF requires the integration of innovative methods (the use of a narrative format, boxes, colours and illustrations) when presenting relevant information in an ICF. An extensive review of the influence of colour on memory performance demonstrated the marked effect of the use of colour on the human memory (24). The literature has taken note of the usefulness of graphics or illustrations in enhancing subjects' comprehension and satisfaction (25,26). An ICF should not only provide relevant information in a short form, but should also present it in a simplified manner to effectively convey important information to the target population. The SIDCER ICF template was thus arranged to organise all pertinent information related to clinical trials in a simplified concise form, making it easier for investigators to develop an ICF based on the SIDCER ICF principles.

Conclusions

The quality of the SIDCER ICF based on the three principles as well as the developmental guideline would be assured with respect to compliance with internationally recognised regulatory ICF requirements, the appropriateness of the extent of information, and the simple format of information presentation. What is required is the validation of its applicability across a variety of clinical studies with different designs.

Statement of competing interests

We declare that we have no conflict of interest.

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*** Note :** Appendix 1 available from: htpp://ijme.in/pdf/appendix-1.pdf

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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