



Ethiopian Public Health Institute Scientific & Ethical Review Office

INFORMATION AND INSTRUCTION SHEET FOR PROPOSAL AND INFORMED CONSENT FORM PREPARATION, AND SUBMISSION TO EPHI-IRB SECRETARIAT OFFICE

EPHI-IRB has passed through SIDCER review process and received feedback that need to be addressed to improve quality of protocol review and determination processes; continuing review; documentation and archiving; and obtain accreditation. EPHI-IRB has accordingly revised the proposal writing format and proposal review process so as to meet the requirements of the accrediting body and continue executing its tasks in harmony with international standards. You are therefore kindly requested to rigorously go through this information and instruction; EPHI-IRB proposal writing format; Informed Consent Form template, which is adopted from SIDCER; and adhere to the instructions therein in the preparation and submission of a proposal to the Scientific and Ethical Review Office (SERO), secretariat office of EPHI-IRB, for subsequent review and determination.

Protocol preparation

1. Investigators, principal investigator in particular (PI), are expected to have the required academic background (discipline and degree) to execute the project. The principal investigator should also have the research experience to coordinate human resource, budget and logistics so as to meet the project objectives. If the PI is a student, s/he must include the advisors' name in the investigators' list, and describe them as advisor/supervisor in the responsibility section of the proposal,
2. Proposal/protocol must be prepared based on EPHI-IRB format, with all the details described (requirements) under each main heading and sub-headings (Annex 1 below),

Informed consent form preparation

Any project must be ethically acceptable for its execution. IRBs major responsibility is to ensure ethical acceptability of submitted protocols. The ethical considerations section in the body of the protocol and separate Informed Consent Form (ICF) are sections in which ethical issues need to be clearly addressed. Unless and otherwise, waiver of informed consent and/or assent is requested and allowed by the IRB, all projects involving human study participants must contain details of the informed consent/assent process as follows:

3. In the ethical consideration part, details of the ethical review process should be described. Answer must be clearly provided for the four "WH" questions (See Annex 1), and
4. There is a need to address basic elements of ICF (Annex 2). Although, there can be minor variations among ICFs based on the nature of projects, the following basic issues must always be addressed in a language that the study participant can understand in a clear and respectful manner BUT NOT to the interest/ease of researcher:
 - a statement that the study involves research,
 - title of research,
 - expected duration for the study participant's participation,
 - researchers involved,
 - purpose of research,
 - description of research,
 - foreseeable risks or discomforts to the participant,

- expected benefits to the study participant or others,
- treatment alternatives (if any) that might be advantageous to the participant,
- statement of privacy and confidentiality,
- information and data to be collected,
- data storage duration, how it will be stored and who can access it,
- voluntary participation, refusal to participate without penalty or loss of benefits to which the participant is otherwise entitled,
- right to withdraw from participation at any point without penalty or loss of benefit,
- costs and payments/compensations for participating in the study,
- contact addresses of principal investigator and a co-investigator for answers to pertinent questions about the research; and IRB office for research participants rights, and
- declarative statement of understanding that the potential participant agrees to and signs (if written).

Protocol and ICF Version numbers and date

5. Proposal and Informed Consent Form (ICF) should have the same version number during initial submission. Hence, include Version 01 and first submission date (DD/MM/YYYY) on full documents (proposal including tools and other annexes, and ICF) as footnote,
6. When comments are provided solely on the proposal (not on the ICF) and amended accordingly, the final submitted document will have Version 02 and date of final submission (DD/MM/YYYY) for the proposal but the same (initial) version number and date for the ICF (Version 01 and date (DD/MM/YYYY)). The same will be true if comments are provided on ICF but not on the proposal (changing Version number and date of the ICF but not proposal), and
7. When amendments are requested following approval, version number and date will also be changed depending on whether the amendment is made on the proposal and/or ICF.

Export of biological material

8. If biological specimens of any type are to be exported abroad, there is a need to attach Material Transfer Agreement (MTA) between **HEADS OF THE PROVIDER AND RECIPIENT INSTITUTIONS** (not individuals; investigators; case team or directorate heads) during initial submission of the proposal.

The MTA must include but not limited to the following information

- Objective and detailed activities to be executed with time frame.
- Details of the type and quantity of the biological material to be exported,
- Export of the material merely for research purpose indicated in the protocol,
- Distraction or returning the biological material to the provider institution soon after completion of the project,
- Use of biological material for any other purpose outside the specifics indicated in the proposal will be taken as violation of the agreement, and infringement of international research ethics principles. The matter can be taken to international and/or national tribunal and justice, and condemnation through different media outlets.

Language of data collection instruments and informed consent form

9. All data collection instruments and informed consent forms must be prepared in English,

10. Data collection instruments and informed consent forms (ICF) must be translated to local language, unless and otherwise, credentials of study participants unambiguously show that they are fluent in English and the data collection instruments are extremely challenging to be translated to local language,
11. If translation is found appropriate, both data collection instruments and ICF must be translated both to Amharic (obligatory) and main language being spoken in the study region. Ethiopia is rich in ethno-linguistic diversity. Researchers may however find it daunting to translate data collection instruments and ICF to local languages of all study communities. Given the feasibility and appropriate (technical) translation, studies to be conducted in Oromiya, Tigray and Somali regions must at least be translated to Oromifa, Tigrigna and Somali languages, respectively.

Collaborative projects

12. If projects are to be executed by two or more collaborating parties, the parties must sign memorandum of understanding (MOU) at the start of collaboration. The signed MOU must be submitted as attachment during initial protocol submission.

Project document submission for review and decision-making

13. Submit four bind hard copies (signed by the PI, all Co-investigators and head of the PI) and a soft copy of the proposal, and all other relevant documents including but not limited to informed consent form (if protocol involves human study participants); data collection instruments; material transfer agreement and memorandum of understanding among collaborating institutions executing the project as appropriate etc.,
14. Attach full CV of the PI and one-page summary CVs of all co-investigators during initial and final submission of the proposal,
15. The principal investigator or his/her designee need to complete protocol submission form, and obtain signed document receipt form from SERO during submission,
16. Supporting letter (including source of fund) from your respective directorate or Deputy Director General (NOT case team or individuals),
17. Ethical clearance certificate/letter if the project has already obtained approval from other IRBs or ethical committees, and
18. Other relevant documents.

Protocols unacceptable for submission

19. Commencing project (involving human study participants in particular) execution prior to obtaining approval from an IRB is considered as violation against international research ethics principles. Recruitment and training of data collectors are considered as part of the project, and MUST only be conducted after obtaining approval certificate from EPHI-IRB. SERO/EPHI-IRB will not receive protocols in which part of the aforementioned activities (part of the project) were executed before submission,
20. Protocols that are not prepared based on an updated version of EPHI-IRB protocol writing format, and
21. Relevant documents are not attached with the protocol.

Follow up of approved projects

22. Investigators must submit progress report on approved and ongoing projects as per the time specified in the approval certificate,
23. EPHI-IRB provides approval for ONLY one year for all protocols. Approval dates are always indicated in the certificate. Continuation request should therefore be submitted to and approval obtained from SERO for projects initially planned to be executed in one year but required for extension for any reason or projects with implementation period of

more than one year so as to continue execution of the project. Continuing execution of projects without prior continuation approval will be considered as ethical breach and investigators are liable for any subsequent negative measure,

24. Investigators must report Protocol Deviation/Non-compliance and Adverse Event as soon as possible. Serious Adverse Event (SAE) must however be reported to SERO within 48 hours of the event,
25. SERO and/or EPHI-IRB may conduct site visit in the project area or laboratory. Investigators are expected to include cost of travel and logistics in their protocol, create conducive conditions for the timely visit and collaborate for the successful accomplishments of the visit, and
26. Final reports must be submitted to EPHI-IRB or SERO within three months of completion of the project.

Protocol amendment

27. Any amendment required to be made by the investigator on the approved project should be reported to SERO using amendment request form and obtain written approval from SERO prior to execution, and
28. Deviation from the original protocol that might significantly affect the rights or interests of research participants and significantly impact the scientific validity of the data is considered as protocol violations. In such circumstances, the IRB may halt continuation of a previously approved protocol.

Declaration of conflict of interest

29. Investigators have the right to name EPHI-IRB member or alternate voting member or potential reviewer with whom they have conflict of interest, which may positively or negatively bias evaluation of their protocol. The PI must describe details of the conflicting interest in writing and submit to SERO. The protocol will not be sent to the specified person for review. The IRB member or alternative voting member may also be requested for recusal from the IRB meeting for discussion on the specific protocol/project, when the board decides after hearing the issue from the secretary and/or chairperson of the IRB, and
30. Investigators should disclose presence or absence of any conflict of interest they have in relation to the protocol/project. If they have any, the conflict of interest must be declared in detail.

When is protocol deviation acceptable?

31. Deviation from protocol is ONLY allowed to manage/treat a serious adverse event that endangers the participant's life or is presumed to result into serious or permanent disability and should be reported to EPHI-IRB.

Communications with SERO on any protocol/project related issues

32. The PI or his designee (written) should only directly communicate with SERO on any issues related with the protocol and project,
33. Investigators have every right to obtain information, except with confidential issues, and advice on their protocol review process etc. from SERO, and
34. Approaching EPHI-IRB or SERO by a third party whom one might wrongly understand can put pressure on the review and decision-making by the IRB is violation of national and international research ethics guidelines.

Premature project suspension or termination

35. Approved and ongoing projects may be suspended or terminated if part of the work was found executed prior to protocol approval,
36. When learning with proof of evidence that part of the project was executed prior to obtaining approval,
37. Projects being executed without continuation and amendment request and approval,
38. Failure of investigators to immediately report protocol deviation and adverse event, serious adverse event in particular, as specified elsewhere above,
39. Written premature suspension or termination request by the principal investigator or designee.

Additional notice

40. Failure to prepare the proposal as per the format (Annexes 1 & 2) will delay the review and IRB determination process. This will be the responsibility of the investigators, principal investigator in particular, but not secretariat office/EPHI-IRB.

Whistleblowing

41. EPHI is committed to the highest standards in its research, underpinned by the quality of the research process, from conception through to dissemination and application. The institute strives to see its researchers execute projects and disseminate the findings with the highest possible integrity. The institute strongly believes that research misconducts create “ripple effect” that can damage individuals, the public, the institute, the country, and global scientific community, at wider perspective. EPHI-IRB and SERO are very much responsible to ensure research is conducted and findings disseminated without any misconduct in the institute. Any person who obtained information on research misconduct by any EPHI researcher and projects that obtain approval from EPHI-IRB has the responsibility to blow the whistle/report the incidence soon to SERO.

Annex 1. EPHI-IRB proposal/protocol writing format with details

**ETHIOPIAN PUBLIC HEALTH INSTITUTE
INSTITUTIONAL REVIEW BOARD (EPHI-IRB)
RESEARCH PROPOSAL FORM**

Project no. _____ (Given By EPHI-IRB)

1.

Title:			
Person(s) undertaking the project in order of contribution			
Name	Qualification (Area of study & Degree)	Institution/Company	Country
Source of budget:		Total budget required:	
Contact address of the PI: Tel. Address, Email			
Contact address of first co-investigator: Tel. Address, Email			
Study period:	Date of commencement:	Date of completion:	
Institution at which study to be conducted and address: (Please include full address, telephone No. and e mail)			

NB: The first cited investigator is a principal investigator (PI) and the co-investigators should be listed below the PI according to their level of contribution

- 2. TABLE OF CONTENTS**
- 3. ABBREVIATIONS AND ACCRONYMS**
- 4. LIST OF APPENDICES**
- 5. SUMMARY (Summarize the research proposal in one page. Make it structured with introduction which includes purpose and hypothesis; objective; methodology; and expected benefit)**
- 6. BACKGROUND AND JUSTIFICATION:**
(Please include literature review, rationale/purpose of the study, research question(s) and hypotheses)
- 7. OBJECTIVE OF THE RESEARCH PROJECT**
 - 7.1. General Objective (synthesized from specific objectives)**
 - 7.2. Specific objectives**
 - 7.2.1. To ...**
 - 7.2.2. To ...**
 - 7.2.3. To ...**
- 8. MATERIALS AND METHODS**

(This should include all major aspects such as details of study setting/area; study period; study design; source population, study population and study participants; Inclusion criteria (Sampling characteristics that the prospective study participants must have if they are to be included in the study) and Exclusion criteria (those characteristics that disqualify prospective participants from inclusion in the study); sampling/participant recruitment methods and procedures; sampling size calculation; independent and dependent variables; laboratory procedures with references; data collection tools and standard analytical techniques; data quality control measures; operational definitions; etc. as appropriate)
- 9. STRENGTHS AND LIMITATION OF THE STUDY**
- 10. COMMUNICATION AND DISSEMINATION OF STUDY FINDINGS**
(identifying stakeholders or target groups; selecting appropriate dissemination channel(s) such as reports, peer reviewed articles, presentations etc.)

11. ETHICAL CONSIDERATIONS AND REVIEW PROCESS

(If the project involves human study participants, please attach standard/detailed information sheet, consent form, and assent form for 12 to 18 years old participants).

You are also required to describe:

- Whether you will use oral or written informed consent. Written consent is highly preferred unless any possible breach in confidentiality might expose the study participant to risks such as self embarrassment, stigmatization etc.
- Any possible risk on the participant and/or community and means of its minimization,
- Presence and absence of any benefit of the study for the participant, specific population group and generating generalizable knowledge, and how to maximize the benefit. Absence of any benefit should also be described.
- Vulnerability of the study participants and how you will provide extra protection. The vulnerable populations refer but not limited to children (under 18 years old); pregnant women; fetuses; prisoners; employees, military persons and students in hierarchical organizations; terminally ill; comatose; physically and intellectually challenged individuals; persons with incurable diseases; institutionalized persons (as prisoners and those confined in mental institutions); elderly individuals; visual or hearing impaired; ethnic minorities; refugees; persons under emergency or disaster situations; economically and educationally disabled. Please also indicate if study participants are not vulnerable.
- Describe the informed consent process using Who, When, Where and How questions as follows:
 - **Who:** **Who** should present and obtain the informed consent? Principal Investigator and/or Study personnel designated and trained by the PI. Can be co-investigator or other recruited data collector (based on data to be collected and parallel required academic background and experience) who is appropriately trained and intimately familiar with protocol.
 - **Where:** **Where** should the informed consent obtained? Best practices are comfortable setting; private; neutral; with or without family/friends as per participants' wish. Optimize based on these above best practices and provide adequate time
 - **When:** **When** should the informed consent obtained? Consent before any study procedures are performed; Questions and concerns of the participant are answered; Discussion made with family, friends and others as participant wishes; Adequate time for consideration; Convenient time for the participant are allotted. Re-consenting may be required when new information is learned, during the course of the study that may affect the participant's willingness to continue participation
 - **How:** How should we approach participant to obtain informed consent? Provide non-judgmental, safe and welcoming environment; Friendly approach; Know your target audience/participant and adapt appropriately; Avoid using technical words or scientific jargon; Use demonstrations using local materials; Speak clearly and slowly; Assess comprehension as you move; Avoid undue influence or Coercion; Finally, document the Informed Consent and maintain confidentiality.

These four questions must be answered in this section. The Information sheet, consent and/or assent forms must also be prepared in detail separately.

Put the following contact address for the participants in the information sheet:

- For any questions related to the study or you experienced any adverse event before/during/after participation in the study

PI's full name _____

Cell phone address _____

Email Address _____

First co-investigator's full name _____

Cell phone address _____

Email Address _____

- For any ethical complaint and your right
Ethiopian Public Health Institute/EPHI
Scientific and ethical Review Office/SERO
EPHI-IRB [Tel:+251 118685503/15](tel:+25111868550315)

12. IMPLEMENTATION OF THE PROJECT (as Gantt Chart):

(Give breakdown of the project to tasks/major activities, estimate the amount of time which will be required to execute the respective major activities, and present an approximate time table for its accomplishment as Gantt chart)

13. COST OF THE PROJECT WITH COMPLETE BUDGET BREAKDOWN (This should include detailed calculation of expenses on salaries, travel expenses, expendable and non-expendable materials and equipments, as well as miscellaneous expenses)

14. BENEFITS OF THE STUDY RESULTS

(Please state the expected results, potential consumers of results and means of delivery of results to the consumers)

15. FACILITIES AVAILABLE FOR THE STUDY (MAJOR FACILITIES)

16. AUTHORSHIP RIGHT

17. DECLARATION OF CONFLICT OF INTEREST (Mention as: "We declare that we have no conflict of interest" or No, I don't have conflict of interest to declare," if you don't have any; or "Yes, I do have conflict of interest to declare" and describe all the relevant facts and circumstances you consider give rise to a real or apparent conflict of interest)

18. REFERENCES (Use Harvard referencing style and make sure you have included all the references cited in the body of the proposal and vice-versa)

19. ASSUMPTIONS, RISKS AND MITIGATION ACTIONS

20. ASSURANCE OF THE PRINCIPAL INVESTIGATOR:

I the undersigned agree to accept responsibilities for:

- The scientific, ethical and technical conduct of the research project,
- Requesting amendment for ANY change on the protocol that might need to happen during execution of the project, and obtain written approval for the request from EPHI-IRB,
- Submitting progress report every year and technical report within two months after completion of the project,
- Reporting any adverse event that might happen to the study participants, data collectors, supervisors and coordinators during investigation,
- Submitting scientific publications that emanate from the project within two months of publication, and
- Reporting any unprecedented protocol violation within seven days of event if the project is approved as a result of this application.
- Submitting raw cleaned data to EPHI Data Management Center after writing the final report (Only for EPHI and collaborative projects)

Name _____ **Signature** _____

Date _____

21. COMMITMENT FOR AND SIGNATURE OF CO-INVESTIGATORS.

Name	Specific Roles and Responsibilities	Signature
1. _____	_____	_____
2. _____	_____	_____
3. _____	_____	_____
4. _____	_____	_____
5. _____	_____	_____
6. _____	_____	_____
7. _____	_____	_____
8. _____	_____	_____

22. COMMENT AND CONCURRENCE OF THE RESPONSIBLE HEAD FOR PRINCIPAL INVESTIGATOR.

Name_____ **Signature**_____ **Date**_____

23. ATTACH MEMORANDUM OF UNDERSTANDING (If the project is to be executed by two or more collaborating parties)

24. APPENDICES (Cite all appendices in the body of the proposal; Attach all appendices under this section)

Annex 2. SIDCER Informed Consent Form Template

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

<p>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.</p> <p>_____</p> <p>Printed name of the participant</p> <p>_____</p> <p>Signature of the participant</p> <p>Date _____</p> <p style="text-align: right;">day/month/year</p>	<p>I confirm that the participant was given an opportunity to ask questions about the study and all questions have been answered correctly. I confirm that the consent has been given voluntarily.</p> <p>_____</p> <p>Printed name of the person taking the consent</p> <p>_____</p> <p>Signature of the person taking the consent</p> <p>Date _____</p> <p style="text-align: right;">day/month/year</p>
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Adopted from: Koonrungsesomboon N, Othavorn J, Chokevivat V, Hirayama K & Karbwang J (2016). SIDCER informed consent form: principles and a developmental guideline. Indian Journal of Medical Ethics I (2): 83-90.