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Checklist, Document, Explanation, Research Participant Information Sheet (Patient Information Sheet)

Central Committee for Human Research Ethics (CREC)

Project name	
Head of the main research project	
Affiliation	

Please check and check ✓ the box in ☐ front of the list to speed up document management.

	General format
☐	If a translation program is used, the translation has been verified to be correct by someone knowledgeable in the research topic.
☐	It has been verified that common language is used that is easily understood by the general public.
☐	It has been verified that no English, medical or technical terms are used. If necessary, they must be explained in a way that is easily understood by the general public.
☐	It has been verified that the details in the document are consistent with those specified in the research project proposal.
☐	It has been verified that there is no unnecessary detail that would be too much of a burden for the research participants.
☐	When creating a document for the first time, identify the document as Version 1.0 and include the date, month, and year of creation. If there are any revisions, change the document version and include the date, month, and year each time there are revisions.
	Unique format
☐	There is a clear statement that this is research, explaining the freedom of decision-making in participating in the research, that it is voluntary, and that there will be no punishment or loss of benefits for not participating or withdrawing from the research.
☐	There is a title Name of the principal investigator , affiliation , and 24-hour contact telephone number .
☐	Research location
☐	Research Funder/Research Product Sponsor (If none, please state “No Sponsor”)

☐	state the reasons and necessity for conducting the research and its relevance, including the research objectives.
☐	The reason (qualification) for which the person was invited to participate in the research. and the number of research participants
☐	How research will be conducted with research participants (Relevant parts only) The total time spent in the research, the number of times and the frequency of travel to meet with the researcher. In cases where there are many steps or it is complicated, it should be summarized in a table or diagram for easy understanding.
☐	The number of times blood draws or procedures were required (if any), along with the amount of blood drawn each time and the total amount (specify in teaspoons, tablespoons, or cups).
☐	Withdrawal from the research can be made at any time without having to give a reason, and the researcher can terminate participation in the research if a potentially dangerous condition is found or the participant does not comply with the agreed-upon procedures.
☐	Criteria for cessation of research participation, guidelines for managing such events and management guidelines when research participants request to withdraw from the research
☐	Potential benefits of participating in research Both directly to the research participants, to the profession and to the public.
☐	The risks and discomforts that may arise from participating in the research and their precautions, including identifying any unknown or unforeseen risks, such as drug allergies, risks to the fetus or to the breastfed infant (if applicable).
☐	Guidelines for care and compensation In the event of danger or adverse effects resulting from participating in research Responsible persons and what research participants will receive
☐	Alternative options in case you do not voluntarily participate in this research Especially the practices or care that will be received
☐	Compensation for lost time, travel expenses, etc. The rewards will be paid for participating in the research, which are not too motivating and are paid in installments each time the research participant comes for an appointment. In addition to regular check-up appointments
☐	Information is available about the additional costs that research participants will be responsible for, in addition to their usual care.
☐	Confidentiality and limitations on confidentiality of health information, including who can access the information (e.g. funders, ethics committees, etc.)

☐	If there is any new information regarding the benefits or risks that may affect the decision to participate in the research, you will be informed promptly and without concealment.
☐	If there are clinically useful research results, including individual results, will this be communicated or not ? How?
☐	Contact channels for researchers, which include the name and telephone number that can be contacted at all times in the event of danger, adverse effects, or questions about rights/complaints.
☐	Procedures if research participants feel they have not been treated fairly and channels for making complaints to the Research Ethics Committee
☐	Management of research participants' data and biological samples after the research is completed
☐	Information related to clinical trials is registered and available on the ClinicalTrials.gov website.
☐	The signature and date of (1) the person who will participate in the research, (2) the researcher requesting consent, (3) the witness, if verbal explanation is used, to ensure the participant understands (4). A legal representative in the event that the prospective research participant is unable to sign, and (5) a legal guardian (if applicable).
	other
☐	separate information and consent form must be prepared and submitted for consideration , containing complete information as per the FERCIT Template (fercit.org/template.htm) in the following cases: - Participation in optional research projects - A statement and consent form for the partner of a pregnant research participant if the researcher or the partner of a pregnant research participant is to be followed up to collect data on the pregnant researcher or the partner of a pregnant research participant in cases where there may be a risk. - A document clarifies and requests broad informed consent if data and biological samples are to be collected for future research.
☐	Consideration is given to reviewing and amending various documents to comply with the frequently asked questions at the end of this document.

Signature of Evaluator ..... (Researcher / Project Coordinator)	date .....

Frequently asked questions

Format for preparing research participant information documents and consent letters

As the research project is multi-institutional, a document explaining the research participants and a letter of consent are required for every research center collecting data in the research project. The committee accepts the following document formats:

- The research participant information document (PIS) in the master country contains sufficient research project information for the volunteers to decide to participate in the research project.
- An informed consent form (ICF) containing site-specific information and a signed consent form to participate in the research project is included in the same document.
- Create PIS + ICF (Site specific) for each document type such as main, pregnant partner, optional research, etc.
- Site-specific information includes (1) a list of the research project leaders and/or co-researchers and 24- hour contact telephone numbers of the hospital or research center where the data were collected; (2) the name of the institutional research ethics committee overseeing the research conduct of the hospital or research center where the data were collected, along with the location and contact telephone numbers of each institution; and (3) the Central Research Ethics Committee (CREC), 196 Moo 5, Phahonyothin Road, Lat Yao Subdistrict, Chatuchak District, Bangkok 10900, Tel. 098-325-2765 , 082-258-9529, email official@crecthailand.org.

All types of explanatory documents

Name, address and contact telephone number of the researcher

- number must be provided in the event of danger, adverse effects, or questions regarding the research. The number should not be 02, as it may not be truly contactable 24 hours a day.
- Identifying telephone numbers Must be in accordance with Thai standards , such as “Telephone: ~~+66~~ 0 2 579 0117 Mobile phone: ~~+66~~ 0 98 325 2765”

Address and contact telephone number of the committee

- The name, address, and contact telephone number of the Institutional Research Ethics Committee must be included in all documents of every type for each research center . The correct name and address of the Institutional Research Ethics Committee can be checked according to the information in 06.0_Database_contact_Local EC update 4.xlsx (sharepoint.com).

Use of language : The entire document should be checked for typos.

- The language and content of the document should be written in Thai language that conveys meaning according to grammar principles. Avoid using text that is translated directly from a foreign language because it will make it difficult to read and understand. It may lead to a misunderstanding of the research project and not in line with the objectives of the research project.

All types of explanatory documents
• Remove unnecessary English words in parentheses , such as end-stage renal disease ~~(ESKD),~~ etc. , including technical or medical terms. If necessary, they should be translated into Thai or explained in easy-to-understand Thai. If there are Thai translations or Thai transliterations, remove the English words, such as: “eGFR value ” “IP address ” “Device ID ”
• When using abbreviations, the first time they are mentioned, they should include the full word (abbreviation), such as milliliter. (ml.) Then the following words can be abbreviated. To make it easier for volunteers to understand
• Avoid and correct the use of imperative phrases in writing, such as must, must, etc.
• Consider separating " treating physicians " “ Your doctor ” and “ Researcher ” To be consistent with the context and consistent throughout the document to reduce confusion. • Consider using “your family doctor ” or other pronouns that are consistent with the Thai social context .
• The term treatment may be used as “research” or “research drug” or other terms. It is appropriate if the context is related to research, so as not to confuse volunteers with standard treatment. • Use the term "education group" instead of "treatment group " .
• The pronoun “patient” referring to volunteers should be “volunteer” or “you” as appropriate to the context of the message and consistent throughout the document.
• The terms “…. local law”, “ local regulations” should clearly state what the locality is. For example, in Thailand , in hospitals Research Center • Organizations or agencies such as “vendors”, “national health agencies”, who are they referring to, and which agencies must be clearly identified.
• The text “Thai Food and Drug Administration (Thai FDA)” is “Food and Drug Administration”.
• Consider “by ticking ”☐ Yes ” is “agree” means that I give my consent And check the box “☐ No, it is “not consent”. means that I do not give my consent.” To be consistent with the context

Main explanatory document
Reasons for inviting to participate in research
• It should not be a translation from English that is difficult to understand and too long. It should be concise and important.
Participation in the project is voluntary. Right to participate/refrain from participating in the research.
• There must be a statement explaining that volunteers are not coerced into participating in the research project and can freely decide whether or not to participate and have sufficient time to make that decision.

Main explanatory document
Volunteer conduct procedures
• It is important to emphasize only those related to research. Routine medical examinations should not be mentioned, as this can lead to confusion. • There should be a research progress summary table/activity table. In Thai, so that volunteers can understand what they need to do. • It should be stated how many visits (appointments) the volunteer will have to make to the research physician, whether they will be during regular appointments or at out-of-schedule appointments, and whether the volunteer will be compensated for travel if these are out-of-schedule appointments. • It should be stated how many additional times each questionnaire will take, how many minutes each questionnaire, and how many times in total it will take, so that volunteers/relatives are aware of the additional burden.
Randomization into study groups
• It should be explained in a way that is easy to understand according to the Thai context, such as randomly drawn from a box or jar. Random ball selection, random draw
Blood test
• The amount of blood samples to be collected at each appointment and throughout the research project should be specified to inform volunteers, using units of ... Milliliter (... teaspoon/tablespoon) • Vague information such as collecting a small amount of blood sample should not be specified.
HIV and hepatitis testing
• In cases where research projects require HIV and hepatitis test results, in Thailand there are no requirements for reporting. This should be removed to reduce confusion among volunteers.
Risks and complications
• Phase 1 FIH research projects , the introduction should state from the first page that the research drug has not been tested in humans before and there is no information on any side effects of the research drug. This should make volunteers aware and use this as a consideration for participating in the research project. • Risks of investigational drugs: Are there any risks that are commonly, frequently, or frequently reported? These risks should be listed so that volunteers are aware of them and can monitor their symptoms.
Alternative options if not participating in the project
• It should include language that indicates that volunteers can freely withdraw from research participation at any time, without giving any reason, without penalty, and without losing any future rights or benefits.

Main explanatory document
• There is sufficient time to make a decision and it will not affect any future medical treatment.
Compensation for injuries resulting from research
• FERCIT guidance on the Care and Compensation of Research Participants Should They Be Injured or Disadvantaged by Research Participation should be used. • The sponsor of the research will be responsible for the costs incurred by the participant in the research . If insurance is not provided, the sponsor must clearly identify the person responsible for these costs. The volunteer must not be responsible for these costs.
Travel expenses / compensation for volunteers
• It should not be stated that compensation will be given for research participation. It should be used as compensation for time/travel expenses/research participation and should be specified when it will be given. It should not be given to volunteers at the end of the research. It should be given each time they meet with the researcher to avoid coercion to complete the research. • Please remove any ambiguous text that will require the volunteer to interpret. Such as reasonable travel compensation • If telephone follow-up is required, volunteers must be informed whether compensation will be provided for their lost time. • Please add this section and clearly state that there are no cases where the research project does not provide travel/compensation expenses to the volunteers.
Expenses that research participants must pay themselves
• This section must be included and clearly stated that there will be no cost for participation in the research project. • It is clearly stated that for treatment and assessment purposes Normally, volunteers are responsible for these expenses. • The wording “ Test ” should be changed to “ Standard care ” to clearly state that in all research, the sponsor is responsible.
Confidentiality of volunteers
• The period for keeping the volunteers' data should not be specified as "at least X years". It could be specified as "not more than X years after the end of the research" or "at least X years but not more than X years", etc., or as actually required by law, because the word "at least" may lead to the understanding that after X years, the researcher may continue to collect data. etc. • Additional information on contacting the Personal Data Protection Agency is as follows: “The agency responsible for protecting personal data is the Office of the Personal Data Protection Committee (PDPA), Ministry of Digital Economy and Society, which is an independent organization responsible for overseeing personal data. If you have any questions about the PDPA or have a complaint, you can contact us at 02-111-8800 and via Email pdpc@mdes.go.th “

Main explanatory document
• Add text on personal data management to comply with Thailand PDPA , such as: " In accordance with the Personal Data Protection Act and other relevant laws in Thailand, you have the right to access the information about you that the researcher has collected and maintained. You also have the right to request that any information you disagree with be corrected. Please contact the researcher if you would like to access your information. "

Other issues in the main explanatory document
• <u>In cases where it is stated that there will be an additional optional examination,</u> it should be considered that it must not be part of the main research (if yes , then the action in this section is necessary, not optional). However, if it is not, then it is part of the additional optional. Please separate the explanatory document for future optional research from the main document.
• <u>In cases where data or biological samples are collected for future use</u> This section should not be included in the main document and details related to future research should be provided in a separate document from the main document . It must clearly state what biological samples will be stored for future research , such as blood samples, cancer tissue samples, urine samples, and if additional blood tests are performed, the blood volume must be clearly stated.
• Although the purpose of future research cannot be clearly stated, stating "health science research only to find new methods for diagnosing, treating, preventing, or solving health problems" may be too broad. The scope of the data and sample collection objectives for future studies related to the investigational drug or disease involved in the current research study should be clearly specified . A guideline and template document for information and consent for clinical research in Thailand (Broad Informed Consent Form for Storage and Use of Data and Biospecimens for Future Research) can be found at http://www.fercit.org/template.htm.
• The information provided in the separate explanatory document should be clearly and concisely stated to volunteers. It should not be redirected to the main document .
• The word "donate" should not be used. It should be "give".
• Avoid personal identifiers such as date of birth (only year of birth is acceptable) in documents such as invitations, diaries, questionnaires , etc.

Explanatory document for genetics research
• <u>In cases where it is stated that genetic/genetic testing or other</u> genetic testing will be performed, it should be considered whether this is part of the main research or not. If so, is this consent required? Because it is part of the main research, it is not an optional item. However, if it is an optional item, please separate the explanatory document for the optional biopsy from the main document.

Explanatory document for genetics research
• Any statements regarding genetic testing/genetics or other genetic testing should be separated from the main explanatory document.
• The risk information may lose privacy and confidentiality because WES, WGS are personally identifiable information.
• Although the purpose of the alternative genetic research study cannot be clearly stated, the statement that "genetic research is important for scientific and public health development" may be too broad. Consideration should be given to clearly stating the purpose of the genetic data analysis as being relevant to the investigational drug or disease involved in the study.

Explanatory documents for relatives or caregivers
• should be considered to be relevant to the reader of the document, for example, using the term "patients under your care" if referring to the patient.
• The activities of the relatives or caregivers should be considered , as they may not be the same as those of the other group of patients who volunteer. Specific activities that the relatives or caregivers are expected to do should be clearly stated.
• Compensation for travel or lost time should be clearly stated whether the group, relatives or caregivers will receive it or not. If the project considers providing it only to the patient group, it should be stated in the documents for the relatives or caregivers that there is none.

Volunteer Access and Consent Process
• Specify the method of informing the attending physician/related physician of the participant's participation in the research project.
• It should explain how volunteers are approached to encourage them to identify where volunteers are recruited, what methods are used, and so on. ○ Further explain the process of who provided the information and obtaining consent if the researcher is the treating physician, to avoid undue influence. ○ Researchers must inform volunteers that this is a research study and not a routine medical treatment. The volunteers must be informed before deciding to participate in the research, and clearly state which parts of the process or steps are standard routine medical treatment and which parts are additional research processes or steps.
• Consent request process: The consent request location should be a private room, not crowded .
• Specify clearly that The person requesting consent from the volunteer must not be the attending physician.
• In cases where volunteers are vulnerable and lack or are unable to understand the details of the research project, before deciding to give consent to participate in the research, details

should be provided as to who will be asked: the volunteer or the patient, or whether the request must be made verbally or in writing from a legal representative, a relative or caregiver.

Explanatory document for research studies in children

For research projects involving minors and requiring written informed consent, a document explaining the volunteer information and consent form should be prepared , divided according to the age range of the research participants as follows :

- For research participants who are children aged from birth to 6 years (less than 7 years) , parental consent is requested without the need to prepare any documents for children .
- For research participants who were children aged 7-12 years (7 years of age but under 13 years of age) Prepare documents for the child (Assent form) separate from the information statement and consent request document for the parents .
    - Assent forms should be formatted and language appropriate for the age group. They may use large fonts, charts, or pictures to make them easy to understand, and should be limited to one or two pages in length.
- For research participants who were children aged 13-17 years (13 years of age but under 18 years of age) Use the information sheet and the consent letter for research participation for children and parents. Read and sign the same document .
    - The materials for teens can contain the same content as adult volunteers because teens have a similar level of understanding to adults.
    - If the researcher wishes to prepare a separate set of documents for the child from the parent 's version , this can be done as appropriate to the research design and the child's condition.

In providing information, researchers should take into account the child's age, intelligence, comprehension ability, social and cultural background, and the child's experience with illness, along with the complexity and risks of the research. Furthermore, appropriate language should be used to ensure that children can understand the information according to their developmental stage.