MINIMUM information that should be available in a clinical trial protocol

1. **Title** in PICO format (Participant - Intervention - Control - Outcome)
2. **Investigators**
   2.1. Identify the principal investigator and co-investigators
   2.2. Name, address, contact details, designation, institutional affiliation, qualification, area of expertise and experience
   2.3. Prior experience with clinical trials
   2.4. Good Clinical Practice (GCP) certificate (A requirement for all investigators of the clinical trial, conditional approval will be granted pending GCP certificates)
   2.5. Role of each investigator in the conduct of clinical trial
   2.6. Recent short CV (1-page document)
3. **Other personnel:** Name, qualification, designation, area of expertise, role in the clinical trial (e.g.; data collector, translator, etc.)
4. **Clinical trial setting:** Adequacy of facilities for safe and appropriate conduct of the clinical trial: Confirmation letter (confirming the facilities) from the chief administrative officer of the setting
5. **Background**
6. **Social value** of the trial question
7. **Literature review**
   7.1. Should be detailed with accurate references.
   7.2. Should summarize all possible previous studies on the topic both published and unpublished (if applicable), including the nature, extent and relevance of animal studies and other preclinical and clinical studies (if applicable)
8. **Justification**: Very important. The proposal should give accurate and up-to-date information justifying the need for the said clinical trial. Protocol also should address how the outcome of the trial would influence management, prevention or health policy. It also should state overall aim of the clinical trial. (CIOMS: A clear statement of the justification for the study, its significance in development and in meeting the needs of the country /population in which the research is carried out)
9. **(Western medications):** Type of clinical trial: Pre or post marketing, if post marketing the reason for the trial with justification (e.g. new indication, new information, new formulation)
10. Detailed description of the design of the study including superiority, inferiority or equivalent with reason

11. Research question
12. **Null hypothesis** (should include PICO with effect size for the outcome): Example: In children under the age of 5 years with asthma, the difference in school absenteeism between children treated with medicine X and children treated with medicine Y is not more than 5 days in a month (this is one way, but there are many other ways that you can write the hypothesis)
13. **Trial participants**: Case definition, inclusion criteria, exclusion criteria (*Inclusion and exclusion criteria should be based on science and not based on convenience, providing informed consent is not part of inclusion criteria)*
14. Justification for the exclusion of any groups on the basis of age, sex, social or economic factors, or for other reasons
15. Process of recruitment of trial participants (if applicable, submit recruitment flyer/poster/ leaflet in all 3 languages). The process of recruitment, e.g. advertisements, and the steps to be taken to protect privacy and confidentiality during recruitment
16. Provide evidence for fair subject selection
17. If trial participants are vulnerable population, additional information including justification, addressing the vulnerability, informed consent process, confidentiality, risk vs benefits assessments should be documented
18. **Intervention**: Information required depends on the nature of the intervention (See Annexure 1)
19. **Control/Reference**: This is also considered as an investigational product. Provide details similar to the intervention. In composition, placebo should be similar to the interventional investigation product except the active ingredient. If the control is standard care, provide details of the standard care. Provide evidence that the given standard care is the one which is available for patients in Sri Lanka. If active comparator, details as for the interventional product.
20. Source of continuous supply of the investigational products
21. Justify use of placebo/standard care in one arm
22. **Primary outcome**: Definition, scientific validity, reliability, measurement, scale/tool used, when measured, who measures, if investigations where the investigations are done, etc.
23. **Secondary outcomes**: Same details as for the primary outcome
24. Trial end points (if different from the primary outcome)

25. **Sample size calculation** (all the parameters should be provided). Effect size should be justified. Prior references (if applicable) should be cited. Loss to follow up should be considered. Feasibility of recruiting the required sample size should be provided
26. Details of randomization and how it will be implemented
27. Study procedure (follow the CONSORT[1] flow chart for reporting) and personnel responsible for each step
28. Details of blinding and how it will be implemented, Breaking the blinding
29. Details about concealment of allocation
30. Ethical considerations (PI's assessment of ethical considerations)
    - 30.1. Social value
    - 30.2. Scientific validity
    - 30.3. Autonomy
    - 30.4. How informed written consent will be obtained *
    - 30.5. Addressing the vulnerability
    - 30.6. Confidentiality
    - 30.7. Privacy
    - 30.8. Risk versus benefits assessment (benefits should be direct benefit from the trial)
    - 30.9. Fair subject selection
    - 30.10. Collaboration
    - 30.11. Post-trial benefits (Provision for continued access to study interventions that have demonstrated significant benefit, indicating its modalities, the parties involved in continued care and the organization responsible for paying for it, and for how long it will continue)
31. Ensuring safety of participants (Definitions, reporting process, handling the adverse events, reporting time lines, insurance, actions to be taken, treatment facilities, compensation, etc.)
32. Plans and justification for withdrawing or withholding standard therapies in the course of the research, including any resulting risks to persons (if applicable)
33. Any other treatment that may be given or permitted, or contraindicated, during the study
34. Clinical and laboratory tests and other tests that are to be carried out
35. Plan for follow up
36. Rule or criteria for termination of trial, withdrawing participation, discontinuing a centre, etc.
37. Data and Safety Monitoring Board: Members, short CV, TOR, declaration of CoI
38. Details of data collection, sample processing

39. Study instruments (validity, reliability, etc) if applicable
40. If laboratory investigations are included, details of the laboratory (including certificate of accreditation, etc.) to be provided
41. Plan for data analysis – Based on the null hypothesis and outcomes. Intention to Treat analysis or per protocol analysis, Statistics
42. Costing – Confirmation that participants will not be bearing the cost
43. Sponsors- Role of Sponsors, ToR, Agreement, CoI, etc.
44. Site specific information (if multinational trials)
45. Dissemination of results, plan for registering with a clinical trial platform, publication policy: Particularly in the case of an industrial sponsor, a contract stipulating who possesses the right to publish the results of the study, and a mandatory obligation to prepare with, and submit to, the principal investigators the draft of the text reporting the results)
46. In the case of a negative outcome, an assurance that the results will be made available, as appropriate, through publication or by reporting to the drug registration authority
47. Plans to inform participants about the results of the study
48. Source of funds and budget
49. Declaration of conflicts of interests
50. An account of any economic or other inducements or incentives to prospective participants
51. Patient and public involvement and engagement (PPIE)
52. Data management (ensuring quality of data)
53. References

* ***(CIOMS)***
The means proposed to obtain individual informed consent and the procedure planned to communicate information to prospective participants, including the name and position of the person responsible for obtaining consent
When a prospective subject is not capable of informed consent, satisfactory assurance that permission will be obtained from a duly authorized person, or, in the case of a child who is sufficiently mature to understand the implications of informed consent but has not reached the legal age of consent, that knowing agreement, or assent, will be obtained, as well as the permission of a parent, or a legal guardian or other duly authorized representative

1. BMJ 2010;340:c869 doi: 10.1136/bmj.c869

Annexure A.1.

When the Intervention is medicines which come under the purview of the National Medicines Regulatory Authority (NMRA)

A.1.1. Post-marketing (medicine is registered with NMRA):

- ❖ If the aim is to obtain new information: Evidence should be provided regarding the social value of the new information and justification to seek the new information. Detailed literature review is to be submitted.
- ❖ If the aim is to test for unauthorized indication: Evidence for the proposed dosing schedule, justification for the new indication, literature review on prior use for the proposed indication, etc. need to be submitted
- ❖ If the aim is to test the medicine which is assembled (dosage form, manipulation, etc.) differently from the authorized form: Evidence for the modified formulation, Justification for the modified formulation, additional studies of the formulated product(s) (e.g. stability, dissolution rate, bioavailability) to assess whether these changes would significantly alter the pharmacokinetic profile of the medicine, evidence for the proposed dosing

For all three categories, the following information need to be provided

1. Brand name (if applicable)
1. Generic name
2. Dose
3. Dosage form
4. Route of administration (IV- Rate of administration)
5. Dosing interval / frequency
6. Duration
7. Registration status: Registration certificate to be submitted
8. Precautions, risks, etc.
9. Single source of supply
10. Storage
11. Quality
12. Dispensing
13. Administration
14. Adherence
15. GMP if applicable

A 1.1.2 Pre-marketing (medicine is not registered with NMRA): Phase III

1. Sufficient safety and efficacy data in pre-clinical and prior clinical trials
2. GMP
3. Applicable GMP
4. Coded and labelled to protect blinding
5. Labelling
6. Storage
7. Temperatures, storage conditions (e.g. protection from light), storage times, reconstitution fluids and procedures, and devices for product infusion
8. Packing
9. Coding in blinded trials
10. Trial pharmacist
11. Investigators' brochure
12. Written instruction to PI about the procedures for adequate and safe:
    a. Receipt, Handling, Storage, Dispensing
    b. Retrieval of unused product from subjects
    c. Return of unused IMPs to sponsor or alternative disposition (approved by the regulatory authority)
13. Plans for
    a. timely delivery
    b. maintaining records
    c. shipment, receipt, disposition, return, and destruction of the investigational product
    d. maintaining a system for retrieval for deficient product recall, reclaim after trial completion, expired product reclaim
    e. maintaining a system for the disposition of unused IMPs
    f. ensuring continuous supply
    g. ensuring that the product will remain stable
14. Serial number of the product (as name would not have been given)
15. Dose
16. Dosage form
17. Route of administration (IV- Rate of administration)
18. Dosing interval / frequency
19. Duration

Note: The CTSC may demand additional information not listed above if deemed necessary

Annexure A.2: If the intervention is related to behavioural therapy/communication or having some form of psychological dimension

1. Clear definition/ description/ operationalization of construct/s being measure
2. Alignment of objectives, intervention/ therapy and study outcomes, in relation to theoretical basis
3. Validation details of outcome measures/ clear description of development/ adaptation process of measures that have not been validated
4. If intervention/ therapy is developed by the PI
    a. clear description of steps involved in development process
    b. theoretical basis for development/ review of literature which provides scientific basis for components of intervention/ therapy
    c. if expert panel involved in development process, qualifications/ training of such persons to provide such expertise
5. Delivery of therapy/ intervention
    a. details of sessions, mode of delivery, expectations of participants
    b. qualifications/ training of persons involved in delivering such interventions/ involved in assessing behavioural outcomes
    c. Indicators to monitor if participants have been exposed to the identified intervention/ therapy- e.g., number of sessions they have participated in/ number of hours of engagement/ if homework activities included, degree to which these should have been completed
    d. Training and adherence
6. Details regarding how suitability to be subjected to intervention/ therapy will be assessed
7. Procedures put in place for those who experience negative effects of therapy/ intervention and safeguards put in place for participant
8. Study tools (locally validated, etc.)
9. Participant perspectives of feasibility, acceptability, accessibility, and safety

Annexure A.3: If the intervention is diet/nutritional therapy

World Health Organization (WHO) classification of nutritional interventions

1. Behavioral interventions (modifying eating habits by changing them)
2. Fortification (addition of nutrients to basic foods)
3. Supplementation (administering a specific nutrient to a specific population)
4. Regulatory interventions (regulating certain activities in order to modify nutrition and improve health)

A diet/ nutritional therapy would contain multiple constituents/ substances within the same diet/ supplement.

Information needed to support a clinical trial for diet/nutritional therapy

1. Details on specification of the interventional product and placebo (where relevant) are needed
2. Details on product manufacture with quality specifications whenever necessary including the method of manufacture of the dietary supplement/ nutritional therapy
3. General details of the food / food additive used in the clinical trial (Need to ensure that the intervention planned should align with the relevant dietary guidelines/ recommendations that are already in place)
   3.1. Proposed dose
   3.2. Dosage form
   3.3. Method of preparation (if applicable)
   3.4. Route of administration
   3.5. Dosing interval / frequency
   3.6. Duration of treatment
   3.7. Precautions to be taken
   3.8. Storage conditions (prior to administration and any storage of product in use)
   3.9. Method of ensuring adherence to therapy
   3.10. Packaging/ storage
   3.11. Registration status with the NMRA if indicated
   3.12. Absorption, metabolism, tissue deposition and routes for excretion
   3.13. Half-life in the human body

3.14. Interactions with other food and drugs that may compromise availability

3.15. How organ / organ systems are affected

3.16. Adverse effects in the general population as well as specific populations where relevant

3.17. Measures undertaken to ensure quality control

3.18. Pre-clinical test safety data

Note that the scientific basis for the above should also be included eg; scientific basis for a particular dose, frequency, duration etc.

4. Study design with appropriate control groups (if applicable)
5. Efficacy: for products already available in the market appropriate literature needs to be cited.
6. Toxicology: Toxicity of the ingredients and the finished product should be disclosed by citing appropriate literature (clinical and non-clinical data).
7. Claims: Scientific evidence should be presented for all claims including nutrient content, structure and function and health etc.

Annexure A.4: If the intervention is "herbal/Ayurveda/ other complementary alternative medicine / related intervention

Herbal medicines generally contain multiple components. Traditional herbal preparations and ayurvedic products will be widely used with little information on their short-term and long-term safety. Therefore, clinical trials for both traditional ayurvedic preparations and novel herbal mixtures are justified.

Information needed to support a clinical trial for an herbal product

1. Details on specification of the interventional product and placebo (where relevant) are needed
2. Details on product manufacture with quality specifications

   2.1. Herbal substance

   - Description of the plant: genus, species (cultivar where appropriate); region(s) and country(ies) of origin; time of harvest; parts to be harvested
   - Plant processing: drying, mechanical disruption, solvent extraction (aqueous or organic solvents, others)
   - Analytical procedures
   - Specification
   - Storage conditions/shelf-life.

   2.2 Herbal product

   a. Quantity of active ingredient/s
   b. List of excipients
   c. Dosage-form
   d. Method of manufacture of the dosage form
   e. Analysis of putative active ingredient(s) via chemical or biological parameters
   f. Analysis of a sizeable chemical constituent (analytical marker compound)
   g. Analysis via chemical fingerprint (analytical markers)
   h. Analysis for lack of contamination by pesticides, herbicides, heavy metals, synthetic drug adulterants, microbials, toxins and any other relevant contaminant
   i. Dissolution studies (where relevant)
   j. Storage conditions and stability of the product over the length of the trial

k. Specification against which a certificate of analysis can be assessed before the clinical trial material is released.

3. General details of the product used in the clinical trial
    a. Proposed dose
    b. Dosage form (if the product needs further preparatory steps prior to administration the details to be mentioned)
    c. Method of preparation (if applicable)
    d. Route of administration
    e. Dosing interval / frequency
    f. Duration of treatment
    g. Precautions to be taken
    h. Storage conditions (prior to administration and any storage of product in use0
    i. Method of ensuring adherence to therapy
    j. Packaging
    k. Registration status with the Department of Ayurveda (Registration certificate to be submitted)
4. GMP standards (especially for phase III studies)
5. Study design with appropriate control groups (especially for phase III studies)
6. Environmental impact statement (especially for phase III studies)
7. Efficacy: for products already available in the market appropriate literature needs to be cited.
8. Toxicology: Toxicity of the ingredients and the finished product should be disclosed by citing appropriate literature (clinical and non-clinical data)
9. Pharmacokinetics: Appropriate pharmacokinetic data used to determine dose can be cited. When such data is not available, suitable clinical study or traditional data need to be cited.

Information needed for a standard intervention

This depends on the proposed phase of the trial. Investigators have to decide on the type of information that need to be submitted based on the proposed phase of the trial. This list is not exhaustive. CTSC will request additional information depending on the aim, hypothesis, study design, proposed phase, intervention and indication

1. Results of dose ranging studies (if applicable)
2. Verification of tolerance
3. From the literature or protocol provisions on evaluation of clinical safety parameters such as

- Neurological
- Skin
- Musculoskeletal
- Gastrointestinal
- Liver
- Kidney
- Endocrine system and metabolism (Na, K, Ca)
- CVS
- Haematopoietic
- Any other relevant

4. Preliminary efficacy data (if applicable)
5. Sample size (details of calculation to be given: Primary end point and null hypothesis should be taken into consideration)
6. Information on administration of the intervention including

    - Coding in blinded trials
    - Trial pharmacist
    - Investigators' brochure
    - Written instruction to PI about the procedures for adequate and safe:
        - Receipt, Handling, Storage, Dispensing
        - Retrieval of unused product from subjects
        - Return of unused IMPs to sponsor or alternative disposition (approved by the regulatory authority)
    - Plans for
        - timely delivery
        - maintaining records
        - shipment, receipt, disposition, return, and destruction of the investigational product
        - maintaining a system for retrieval for deficient product recall, reclaim after trial completion, expired product reclaim
        - maintaining a system for the disposition of unused IMPs
        - ensuring continuous supply
        - ensuring that the product will remain stable

7. Other ethical concerns to be addressed wherever applicable

- Product adulterations
- Interactions between herbal and other remedies
- Reproductive and organ toxicity data

- Evidence of training of the investigators
- GCP

Annexure A.5: If the intervention is a device/surgical intervention

1. Intervention Details
    a. Detailed description of the medical device or surgical intervention.
    b. How the device/intervention will be administered or used.
    c. Any specific techniques, procedures, or training required.
    d. Comparison group details (if applicable).

2. Investigational Product (Device):
    a. Class of the medical device –
    The classification is based on the level of invasiveness and whether the device is active (i.e., depends on a source of energy for operation, a source other than the energy generated by the human body or gravity).
    Class I represents the lowest risk medical devices while Class III represents the highest risk. If a medical device can be classified into more than one class, the class representing the highest risk applies.
    (https://nmra.gov.lk/images/PDF/draft_guidelines/Guideline-for-classification-of-Medical-device-in-Sri-Lanka.pdf)

    b. Description of the device's specifications, including manufacturing details.
    c. Drawings of the design of the medical device, including components, subassemblies, or circuits, if relevant
    d. Whether or not the medical device incorporates, or is intended to incorporate, as an integral part, a substance that may be considered to be a medicine
    e. Sterilisation processes used in the manufacture of the medical device
    f. Where the medical device is to be used in conjunction with (for example, connected to) other medical devices, results of tests demonstrating the safety and performance of each medical device
    g. Storage and handling instructions.

3. Investigational procedure / Surgery
    a. Description of the interventional procedure in detail – including approach, specific procedure, consumables used
    b. If the procedure / surgery is part or segment only of a larger operation or procedure, details of the whole procedure and surgery including the standardization of the rest of the procedure / surgery
    c. Details and qualifications of person/persons performing the procedure

4. Regulatory Information:
    a. Compliance with relevant regulatory requirements including local (e.g., NMRA) and overseas (e.g., FDA, EMA).
    b. Submission of investigational device exemption (IDE) or equivalent applications, if required.
    c. Regulatory reporting requirements and timelines.

Annexure A.6: If the intervention is exercise/life style modification/ public health intervention

1. **Type of the intervention**
    a. Type of the intervention (Behaviour change/Health promotion/ health systems/ environmental modifications/ legislation, legal action, taxation)
    b. Justification for selection of the stated intervention (literature/ expert opinion/ guidelines/ personal experience). If it is a behaviour change intervention, the theoretical basis for the intervention
2. **Development of the intervention**
    a. Development of the intervention (participatory approach with the communities/ based on available national or international guidelines/ Delphi technique/ literature)
    b. Validation of the intervention (by experts/ authorities)
3. **Alignment of the intervention**
    a. Alignment of the intervention with study objectives (conceptual framework/ fishbone diagrams)
    b. Alignment of the intervention with main outcome measures (logical framework analysis (LFA), Results based analysis)
4. **Delivery of the intervention**
    a. Personnel delivering the intervention and their qualifications / experience
    b. Material used for delivery - Health education material, PowerPoint presentations, hand books, trainer manuals
    c. Plan for delivery - number of contact sessions and their duration, frequency of sessions, duration of the intervention
    d. Methods of reinforcement - Measures taken to ensure adherence /compliance
    e. Measures to ensure uniformity of the delivery (if more than one person is involved in delivering the intervention)
    f. Measures to ensure participant safety (in the case of an exercise related intervention) - Persons/facilities available for care in case of an emergency
5. **Other ethics concerns:** If the intervention is a public health / health system intervention at macro level (e.g. water purification, legislation etc.) individual consent will not be applicable.

Annexure B - Documents to be submitted

1. Cover letter
2. Research proposal
3. ERC application – to be duly completed
4. Data collection tools/ forms – In all 3 languages
5. Recruitment flyer (all 3 languages)
6. Information sheet and consent forms – In all 3 languages
7. Assent form (Only if required)
8. CONSORT Flow diagram / Trial process
9. CVs of all Investigators
10. CVs of DSMB members (Brief CV)
11. ToR for DSMB
12. GCP certificates of all investigators
13. Statement giving that the trial will be registered with SLCTR
14. Valid certificate of product registration with the responsible National Authorities (If applicable)
15. Good Manufacturing Practice (GMP) certification (if applicable)
16. Case Report Form
17. Check list for adverse effects
18. Investigator's brochure
19. Any labels /package inserts
20. Art work of intervention (if applicable)
21. Insurance (if applicable)
22. Agreements (if applicable)
23. Budget
24. Declaration of interest document
25. Administrative approval from the institutional head. (The application will be reviewed pending administrative approval, this will be a mandatory requirement prior to final approval)

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1. This is the minimum list of documents. CTSC will request additional documents if deems necessary
2. All the documents listed above may not be required for you trial

Annexure C: Templates for information sheet, consent form and assent form

1. Information sheet
2. Consent form
3. Assent form

Introduction

In any clinical trial proposal, the inclusion of essential documents such as an information sheet, assent form, and consent form is of paramount importance. These documents are pivotal components that serve to uphold the ethical integrity, transparency, and protection of all parties involved in the clinical trial process participants, researchers, and regulatory bodies. They play a critical role in ensuring that individuals are well-informed and voluntarily agree to participate in the trial.

Annexure C1

Participant Information Sheet

The information sheet acts as a detailed guide that provides prospective participants with comprehensive and understandable information about the clinical trial. It elucidates the study's purpose, procedures, potential risks, benefits, and any other pertinent details relevant to their involvement. This document empowers individuals by offering a clear understanding of what their participation entails, enabling them to make informed decisions regarding their involvement.

General Instructions

Creating an information sheet for a clinical trial is a critical aspect of ensuring that participants understand the study's purpose, procedures, risks, and benefits before they consent to take part. Here's a step-by-step guide to prepare an information sheet for a clinical trial:

1. Use Simple Language:

Keep it Understandable: Use clear, straightforward language that is easily understood by the general population, avoiding medical jargon as much as possible.

2. Content to Include:

2.1. Title and Introduction: The title should be concise and descriptive of the study. Introduce the purpose and objectives of the clinical trial
2.2. Study Overview: Briefly explain the nature of the trial, what will be studied, and why it's important.
2.3. Procedures and Involvement: Describe the different phases and procedures involved in the trial. Outline what participants will be expected to do during the study, including any medical procedures, tests, or medications.
2.4. Risks and Benefits: Clearly state the potential risks and benefits associated with participation. Enumerate the common and potential side effects.
2.5. Confidentiality and Data Use: Explain how participant data will be handled, stored, and anonymized to protect privacy.

2.6. Voluntary Participation and Withdrawal: Emphasize that participation is entirely voluntary and that participants can withdraw at any time without penalty.

2.7. Contact Information: Provide contact details for the principal investigator or a designated person for questions and concerns.

3. Formatting and Design:

3.1. Layout and Readability:

3.2. Use a clear and organized layout with headings, bullet points, and sections.

3.3. Ensure the font is easily readable and the document is well-structured.

3.4. Visual Aids (If Applicable only): Incorporate diagrams, charts, or visuals to aid in understanding complex information.

3.5. Translation and Accessibility: Provide translations into Sinhalese and Tamil languages and ensure accessibility for individuals with disabilities. Also, any amendments done with the Sinhala and Tamil version should be updated with the English version. Information sheets attached with assent forms should be written in a language where Child/minor can understand.

4. Review and Approval:

4.1. Expert Review: Have medical experts in the field of study, other allied health care professionals and ethicists review the information sheet for accuracy and completeness.

4.2. Ethical Approval: Ensure the information sheet complies with ethics committee requirements.

4.3. If there are any changes done during the study with permission of the Ethical Review Committee updated information should be provided to the participants.

5. Distribution

5.1. This should be given to the participants at the beginning of the Study.

5.2. Make sure each participant reads the information getting signed before the consent form.

5.3. Separate information sheets need to be provided for the different groups involved in the Study (for example: Intervention group, Control Group, Family Member)

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TEMPLATE - PARTICIPANT INFORMATION SHEET

Date

Version

Title: The titles must be consistent throughout the documentation.

Invitation paragraph: It must be clear that you are inviting potential participants to consider taking part in your research and that participation is entirely voluntary.

Example:

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

Provide a brief outline of the purpose of your study in lay language. Do not cut and paste directly from the protocol.

Why have I been invited?

- Explain specifically why the participant has been invited (e.g. because they have a specific condition, or because they are healthy individuals, if available any geographical details)
- State how many participants you are intending to involve and their characteristics (e.g. healthy volunteers, people with xy condition).

Do I have to take part?

- The answer is 'No': It should be clear that taking part is entirely voluntary.
- Participant can withdraw if he/she later changes his/her mind, without giving a reason;
- Withdrawal will not affect clinical care (if participants are patients).

What will happen to me if I decide to take part?

- This section details what will be involved in your research study from a participant's point of view, and in the order they will experience it. If there are multiple study visits, describe them in turn.
- In the context of clinical care, make clear which parts are research and which standard care.
- A table or clear steps can provide clarity when describing a complex series of interventions (These include: how long the participant will be involved in the research; how often they will need to attend a research session/Clinic visits; and how long visits will be, if you will be allocating participants randomly to study medication(s) and/or placebo.) Describe the processes in **lay terms.** If you will be collecting samples, give an idea of amounts. Blood volume may be more meaningfully, expressed in tablespoons: 5ml is equivalent to 1 teaspoon, 15ml is 1 tablespoon. Biopsies may be compared to grains of rice, Outline any plans for long-term monitoring/follow-up.

What should I consider?

- Researcher should explain:
- Conditions which may exclude individuals from participation;
- Whether they can continue to take their regular medication or other prescribed or over-the-counter medicines;
- Whether they can participate if they are involved in other research studies?
- Are there any possible disadvantages or risks from taking part;
- Provide a fair and honest evaluation of the possible consequences of key research procedures and drugs: risks and their relative likelihoods, as well as what you will do to mitigate these risks. For example:
- Procedures:
- Blood samples: the possibility of bruising and/or fainting
- Questionnaires or interview questions that may cause distress: give indication of kinds of questions you will be asking, and outline would happen if a participant becomes upset.

Study Drugs:

- State whether the drug is commonly used for the indication being researched or for other conditions, or whether it is ‘first in man’

- State known side effects of study drugs. You could use a table such as:
- Side Effect Frequency
- Very common (in more than 1 in 10 participants)
- Common (more than 1 in 100 but fewer than 1 in 10)
- Uncommon (more than 1 in 1000 but fewer than 1 in 100)

What are the possible benefits of taking part?

- Sometimes participants can benefit directly. If this is so, be clear; if not, be equally clear that there is no benefit.
- Ensure that potential participants are aware that you do not know what the outcome will be, and this is why you are conducting the research.

Will my General Practitioner/family doctor (GP) be informed of my participation?

Any routine medical practitioners should be notified if study participation could affect clinical care of participants. (Specific clinics the participant is already registered should informed with a letter and the study information sheet.)

Will my taking part in the study be kept confidential?

- Explain arrangements made to ensure that information is kept secure.
- Explain in what form you will hold information. For example, will participants be identified by study code only? Will you destroy all direct identifiers and store only fully anonymised data? Note that if you anonymise during the study, it will not be possible for participants to withdraw their data. They should be informed of this here and/or in the section discussing withdrawal.
- Include the following text:
- Responsible members of the XY Institute may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Other considerations:

- If you are not part of the clinical care team of patients, you cannot access their medical notes without their consent for screening/identification for recruitment.

- If your study will involve video/audio-recording, outline what will happen to these recordings in the longer term; and, if transcribed, whether the recordings will be destroyed. If video or audio recording, please add template consent form point 5 to your consent form.

Will I be reimbursed for taking part?

Make clear whether they will be compensated for their time, inconvenience for having to take medications or for having to donate blood samples or any other way. It is important that potential participants understand how these payments might be influenced by their duration of involvement in your study. Make clear whether they and/or others who might accompany them will be reimbursed for their expenses such as: travel, meals etc. It should not cost participants to contribute to research; at a minimum, travel should be reimbursed. This expense may sometimes be avoided by having research visits coincide with regular clinical appointments.

What will happen to the samples I give?

- State how they will be used in the research (where they will be transferred or held, what analysis will be done)
- You should also give potential participants information on your plans for any samples remaining after your specific piece of research has ended, such as whether they will be destroyed or stored, with consent, for future use.

What will happen to my data?

- General Data Protection Rules and regulations followed by the researchers and more explicit details about what personal data will be held by whom, for what purposes, and for how long. For example:
- We will be using information from [source: e.g. you and your medical records] in order to undertake this study. Research is a task that we perform in the public interest. XY Institute, as sponsor, is the data controller. This means that we, as XY Institute researchers we are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible.

- If personal data will be shared with others outside the place where the research originally conducted, you should make potential participants aware that some countries might not offer the same level of protection of privacy as that demanded by participants

What will happen if I don't want to carry on with the study?

Make clear that:

- Participation is voluntary and participants may change their minds at a later stage.
- Withdrawal will not affect the care they receive from any relevant service (e.g. for patients, from the relevant Institution).

What procedure is in place in case of withdrawal?

- Are there any safety implications? Will participant be followed up and a final visit arranged?
- Will samples and data collected to point of withdrawal be retained for the study, removed, or will the participant have a choice?

What will happen to the results of this study?

1. Reassure potential participants that they will not be identified from any report or publication placed in the public domain. If they will be (for instance, with images of faces) it will be necessary to obtain specific consent for this.

Further information and contact details: (Principal Investigator and investigator)

Please contact (telephone, e-mail, in writing)

If you have questions about any of the information, please feel free to ask any of the persons listed below. Example

Name:

Phone:

Email:

Who has reviewed the study?

2. Provide details of the research ethics committee who has reviewed and approved the study.

3. This information has been provided to allow you to give informed consent.

4. You may contact the committee if you wish to seek clarifications, record any concerns or make
5. Complaints about the study by calling 0112695300 extension 240 (between 9am and 4pm) or by sending an email to info.ethics@med.cmb.ac.lk
6. At the end Thank the participants

Reference: Adapted by the Oxford University Hospitals NHS Foundation Trust.

https://www.ouh.nhs.uk/researchers/planning/documents/participant-information-sheet.pdf

Note: Applicant should adapt this template to suit his/her proposal

Annexure C2 - **Consent form**

Consent forms, on the other hand, are legal documents that formally demonstrate a participant's voluntary and informed agreement to participate in a clinical trial. They outline the study's specifics, potential risks, benefits, and participants' rights. Signing a consent form is a tangible demonstration of an individual's commitment to the study, and it represents a vital step in ensuring ethical research practices.

General Instructions

Creating a consent form for a clinical trial protocol is a crucial part of the research process. It should be detailed, comprehensive, and understandable to the participants. Here's a guide on how to prepare a consent form for a clinical trial:

1. Title and Introduction: Title of the study and the target group should have mentioned of the clinical trial.
2. Language and Readability: Ensure the form is written in clear, simple language that the participants can understand. Consent forms should be available in Sinhala and Tamil language and the translated version should be compatible with the English form. Also, any amendments done with the Sinhala and Tamil version should be updated with the English version.
3. Ethics Committee Approval: If there are any changes done during the study with permission of the Ethical Review Committee updated consent form should be provided to the participants.
4. Signature and Date: Include a space for the participant's signature and the date. Also, include a signature from the person obtaining consent.
5. Additional Information:
   5.1. Make sure each participant reads the information getting signed before the consent form.
   5.2. Separate consent forms need to be provided for the different groups involved in the Study
   5.3. Remember, the consent form is a legal document designed to protect both the participant and the researcher. It should accurately represent the trial, ensuring that participants are well-informed and willingly agree to take part in the study.

TEMPLATE - CONSENT FORM

Date

Version

Informed Consent form for _____ _____]

Name the group of individuals for whom this informed consent form is written.

(Example: This Informed Consent Form is for men and women who attend clinic Z, and who we are inviting to participate in research on X)

1. Have you read the information sheet? (Please keep a copy for yourself) YES/NO
2. Have you had an opportunity to discuss this study and ask any questions? YES/NO
3. Have you had satisfactory answers to all your questions? YES/NO
4. Have you received enough information about the study? YES/NO
5. Who explained the study to you? ……..
5. Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting his/her future medical care? YES/NO
6. Information held by the investigators relating to your participation in this study may be examined by other research assistants. All personal details will be treated as STRICTLY CONFIDENTIAL. Do you give your permission for these individuals to have access to your records? YES/NO
7. Have you had sufficient time to come to your decision? YES/NO
8. Do you agree to take part your family member in this study? YES/NO
9. (Required) I agree to take part in this study.

Participant/participant's s family member's signature:

Date:

Additional:

1. (If relevant) I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies. YES/NO

2. (If relevant) I agree for my samples to be used, in a form that does not identify me, in future research here or abroad, which has ethics approval. I understand this research may involve commercial organizations. YES/NO

Signature of investigator:

Date:

Name (BLOCK CAPITALS):

Annexure C 3: Assent form

Assent forms play a particularly important role when dealing with vulnerable populations, such as minors, individuals with cognitive impairments, or those lacking decision-making capacity. These forms ensure that, to the best of their abilities, these individuals understand the study's purpose and agree to participate voluntarily. Assent forms are a means to uphold ethical standards and respect the autonomy of participants who may not be able to provide full informed consent.

General Instructions

Creating an assent form for clinical trials involves specific considerations to ensure participants, particularly minors, understand the study's purpose, risks, and their role in the research. Here's a guide to help you prepare an assent form:

Assent Form Components:

1. Title and Introduction: Title: Make it clear and straightforward. Introduction: State the purpose of the study and explain why assent is required.
2. Participant Information: Basic participant information: Name, age, and any other relevant demographic details. Briefly describe the study, its goals, and the procedures involved.
3. Risks and Benefits: Outline potential risks and benefits of participating in the study in simple language.
4. Voluntary Participation: Clearly state that participation is voluntary, and they have the right to withdraw at any time without consequences.
5. Confidentiality and Data Handling: Explain how their data will be handled, stored, and who will have access to it. Assure confidentiality measures.
6. Understanding: Include a section where the participant confirms they understand the information provided. This might involve a brief quiz or questionnaire.
7. Contact Information: Provide contact details for questions or concerns about the study.
8. Signatures: A space for the participant and the person obtaining the assent (parent, guardian, or researcher) to sign and date the form.

Tips for Preparing the Assent Form:

- Use Clear and Simple Language: Ensure the language is age-appropriate and easy to understand for the participant. The researcher must explain the information about the study to the child in an appropriate language that a child can understand easily. Maybe can use Pictures and video clips.
- Visual Aids: Incorporate visual aids like diagrams or pictures to assist in explaining the study
- Age-Appropriate Assent: Tailor the information to the participant's age, ensuring it is comprehensible and respectful.
- Informed Consent and Assent: Differentiate between informed consent for adults and assent for minors. Assent complements the consent given by a parent or legal guardian.
- Documentation: Keep a record of the assent forms in the participant's file and ensure the participant and/or guardian receive a copy.
- Note:
    - In the case of minors, the assent form supplements parental or guardian consent and is aimed at ensuring the child understands the study to the best of their ability.
    - Remember, the precise content and structure of an assent form can vary based on the nature of the study and the demographics of the participants. Consulting with legal and medical professionals or ethics committees might be essential to ensure compliance and clarity.

TEMPLATE ASSENT FORM

Date

Version

Informed Assent Form for _____]

Name the group of individuals for whom this assent is written.

This informed assent form is for children between the ages of 12 - 16 who attend clinic X and who we are inviting to participate in research Z.)

(This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one identified as 'suggested wording' below. If the child is illiterate but gives oral assent, a witness must sign instead. A researcher or the person going over the informed assent with the child must sign all assents.)

(Example: I understand the research is about testing a new Vaccine for Y and that I might get either the new vaccine which is being tested or the vaccine which is currently being used. I understand that I will get an injection and that I will come for regular monthly check-ups at the clinic where I will give a blood sample with a ……...)

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

I do not wish to take part in the research and I have not signed the assent below. _____ (initialled by child/minor)

Only if child assents:
Name of the child _____
Signature of the child: _____
Date: _____

day/month/year

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness (not a parent) _____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Name of the investigator_____

Signature of the investigator _____

Date_____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands that the following will be done:

1. Information sheet

2.Infromation leaflet (If applicable)

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Name of the Principal Investigator /Research Assistant taking the assent_____

Signature of the Principal Investigator/Research Assistant taking the assent

_____

Date _____

Day/month/year

Copy provided to the participant _____ (initialled by Principal Investigator/assistant)

Parent/Guardian has signed an informed consent ___Yes ___No _____(initialled by principal Investigator/assistant)

Adopted by: WHO Informed Consent Template for Clinical Studies