World Health Organization

Ethical considerations toolkit for the Unity Studies protocols, Respiratory Investigations and Studies

Unity Studies
Respiratory Investigations & Studies

Version: September 2023

Contents

TOOL 1: Informed consent and assent forms templates

NOTE: This document is relevant to the suite of WHO Unity Studies aligned template protocols for respiratory pathogens with pandemic potential, including the following:

- The First Few X cases and contacts (FFX) investigation template protocol for respiratory pathogens with pandemic potential;
- Household transmission investigation template protocol for respiratory pathogens with pandemic potential;
- Closed settings transmission investigation template protocol for respiratory pathogens with pandemic potential;
- Population-based age-stratified seroprevalence investigation template protocol for respiratory pathogens with pandemic potential.

In some countries, these investigations may fall under public health surveillance (emergency response) acts and may not require ethical approval from an institutional review board. This will be for national authorities to advise on. However, these templates are provided to assist investigators in circumstances where ethical approval is required. Templates must be adapted by investigators for the requirements of their particular investigations and those of their national and institutional regulations. Further details are included in this document.

This document includes the following templates:

- Informed consent form template
- Informed assent form (for children/minors)
- Additional possible consent forms, if the investigation calls for storage and future use of samples

1. Informed consent form

COMMENT: This template is given as an example for country adaptation, if relevant and aligned with national ethical requirements. If not aligned, the country needs to check the relevance of the template.

Notes to implementers:

1. Please note that this is a template developed to assist the investigators in the design of their informed consent forms (ICFs). It is important that investigators adapt their own ICFs to the requirements of their particular investigation and those of their national and institutional regulations. **The logo of the institution must be used on the ICF.**

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations that are for you and that you will not include in the informed consent forms that you develop and provide to participants in your investigation.

4. This template includes examples of key questions that may be asked at the end of each section, which could ensure understanding of the information being provided, especially if the investigation is complex. These are just examples and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:
   - square brackets indicate where specific information is to be inserted;
   - bold lettering indicates sections or wording that should be included; and
   - standard lettering is used for explanations to researchers only and must not be included in your consent forms.

TEMPLATE ON FOLLOWING PAGE

[YOUR INSTITUTIONAL LETTER HEAD]

[Informed Consent Form for _____]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(e.g. This informed consent form is for individuals participating in the investigation entitled. " insert investigation title")

[Name of Principle Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Project and Version]

This Informed Consent Form has two parts:

I. **Information Sheet (to share information about the study with you)**
II. **Certificate of Consent (for signatures if you agree that your child may participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to participate in the investigation being conducted. Inform them that may talk to anyone they feel comfortable talking with about the investigation and that they can take time to reflect on whether they want to participate or not. Assure them that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they may ask questions now or later.

Purpose

Explain in lay terms why the research is being done and what is expected from the results.

Type of Research Intervention

Briefly state the intervention. This will be expanded upon in the procedures section.

Selection of Participants

State clearly why you have chosen them to participate in this study.

Voluntary Participation

Indicate clearly that they can choose to participate or not and reassure there will be no professional or health impact if they choose not to participate. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Participants may also be more alert at the beginning.

Procedure

Explain what each of the steps or procedures involve. Indicate when the investigation will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

Explain the type of questions that the participants are likely to be asked in the interviews or in the questionnaire. If the questions are sensitive, acknowledge this, try to anticipate concerns and protective responses, and address these.

Duration
Include a statement about the time commitments of the investigation. Include both the duration of the study and follow-up, if relevant.

Risks and Discomforts
Explain any risks or discomforts including the collection of blood samples and any limits to confidentiality.

Benefits
Describe any benefits to them, to the community, or any benefits which are expected in the future as a result of the research.

Reimbursements
State clearly what you will provide the participants with as a result of their participation: reimbursement (e.g. for travel expenses) and/or compensation (e.g. for time lost). WHO does not encourage incentives beyond reimbursement or compensation as a result of participation in the investigation. The amount should be determined in accordance with national regulations.

Confidentiality:
Explain how the investigation team will maintain the confidentiality of data, especially with respect to the information about the participant. Outline any limits there are to confidentiality.

Sharing of Research Findings
Include a statement indicating that the individual findings will be shared with the participant and the overall findings of the investigation will be shared in a timely fashion with the community. In the latter, all confidential information will remain confidential. If you have a plan and timeline for the sharing of information, include the details. Also inform them that the overall findings of the investigation will be shared more broadly, for example, through publications and conferences, again on the condition that confidential information will remain confidential.

Right to refuse or withdraw
Explain again the voluntary nature of consent - a participant can refuse to participate or withdraw from the investigation, without justification, at any time by informing one of the members of the investigation team.
If a participant decides to drop out, participants need to inform the investigation team as soon as possible. Any of the previously collected remaining samples and data will be discarded except if the participant informs the investigation team that they can be kept for the purpose of this specific investigation.

Who to Contact
Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

PART II: Certificate of Consent

Certificate of Consent
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 in bold below. If the participant is illiterate but gives oral consent a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the information sheet and not a stand-alone document, the layout or design of the form should reflect this.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate in this study.

Print Name _____

Signature _____

Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant 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 consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

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 person understands that the following will be done:
1.
2.
3.
I confirm that the participant 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 Informed Consent Form has been provided to the participant ____

Print Name of Researcher/person taking the consent_____

An Informed Assent Form will ____ OR will not ____ be completed.

2. Informed assent form (for children/ minors)

COMMENT: This template is given as an example for country adaptation, if relevant and aligned with national ethical requirements. If not aligned, the country needs to check the relevance of the template.

Notes to implementers:

1. Please note that this is a template developed to assist the investigators in the design of their informed consent forms (ICFs). It is important that investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the institution must be used on the ICF.**

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations that are for you and that you will not include in the informed consent forms that you develop and provide to participants in your investigation.

4. This template includes examples of key questions that may be asked at the end of each section, that could ensure understanding of the information being provided, especially if the investigation is complex. These are just examples and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:
   - square brackets indicate where specific information is to be inserted;
   - bold lettering indicates sections or wording that should be included; and
   - standard lettering is used for explanations to researchers only and must not be included in your consent forms.

TEMPLATE ON FOLLOWING PAGE

[YOUR INSTITUTIONAL LETTER HEAD]

An Informed Assent Form does not replace a consent form signed by parents or guardians. The assent is in addition to the consent and signals the child's willing cooperation in the study.

[Informed Assent Form for _____]

Name the group of individuals for whom this assent is written. Because research for a single project is often carried out on a number of different groups of individuals - for example children with malaria, children without malaria, students - it is important that you identify which group particular assent is for.

(e.g. This informed consent form is for parents of adolescent girls and boys participating in the investigation entitled. " insert investigation title ")

[Name of Principle Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Project and Version]

This Informed Assent Form has two parts:

- **Information Sheet (gives you information about the study)**
- **Certificate of Assent (this is where you sign if you agree to participate)**

You will be given a copy of the full Informed Assent Form

Part I: Information Sheet

Introduction
This is a brief introduction to ensure the child knows who you are and what the purpose of the investigation is. Give your name, say what you do and clearly state that you are undertaking the investigation. Inform the child that you have spoken to their parents and that parental consent is also necessary. Let them know that they can speak to anyone they choose about the investigation before they make up their mind.

Purpose: Why are you doing this research?
Explain the purpose of the research in clear simple terms.

Choice of participants: Why are you asking me?
Children, like adults, like to know why they are being invited to be in the research. It is important to address any fears they may have about why they were chosen.

Participation is voluntary: Do I have to do this?
State clearly and in child-friendly language that the choice to participate is theirs and reassure there will be no academic or health impact if they choose not to participate. If there is a possibility that their decision not to participate might be over-ridden by parental consent, this should be stated clearly and simply.

I have checked with the child and they understand that participation is voluntary __(initial)

Procedures: What is going to happen to me?
Explain the procedures and any medical terminology in simple language. Focus on what is expected of the child. Describe which part of the research is experimental.

I have checked with the child and they understand the procedures _____(initial))

Risks: Is this bad or dangerous for me?
Explain any risks using simple, clear language.

Discomforts: Will it hurt?
If there will be any discomforts state these clearly and simply. State that they should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

I have checked with the child and they understand the risks and discomforts ____(initial)

Benefits: Is there anything good that happens to me?
Describe any benefits to the child.

I have checked with the child and they understand the benefits_____ (initial)

Reimbursements: Do I get anything for being in the research?
Mention any reimbursements or forms of appreciation that will be provided. Any gifts given to children should be small enough to not be an inducement or reason for participating. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the investigation. These expenses may include, for example, travel expenses and reimbursement for time lost. The amount should be determined in accordance with national regulations.

Confidentiality: Is everybody going to know about this?
Explain what confidentiality means in simple terms. State any limits to confidentiality. Indicate what their parents will or will not be told.

Compensation: What happens if I get hurt?
Describe to the ability of the child to understand and explain that parents have been given more information.

Sharing the Findings: Will you tell me the results?
Describe to the ability of the child to understand that the findings as they relate to the child, as well as the overall findings of the investigation will be shared in a timely fashion, but that confidential information will remain confidential. If you have a plan and a timeline for the sharing of information, include the details. Also tell the child that the research will be shared more broadly, i.e. in a book, journal, conferences, etc.

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?
You may want to re-emphasize that participation is voluntary and any limits to this. The child can refuse to participate or withdraw from the investigation, without justification, at any time by informing one of the members of the investigation team.
If a participant decides to drop out, participants need to inform the investigation team as soon as possible. Any of the previously collected remaining samples and data will be discarded except if the participant informs the investigation team that they can be kept for the purpose of this specific investigation

Who to Contact: Who can I talk to or ask questions to?
List and give contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).

If you choose to be part of this research, I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

You can ask me any more questions about any part of the investigation, if you wish to. Do you have any questions?

PART 2: Certificate of Assent

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.

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 <u>not</u> signed the assent below._____(initialled by child/minor)

<u>Only if child assents:</u>

Print name of child _____

Signature of 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.

Print 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.

Print name of researcher_____

Signature of researcher_____

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.
2.
3.

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.

Print Name of Researcher/person taking the assent_____

Signature of Researcher /person taking the assent _____

Date _____
Day/month/year

Copy provided to the participant _____(initialed by researcher/assistant)

Parent/Guardian has signed an informed consent ___Yes ___No _____(initialed by researcher/assistant)

3. Additional possible consent forms, if the investigation calls for storage and future use of samples

COMMENT: This template is given as an example for country adaptation, if relevant and aligned with national ethical requirements. If not aligned, the country needs to check the relevance of the template.

Notes to implementers:

1. Please note that this is a template developed to assist the investigators in the design of their informed consent forms (ICFs). It is important that investigators adapt their own ICFs to the requirements of their particular investigation and to those of the national and institutional regulations. **The logo of the institution must be used on the ICF.**

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations that are for you and that you will not include in the informed consent forms that you develop and provide to participants in your investigation.

4. This template includes examples of key questions that may be asked at the end of each section, that could ensure understanding of the information being provided, especially if the investigation is complex. These are just examples and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:
   - square brackets indicate where specific information is to be inserted;
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TEMPLATE ON FOLLOWING PAGE

Additional Consent to [Name of Project]

(e.g. This informed consent form is for participants in the investigation entitled. *"insert investigation title ")*

This Statement of Consent consists of two parts:

- **Information Sheet (to share information about unused samples with you)**
- **Certificate of Consent (to record your agreement)**

You will be given a copy of the full Statement of Consent

Part 1. Information Sheet

Explain that you are seeking permission to store their unused samples for possible future use in either your own research or someone else's research. State that they need to make some decisions about their blood samples because they gave you permission only to use it for the current research.

Explain that sometimes people don't want their samples used for research into areas they might not agree with, for example, research into birth control or reproductive technology. Use lay terms to explain research possibilities. If genetic research is a possibility, explain what this is and any implications for them. State that they can tell you if there is something, they don't want their sample used for, or if they don't want their sample used at all.

Inform the participant that at present, the researchers can trace which blood/tissue/sperm/sputum sample belongs to the participant. In most cases, the participant must decide whether they want to let the researchers keep the sample but get rid of all identifying information, or whether they are comfortable with the researchers knowing whose sample it is. Explain the risks and benefits of each of these options. Inform the participant of researcher obligations in cases where the sample remains linked. These obligations include informing the participant of results which have immediate clinical relevance.

Inform participants that their sample will not be sold for profit and that any research which uses their sample will have been approved.

Right to Refuse and Withdraw
Inform the participant that they may withdraw permission at any time and provide them with the name, address, and number of the person and sponsoring institution to contact.
Explain that the participant may refuse to allow samples to be kept or put restrictions on those samples with no loss of benefits and that the current investigation will not be affected in any way.

Confidentiality
Briefly explain how confidentiality will be maintained including any limitations.

You can ask me any more questions about any part of the information provided above, if you wish to. Do you have any questions?

Part II. Certificate of Consent

If any of the (TYPE OF SAMPLE i.e. blood, tissue) I have provided for this research project is unused or leftover when the project is completed (Tick **one** choice from each of the following boxes)

☐ I wish my [TYPE OF SAMPLE] sample to be destroyed immediately.

☐ I want my [TYPE OF SAMPLE] sample to be destroyed after ____ years.

☐ I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely

AND (if the sample is to be stored)

☐ I give permission for my (TYPE OF SAMPLE) sample to be stored and used in future research but only on the same subject as the current research project: [give name of current research]

☐ I give my permission for my [TYPE OF SAMPLE] sample to be stored and used in future research of any type which has been properly approved

☐ I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research except for research about [NAME TYPE OF RESEARCH]

AND

☐ I want my identity to be removed from my (TYPE OF SAMPLE) sample.

☐ I want my identity to be kept with my (TYPE OF SAMPLE) sample.

I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and my questions have been answered to my satisfaction. I consent voluntarily to have my samples stored in the manner and for the purpose indicated above.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant 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 consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ ***AND*** ***Thumb print of participant***

Signature of witness _____

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 participant understands that the following will be done:
1.
2.
3.
I confirm that the participant was given an opportunity to ask questions about the nature and manner of storage of the samples, and all the questions asked by the participant 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 ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

TOOL 2: (under development)