

# Supplementary document 1: Informed consent form

*COMMENT: This template is given as an example for country adaptation, if relevant and aligned with national ethical requirements.*

Notes to study teams:

- Please note that this is a template developed to assist the investigators in the design of their informed consent forms. It is important that investigators adapt their own informed consent forms 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 informed consent form.**
- The informed consent form consists of two parts: the information sheet and the consent certificate.
- 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.
- 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.
- 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 for informed consent form

## Cohort study to measure COVID-19 vaccine effectiveness among health workers

[Name of Principle Investigator]

[Name of Organisation]

[Name of Sponsor]

[Name of Project and Version]

**This informed consent form has two parts:**

**Information sheet (to share information about the study with you)**

**Certificate of consent (for signatures if you agree to 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 the potential study participant to participate in the investigation being conducted. Inform them that they may talk to anyone that they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the potential participant that if they do not understand some of the words or concepts, you will take time to explain to 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

Briefly state the methods involved in the study, including the length of the study, the frequency of blood draws and respiratory swabs and questionnaires. This will be expanded upon in the procedures section.

### Selection of participants

State clearly why they have been selected to participate in this study.

### Voluntary participation

Indicate clearly that they can choose to participate or not and reassure there will be no work or health impact should they choose not to participate. This can be repeated and expanded upon later in the form as well. 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.

### Procedure

Explain the type of questions that the participants are likely to be asked and the kinds of samples that will be collected over the course of the study.

### Duration

Include a statement about the time commitments of the study, including the duration of the study and follow-up during the study, if relevant.

### Risks and discomforts

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

### Benefits

Describe any benefits to the participant in the future, such as getting frequent information about potential SARS-CoV-2 infections, as a result of the research.

**Reimbursements**

State clearly what reimbursements you will provide the participants with as a result of their participation. We do not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the investigation. The expenses may include, for example, travel expenses and reimbursement for time lost. 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 hospital. 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 the participant that the overall findings of the investigation will be shared more broadly, for example, through publications and conferences, again on the condition that personal identifiable information will remain confidential.

**Storage of tissue samples**

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

**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 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.

## 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 confirm that I have read the information sheet dated [dd/mm/yyyy (version XX)] for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.**
- **I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.**
- **I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor, from regulatory authorities and [site relevant], where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.**
- **I agree for my anonymised samples to be used in future research, here or abroad, which has ethics approval and will not be undertaken for profit.**

Print name of participant \_\_\_\_\_

Signature of participant \_\_\_\_\_

Date \_\_\_\_\_ Day/month/year

### Statement by the researcher/person taking consent

**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 \_\_\_\_\_**

**Signature of Researcher/person taking the consent \_\_\_\_\_**

**Date \_\_\_\_\_ Day/month/year**