INFORMED CONSENT FORM FOR A CLINICAL TRIAL WITH AN INVESTIGATIONAL VACCINE IN ADULT HEALTHY VOLUNTEERS

Evaluation of the immunogenicity and safety of commercial COVID-19 vaccines following normal and modified vaccination schedules:BNT162b2 (Comirnaty®; Pfizer-BioNTech), mRNA-1273 Vaccine (COVID-19 Vaccine Moderna®; Moderna) and COVID-19 Vaccine (ChAdOx1-S [recombinant]) (Vaxzevria®, AstraZeneca)

Shortened title:

Immunogenicity following COVID-19 vaccines in modified regimens

1. Introduction

You are invited to take part in a clinical trial. The aim of this trial is to study the three COVID-19 vaccines mentioned above, developed by Pfizer, Moderna and AstraZeneca.

This informed consent form (ICF) describes the trial and what participating may mean for you. The trial staff will explain the trial in this informed consent form. Please ask them about anything you do not understand.

Before you decide to join the trial, we recommend you talk about it to anyone you trust, such as a family member, friend or your general practitioner (GP). Please read this document carefully and take as much time as you need to make your decision.

The documents related to the trial have been reviewed and approved by the Belgian competent authorities and an independent Ethics Committee. This is done for all clinical trials and as a result should not influence you when deciding whether to take part in this trial.

If you agree to join the trial, you will be asked to sign this informed consent form. We recommend you let any physician in charge of your health know if you do participate. For example, this could be your general practitioner (GP).

2. What is the purpose and the design of the trial?

COVID-19 is a disease caused by the SARS-CoV-2 virus. It was first discovered in the city of Wuhan in China on 31 December 2019. It rapidly spread across the globe and was declared a pandemic by the World Health Organisation. In some people, this disease does not cause any symptoms, or very mild symptoms comparable to those of the common cold, but in other people, it can cause very serious pneumonia and other symptoms that may even result in death. The mortality rate is highest among the elderly and among people with chronic diseases. The strict measures

needed to protect the population from this virus are having a serious impact not only on our economy, but also on everyone's general and mental well-being. Pending an effective treatment, vaccines to prevent COVID-19 could provide a way out of this pandemic. Currently, four COVID-19 vaccines are approved for use in the European Union, but the supply of vaccines depends on many factors. If the supply of a certain brand of COVID-19 vaccine were to be limited due to unforeseen circumstances, this could cause major delays for the national vaccination campaign. Therefore, this study will investigate the effect on the immune response if the interval between two vaccine doses is prolonged, or if a different brand of COVID-19 vaccine is used for the second (booster) dose, or if half of the recommended dose is used. In addition, the study will also investigate whether an intradermal injection (into the skin) with a lower dose can produce a similar immune response as an intramuscular injection (into the muscle of the upper arm) with a normal dose.
In these studies, three COVID-19 vaccines that are currently available on the market will be used, and no placebo will be administered.

These vaccines are:

- BNT162b2 (Comirnaty®; Pfizer-BioNTech)
- mRNA-1273 Vaccine (COVID-19 Vaccine Moderna®; Moderna)
- COVID-19 Vaccine (ChAdOx1-S [recombinant]) (Vaxzevria®, AstraZeneca)

These vaccines will hereinafter be referred to as the Pfizer vaccine, the Moderna vaccine and the AstraZeneca vaccine, respectively.

For each of these 3 vaccines, different administration schedules will be investigated with 1 group receiving the recommended administration schedule each time.. The other study groups of that particular COVID-19 vaccine will follow a different administration schedule: a lower dose, a different booster vaccine, a longer interval between the two doses, or intradermal injection. In total, there are 12 research groups of 70 persons each (840 persons in total).

Participants who are 41 to 55 years old will be assigned randomly (as with a roll of the dice) to one of the 12 groups.

For people under the age of 41, vaccination with the AstraZeneca vaccine is not currently recommended in Belgium. Therefore, participants who are 18 to 40 years old will be assigned randomly to one of the groups not receiving the AstraZeneca vaccine (i.e. group 1a, 1b, 1d, 1e, 1f, 3a or 3b).

These study groups, with their different methods of administration, are listed in Table 1 below:

Pfizer groups

Group	**Day 0**	**Day 28**	**Day 84**
1a	SD Pfizer vaccine	SD Pfizer vaccine	
1b	SD Pfizer vaccine	SD Moderna vaccine	
1c	SD Pfizer vaccine	SD AstraZeneca vaccine	
1d	LD Pfizer vaccine	LD Pfizer vaccine	
1e	SD Pfizer vaccine		SD Pfizer vaccine
1f	*Intradermal Pfizer vaccine*	*Intradermal Pfizer vaccine*	

AstraZeneca groups

Group	**Day 0**	**Day 28**	**Day 84**
2a	SD AstraZeneca vaccine		SD AstraZeneca vaccine
2b	SD AstraZeneca vaccine		SD Pfizer vaccine
2c	LD AstraZeneca vaccine		LD AstraZeneca vaccine
2d	Intradermal AstraZeneca vaccine		Intradermal AstraZeneca vaccine

Moderna groups

Group	**Day 0**	**Day 28**	**Day 84**
3a	SD Moderna vaccine	SD Moderna vaccine	
3b	LD Moderna vaccine	LD Moderna vaccine	

- SD= standard dose,
- LD= lower dose (half or two thirds of the standard dose for intramuscular administration; one fifth of the standard dose for intradermal administration)
- Intradermal =1/5 of standard dose injected via intradermal administration

This study is partially blinded to the participants. This means that you will temporarily not know which group you have been assigned to if this is an intramuscular administration group. After the visit of 28 days after the last administration is reached (D56 for short interval groups and D112 for long interval groups), the blinding will be lifted and you will be informed which group you belong to.

Blood samples are collected at every visit to monitor the immune response. The immune responses of the groups with modified schedules will be compared per vaccine group with those of the reference group. In the event that a group achieves a lower immune response than the reference group 28 days after the last administration, the participants in that group will be offered an additional full-dose COVID-19 vaccine with a regular administration schedule. These participants will

then be followed up for one more month, for their safety and to monitor the immune response, and one year after study start, a final contact will be made for safety follow-up.

3. What will happen during the trial?

You can take part in this trial if:

- You are healthy and aged between 18 and 55 years;
- You have never received a COVID-19 vaccine;
- You have never been infected with COVID-19.

The researcher will go over the other conditions for participation. If you agree to participate and meet all the conditions:

 you will visit the trial site 6 times

 you will receive 2 doses of the vaccine with an interval of either 28 days or 84 days, depending on which group you are assigned to.
After each administration of the study vaccine/product, you will be observed for approximately 30 minutes.

 a blood sample will be taken during every visit. For this trial, the overall volume of blood to be taken will be 270 ml.

 a urine pregnancy test will be carried out on fertile women before vaccination

 you will be asked to keep a digital diary to monitor your safety for 14 days after each vaccination

Groups with short vaccine interval (28 days between the 2 vaccinations) (1a, 1b,1c,1d,1f, 3a and 3b):

Approximately 12 months

	Visit 1 (D0)	Visit 2 (D28)	Visit 3 (D56)	Visit 4 (D112)	Visit 5 (D182)	Visit 6 (D364)
Health questions						
Physical exam						
Vaccination						
Sample collection (Maximum amount per visit)	46 ml	46 ml	46 ml	10 ml	46 ml	46 ml
Return of e-diary						
Pregnancy Test						

Groups with long vaccine interval (84 days between the 2 vaccinations) (1e, 2a, 2b, 2c, 2d, 2e):

Approximately 12 months

	Visit 1 (D0)	Visit 2 (D28)	Visit 3 (D84)	Visit 4 (D112)	Visit 5 (D182)	Visit 6 (D364)
Health questions						
Physical exam						
Vaccination						
Sample collection (Maximum amount per visit)	46 ml	46 ml	46 ml	46 ml	46 ml	46 ml
Return of e-diary						
Pregnancy Test						

4. What are the restrictions, as well as the potential risks and discomforts?

There are known discomforts, or risks of side effects that can happen with the use of a vaccine. There might be other side effects that are not known at this time. You may also feel discomforts related to the procedures. The trial staff are trained to take the right measures to reduce risks and limit any discomforts you may experience. If new information becomes available that may influence your decision to continue to participate, the trial staff will let you know. In this case, you will be asked to sign a new consent form.

Below you will find the discomforts and risks associated with receiving the COVID-19 vaccine that have been observed in previous trials. It is possible that you might have them as well. If you experience any side effects, let the trial staff know.

For a full description of possible side effects, please refer to the vaccine leaflets, which can be consulted via the following links:

- Pfizer: https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf
- Moderna: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-epar-product-information_en.pdf
- AstraZeneca: https://www.ema.europa.eu/en/documents/product-information/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-product-information_en.pdf

Possible side effects of the AstraZeneca vaccine:

Very common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Very rare (<1/10,000)	Unknown
headache	thrombocytopenia (platelet deficiency)	swollen lymph nodes	thrombocytosis (blood clot) in combination with thrombocytopenia*	hypersensitivity reactions
nausea	diarrhoea and vomiting	itching		anaphylaxis (allergic reaction)
joint pain		Profuse sweating		
muscle pain		Rash		
itching at the injection site	redness and swelling at the injection site	dizziness		

pain/sensitivity at the injection site	fever	drowsiness		
sensation of heat at the injection site		reduced appetite		
bruising at the injection site				
fatigue				
chills				
feverishness				

*Severe and very rare cases of thrombocytopenia have been reported post-marketing.

Possible side effects of the Pfizer vaccine:

Very common (≥1/10)	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Unknown
headache	redness at the injection site	swollen lymph nodes	acute peripheral facial paralysis	anaphylaxis (allergic shock)
joint pain	nausea	Hypersensitivity e.g. hives, allergic facial swelling (angioedema)		
muscle pain	vomiting	rash		
pain or swelling at the injection site		insomnia		
fatigue		pain in a limb		
chills		feeling unwell		
fever		itching (overall and at the injection site)		
diarrhoea				

Possible side effects of the Moderna vaccine:

Very common (≥1/10)	Common (≥ 1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥ 1/10,000 to <1/1,000)	Unknown
fever	rash	itching at the injection site	*swelling of the face	anaphylaxis (allergic shock)
headache	redness at the injection site		facial paralysis	hypersensitivity
nausea, vomiting	rash at the injection site			
muscle pain				
joint pain				
swollen lymph nodes				
fatigue				
chills				
pain and swelling at the injection site				

*Found in persons who had received a filler injection (skin-filling liquid) 48 hours before vaccination

Summary of possible side effects:

Vaccination:

Intramuscular administration may cause a local reaction at the injection site such as pain, redness, swelling, hardening or rash.

General symptoms such as fatigue, fever, chills, muscle aches, joint pains, swelling of the lymph nodes and gastrointestinal complaints may also occur. Most reactions are transient and short-lived.

Some side effects are more commonly seen in younger age groups. Overall, side effects are less common and often less severe in older age groups. For the Pfizer vaccine and the Moderna vaccine, side effects are more likely to occur after the second dose, while for the AstraZeneca vaccine, side effects tend to be less severe after the second dose.

In a very small number of cases, thrombosis (blockage of a blood vessel by a blood clot) was found to occur after vaccination with the AstraZeneca vaccine, which is why this vaccine is currently not recommended in Belgium under the age of 41. Consequently, participants belonging to this age group will not be assigned to any group involving administration of the AstraZeneca vaccine.

As with other vaccines, allergic shock (anaphylaxis) may occur shortly after vaccination. This means that you cannot participate in the study if you have had an allergic reaction to a vaccine in the past or if you are allergic to polyethylene glycol or

polysorbate. After vaccination, you will also remain under observation for at least 30 minutes before being allowed to leave the centre.

Intradermal administration:

Pain, redness, rash, swelling and hardening at the injection site may occur. For these COVID-19 vaccines, data for intradermal administration are not yet available, and unforeseen side effects may occur. The same general reactions as for intramuscular administration are to be expected, but their extent is what this study aims to investigate.

Different administration schedule:

The COVID-19 vaccines used in this study have been approved by the Belgian government and are used in the national vaccination campaign. However, the method of administration (intradermal or intramuscular), the dose of the first injection, and the dose, interval and brand of the second injection may differ from the standard schedule. It is therefore possible that the resulting immune response is lower than would be expected on the basis of the regular vaccination schedule. Any participants whose immune response 28 days after the last study vaccination is lower than that of participants who received a regular vaccination schedule will be offered the option to be vaccinated again, this time on a regular vaccination schedule. These participants will be followed up after this additional regular schedule for an additional 28 days, for their safety and to monitor the immune response, and one year after study start, a final contact will be made for safety follow-up.

Blood collection:

Taking blood can cause pain, sensitivity or bruising at the puncture site. General reactions such as dizziness or fainting may also occur in some participants.

5. What do I need to know about contraception, pregnancy, and breastfeeding?

Female participant:

If you are pregnant or breastfeeding, or if you are planning to become pregnant during the study period, until 1 month after administration of the last dose, you cannot participate.

If you are female, sexually active with a man and can have children, you and your partner will have to use one of the permitted methods of contraception: hormonal contraception (birth control pill, vaginal ring, patch, implant or hormone-releasing IUD), an IUD, condoms with or without spermicidal cream, a cervical cap, diaphragm or sponge in combination with spermicidal cream, sterilisation (of the permanent partner) or abstinence. You must use one of these allowed methods of contraception from at

least one month before vaccination until one month after the last dose of the study vaccine.

If you become pregnant during the trial, you should tell the trial staff right away. The investigator will then discuss the options with you.

6. What are the potential benefits?

There may or may not be a personal health benefit to you if you take part in this trial. The results of the trial will help learn about COVID-19 and whether the modified administration schedule works or not.

7. Are there any alternative vaccines and/or treatments?

Currently there is no medical treatment for the disease. The treatment for COVID-19 mainly reduces the symptoms of the disease, but does not cure the disease. The COVID-19 vaccines used in this study are available in Belgium with an approved administration schedule. In addition, a Janssen COVID-19 vaccine is also on the market.

If a new vaccine becomes available, the investigator will discuss this new information with you. You can then decide to leave the trial and receive the new vaccine if you wish.

8. Will I receive compensation for my participation?

The sponsor has agreed to pay the trial site for the conduct of the trial and covers the costs of this trial. You or your health insurer will not need to pay anything to participate in this trial.

You will receive 60 euros per visit to the trial site as compensation for your transportation to the trial site and for any discomfort that could be linked to your participation in the trial.

The trial staff will inform you about the practical arrangements.

9. What if something goes wrong?

Even if there is no fault, the sponsor is liable for any damage you suffered that is directly or indirectly related to your participation in the trial. The sponsor has taken an insurance called ‘No Fault Insurance’ for this situation. This means you do not have to provide proof that the investigator or trial staff made a mistake. A copy of the insurance certificate can be obtained from the trial staff.

In case you suffered any damage, you must inform the trial staff as soon as possible.

If the investigator believes a link between the damage you suffered and the trial is possible, he/she will inform the sponsor. The latter will officially inform the insurance company. The insurance company will then decide whether to appoint an expert to find out if there is a link between the damage you suffered and the trial.

At any point if you disagree with the investigator, you can contact the insurance company. If you disagree with the insurance company expert, you can sue the insurer directly. You can find the name and policy number of the insurer at the end of this form.

In the event of your death your rightful claimants (e.g. your wife, husband, children or parents) can do the above.

10. What will happen to my samples?

As part of the trial, blood samples will be taken. Your samples will be given a unique code number (Ref. 1). The code number will not identify you directly and will not include your personal information (data).

Your samples will be managed and stored in the Biobank of the Antwerp University Hospital (UZA) for 10 years. Your samples may be sent to the sponsor laboratories. They may also be sent to other laboratories working on behalf of the sponsor or institutions working with the sponsor. These institutions and/or laboratories may be outside the country where you live. The tracking of your samples will be ensured by the sponsor.

Your samples will be used to:

- assess your immune response
- learn more about the action and interaction of the vaccines
- check the safety of the adapted schedules

Your samples can also be used to perform additional tests, during and after the trial to:

- make sure the quality of the tests used for the investigational vaccine(s) or disease(s) is maintained over time
- develop and improve tests related to the vaccine(s) or disease(s).

What happens in case of incidental findings?

During the trial new information about your health might be discovered by chance. This is called “incidental findings”. Such information may be important to you or your blood relatives’ health.
If you agree, the investigator will discuss the results with you. You will be asked to indicate your choice on the signature page at the end of this form.

Use of remainders of samples for future research

If you agree, the remainders of your samples may be used for:

- further research related to the vaccine(s) and/or disease(s). This means additional research conducted to understand the vaccine(s) and/or disease(s) better.
- further research NOT related to the vaccine(s) and/or disease(s). This means additional research conducted to understand other vaccines(s) and/or diseases or for the development of new treatments or research methods. In this case, this research will always have to be approved by an ethics committee.

The results of this further research will not be shared with you.

Even if you disagree with the optional use of remainders of samples, you can still join the trial. You will be asked to indicate your choice on the signature page.

11. What happens to my data?

The trial staff will collect data that will identify you. This may include your name, address and phone number. Also data about your health, your medical history, and the results of examinations required by the trial will be collected and processed. All your data collected for this trial will be stored in the trial medical records at the trial site. Below is a table that explains how your data will be handled.

Item	Definition	Who has access?
Non-coded data (Ref. 2) (Examples: your name, birth date etc.)	This data is collected by the trial staff to identify and contact you. The data are stored in the trial medical records at the trial site. **Data that may identify you directly will not leave the trial site.**	Trial staff Other people as listed below: • The sponsor staff who follow up the trial at the trial site. • An independent audit group • Inspectors of competent health authorities worldwide • Representatives of ethics committees People who see non-coded data are bound by professional secrecy. If they get access to the non-coded data, this will always occur under the responsibility of the investigator.
Coded data (Examples: data about your health after vaccination, results from tests of your blood samples etc.)	During this trial, you will be assigned a unique code number. All your data that will be sent to the sponsor will be coded. This means the sponsor will not be able to link the data with you.	Your data may be: • Shared by the sponsor with competent health authorities and ethics committees. • Used to test and improve computer software used by the sponsor. • Combined with results from other studies to learn more about COVID-19 and the COVID-19 vaccines. • Shared with third parties working on behalf of the sponsor and/or institutions working with the sponsor (EU and non-EU) • Given to external (EU and non-EU) researchers (that are not involved in this trial). In the case the external researcher wants to use the data in a project not yet described in this document, this project will need to be approved by an ethics committee. If your coded data are transferred outside of EU, the sponsor must make sure that appropriate and suitable safeguards are used, with equivalent guarantees regarding personal data protection standards. Although the trial results may be published in medical journals, on the internet and discussed in meetings, data that identifies you will not appear in any publication or in any meetings.

Your data will be processed and protected in accordance with the General Data Protection Regulation (GDPR, Ref. 3) and the Belgian law on data protection of 30th July 2018 (Ref. 4).

By agreeing to participate in this study, you consent that your data from this study may be used by the funder (KCE) or by similar public health research institutes in Europe for further analyses, e.g. to determine which of the studied treatments is preferable. The KCE is an independent research centre that provides scientific advice on health care topics. The objective and tasks of the KCE are laid down in Articles 262 to 268 of the Belgian Programme Law (I) of 24 December 2002. In the context of these missions, the KCE must have access to certain personal data relating to the health of Belgian citizens, as it is tasked with carrying out analyses based on encrypted data (pseudonymised data) in the public interest.

For these future projects, either KCE or another similar public health research institute in Europe, taking on the role of the data controller, will seek authorisation from the Social Security and Health Chamber of the Information Security Committee ("ISC") in accordance with the relevant legislation. The decisions of the ISC are public and can be consulted on the website of the ISC (https://www.ehealth.fgov.be/ehealthplatform/nl/sectoraal-comite/documenten). The KCE reports are also publicly available (https://kce.fgov.be/nl/publicaties/alle-

rapporten). It is not possible for the KCE to inform you personally, as it does not have access to your contact details.

Under no circumstances will your identity be revealed to the researchers who carry out the additional analyses, and every researcher will be bound by a professional obligation of confidentiality.

Processing your personal data in this trial is allowed because we are conducting scientific research and because you have given your consent.

What are your rights to access your data?

You can ask the investigator what data are being collected about you and how those data will be used in connection with the trial.

You have the right to access, receive and review your personal data and to request correction if they prove to be inaccurate. However, those rights will be delayed to avoid prematurely lifting the blinding of this study. It is not possible to have all your data deleted, nor to object to their processing or to have their processing restricted, as this could lead to distorted study results.

How long will your data be kept?

The sponsor must keep the coded data from clinical trials for a minimum of 25 years after the end of the trial to ensure the validity of the research. This will also be the case if you stopped trial participation prematurely.

Where else can you find information about this trial?

There will be a description of this trial on the websites of the participating trial sites and/or other clinical trial registries. It may also appear in clinical trial registries in countries where the trial is conducted.

A description of this trial will be available on https://www.clinicaltrialsregister.eu. You can search this website at any time.

After the trial is finished, the website https://www.clinicaltrialsregister.eu will include a summary of the results. Also, a description and the results of this trial may be published in specialised medical journals. A copy of a summary of the scientific publication can be obtained from the investigator or the trial staff.

Who owns the trial results?

The sponsor, the University of Antwerp, will own the trial results. The sponsor plans to use the results, and may get patents, or sell the vaccine in the future, or make profits in other ways. You will not be paid any part of this.

Will my data be used for other purposes?

Your data might be used for:

- further research related to the vaccine(s) and/or disease(s). This means additional research conducted to understand the tested vaccine(s) and/or diseases(s) better.
- further research NOT related to the tested vaccine(s) and/or disease(s). This means additional research conducted to understand other vaccines(s) and/or diseases or for the development of new treatments or research methods. In this case, this research will always have to be approved by an ethics committee.

The results of these further research studies will not be shared with you.

Even if you disagree with the optional use of coded data, you can still join the trial. You will be asked to indicate your choice on the signature page.

12. Can my participation end prematurely?

Can you leave the trial?

Your participation is voluntary, and you can leave the trial at any time. You do not have to give a reason if you choose to leave. Tell the investigator if you no longer want to take part, so that your trial participation can be stopped safely (see section **Fout! Verwijzingsbron niet gevonden.**). Your choice will not affect your relationship with the trial staff and your possibility of taking part in any future trials.

If you decide to leave this trial, no new data will be collected. The data and samples that have been collected before you leave the trial will still be used as described in this form.

Depending on your situation, the investigator will discuss with you if any follow up visits or procedures will need to be done.

You may be asked to leave the trial if:

For example:

- You do not follow the trial instructions
- The investigator thinks it is best for you to leave. For example, based on your test results or if you develop specific health problems.
- The entire trial may need to be stopped for all participants.

If any of this happens, the trial staff will explain the reason to you and ensure proper follow-up.

13. Who can I contact in case of questions?

Name	Function	In case of:	Contact details
Surname, First name	Principal Investigator of the trial site	Information and concerns about possible adverse events or your participation in the trial	Phone N°, E-mail
	The trial staff	Information, problems, concerns	Phone N°
	The trial staff urgency contact	Urgent questions	Phone N°
	Patient rights ombudsman	Concerns relating to your rights as a participant in a trial	Phone N°
Amlin Insurance SE	Insurance Company of the sponsor	In case of disagreement or complaint on a damage claim	Policy N°: 199.535.692 Address: Plantin en Moretuslei 297, 2140 Antwerp
	Data protection officer of the trial site	Questions relating to the confidentiality of your data	Phone N° E-mail
	Belgian Data Protection Authority	Complaints relating to the confidentiality of your data	+32 (0)2 274 48 00 contact@apd-gba.be

Consent statement

Evaluation of the immunogenicity and safety of commercial COVID-19 vaccines following normal and modified vaccination schedules: BNT162b2 (Comirnaty®; Pfizer-BioNTech), mRNA-1273 Vaccine (COVID-19 Vaccine Moderna®; Moderna) and COVID-19 Vaccine (ChAdOx1-S [recombinant]) (Vaxzevria®, AstraZeneca)

Shortened title:

Immunogenicity following COVID-19 vaccines in modified regimens

I understand the purpose of this trial and the content of this form. I am satisfied with the answers to my questions. I had enough time to decide whether I want to take part in the trial. I am aware that I can change my mind and leave the trial at any time without giving a reason.

By signing this form,

I agree:

- **To take part in the trial**
- **That my samples can be used as described in this form**
- **That my data can be used as described in this form.**
- **I understand that data about me will be collected and that they will be treated confidentially.**

Please indicate if you want to be informed of incidental findings:

	Yes, I agree		**No, I do not agree**

Please indicate if remainders of your samples can be used for further research <u>related</u> to these vaccines and this disease**, once the trial is complete**:

	Yes, I agree		**No, I do not agree**

Please indicate if remainders of your samples can be used for further research NOT <u>related</u> to these vaccines and this disease**, once the trial is complete:**

	Yes, I agree		**No, I do not agree**

Please indicate if your coded data can be used for further research <u>related</u> to these vaccines and this disease**, once the trial is complete:**

	Yes, I agree		**No, I do not agree**

Please indicate if your coded data can be used for further research <u>NOT related</u> to these vaccines and this disease**, once the trial is complete**:

	Yes, I agree

	No, I do not agree

Person agreeing to take part (Trial participant)	
First and Last Name:	
Signature:	Date: <DD/MM/YYYY> Time:
Investigator	
I confirm that I have conducted the consent process according to applicable laws and/or regulations. I confirm to operate in accordance with the ethical principles set out in the latest version of the “Helsinki Declaration”, the “Good Clinical Practices” and the Belgian Law (Ref. 5). I verified that the participant understood the study.	
First and Last Name:	
Signature:	Date: <DD/MM/YYYY> Time:

References

[1] Belgian Law of 19 December 2008 on the acquisition and use of human body material with a view to medical application to humans or scientific research, and the applicable royal decrees.

[2] Throughout the document the term “coding” is used as a synonym to the term “pseudonymising”, the term used in the General Data Protection Regulation No 2016/679.

[3] General Data Protection Regulation No 2016/679 of the European Parliament and of the council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

[4] The Belgian Law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data.

[5] Belgian Law of 7 May 2004 related to experiments on humans, and the applicable royal decrees.