

Ron Law

By email: fyi-request-14693-10e5d029@requests.fyi.org.nz

Ref: H202101370

Dear Ron Law

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 16 February 2021 for:


- "1. Can you please provide copies of information that is required to be given to recipients of COVID-19/SARS/CoV-2 vaccines so that they can make an informed choice before deciding whether to have the vaccine or not.*
- 2. Can you please provide a copy of the informed consent form to be given to recipients of COVID-19/SARS/CoV-2 vaccines in New Zealand.*
- 3. Can you please provide instructions to vaccinators administering COVID-19/SARS/CoV-2 vaccines regarding the reporting of any adverse effects following injection of the vaccine into the recipient? Please include details of any forms or information systems being used to report such adverse events."*

Five documents have been identified within scope of your request. These are itemised in Appendix One to this letter, and copies of the documents are enclosed.

I trust this information fulfils your request. Under section 28(3) of the Act you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Yours sincerely



Mathew Parr
Programme Director, COVID-19 Immunisation
COVID-19 Health System Response

Appendix One: List of documents for release

#	Date	Title	Decision on release
1	19 February 2021	COVID-19 vaccination consent form	Released in full
2	15 February 2021	COVID-19 vaccine: what to expect	Released in full
3	16 February 2021	After your immunisation	Released in full
4	19 February 2021	Privacy Statement	Released in full
5	N/A	Information provided to vaccinators about obtaining informed consent	Released in full

COVID-19 vaccination consent form

Patient

Surname First name

Phone Date of birth / / NHI

Address

Medical Centre/GP

Guardian

Name of guardian (if applicable)

Guardian's relationship to patient

Please let the vaccinator know:

- If you are unwell
- If you've had a previous severe allergic reaction to any vaccine or injection in the past
- If you're on blood-thinning medications or have a bleeding disorder
- If you've had any vaccines in the past four weeks
- If you are pregnant or breastfeeding
- If you are currently receiving the cancer drugs Keytruda, Opdivo, Yervoy, or Tecentriq or have done so in the past six months

I have read the COVID-19 information pamphlet on "What to Expect", and/or have had explained to me information about the COVID-19 vaccine.

I have had a chance to ask questions and they were answered to my satisfaction.

I believe I understand the benefits and risks of COVID-19 vaccination.

I understand it is my choice to get the COVID-19 vaccination.

Signature Date / /

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Information for Vaccinator

Details confirmed

Positive answer to any screening questions? Yes No

Record information and advice given:

Informed consent obtained? Yes No

Date / / Time

If deferred, declined or not medical fit for vaccine record detail

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Vaccine							Diluent		
Name of vaccine	Date	Time	Dose	Site	Batch	Expiry	Batch	Expiry	Time of reconstitution
Pfizer/BioNTech COVID-19 Vaccine			0.3ml						

Dose 1 Dose 2

Post vaccination information given

Signature of vaccinator
Name of vaccinator

Observation area information

Details of any AEFI or observations recorded

CARM Report completed

Signature
Departure time

Released under the Official Information Act 1982

Getting your COVID-19 vaccine: what to expect

Vaccines are one of the ways we can fight the COVID-19 pandemic and protect the welfare and wellbeing of our communities.

Protection

COVID-19 vaccines are free and available to everyone in New Zealand.

Vaccines protect your health and prevent disease by working with your body's natural defences so you are ready to fight the virus, if you are exposed.

The COVID-19 vaccine works by triggering your immune system to produce antibodies and blood cells that work against the COVID-19 virus.

Getting a COVID-19 vaccine is an important step you can take to protect yourself from the effects of the virus. However, we don't yet know if it will stop you from catching and passing on the virus.

Once you've been vaccinated, continue to take precautions to prevent the spread of COVID-19. Thoroughly wash and dry your hands. Cough or sneeze into your elbow and stay home if you feel unwell. This will help you protect yourself, your whānau and others.

Continue using the COVID tracer app, turn on your phone's Bluetooth function, and you may wish to wear a face covering or mask.

Safety

Medsafe only grants consent for a vaccine to be used in New Zealand once they are satisfied it's safe and effective enough to use. All COVID-19 vaccines will go through the same safety test and must meet the same robust standards.

Pfizer vaccine

This vaccine will not give you COVID-19. You'll need two doses, three weeks apart. To ensure you have the best protection, make sure you get both doses of the vaccine. If you can't make your appointment, reschedule as soon as possible.

Things to consider before getting your vaccine

If you have had a severe or immediate allergic reaction to any vaccine or injection in the past, please discuss this with your vaccinator.

If you are on blood-thinning medications or have a bleeding disorder, please let your vaccinator know.

If you are pregnant or breastfeeding, please talk to your vaccinator, GP or midwife.

If you are receiving the cancer drugs Keytruda, Opdivo, Yervoy, or Tecentriq, talk with your specialist about whether you should receive the vaccine.

We are not currently offering the Pfizer vaccine to those under 16 years of age until further data is available.

If you have symptoms of COVID-19, get a test and stay at home until you get your results. You can be vaccinated once you have a negative test.

What happens after my vaccine?

You'll need to wait 30 minutes after your vaccination so medical staff can check you do not have a serious allergic reaction.

Potential side effects

The most common reported reactions are pain at the injection site, a headache and feeling tired or fatigued.

Muscle aches, feeling generally unwell, chills, fever, joint pain and nausea may also occur. This shows that the vaccine is working.

Like all medicines, the vaccine may cause side effects in some people. These are common, are usually mild and don't last long and won't stop you from having the second dose or going about your daily life.

Some side effects may temporarily affect your ability to drive or use machinery.

Serious allergic reactions do occur but are extremely rare. Our vaccinators are trained to manage these.

Further support and information

If you experience symptoms that could be COVID-19 related, such as a new continuous cough, a high temperature/fever or a loss or change in your normal sense of taste or smell, stay home and get a COVID-19 test.

If you are unsure about your symptoms or if they get worse, call Healthline on **0800 358 5453**.

If you have an immediate concern about your safety, call **111**, and make sure you tell them you've had a COVID-19 vaccination so that they can assess you properly.

www.health.govt.nz/covid-vaccine

After your immunisation

Like all medicines, the vaccine may cause side effects in some people. This is the body's normal response and shows the vaccine is working. Side effects are usually mild, don't last long and won't stop you from having the second dose or going about your daily life.

What you may feel	What can help	When this could start
Pain at the injection site, a headache and feeling tired and fatigued. These are the most commonly reported side effects.	Place a cold, wet cloth, or ice pack on the injection site for a short time. Do not rub or massage the injection site.	Within 6 to 24 hours
Muscle aches, feeling generally unwell, chills, fever, joint pain and nausea may also occur.	Rest and drink plenty of fluids Paracetamol or ibuprofen can be taken, follow the manufacturer's instructions. Seek advice from your health professional if your symptoms worsen.	Within 6 to 48 hours

Serious allergic reactions can occur but are extremely rare. New Zealand vaccinators are trained to manage these. Some side effects may temporarily affect the ability to drive or use machinery. In the unlikely event this happens, please discuss it with your employer.

If you experience symptoms that could be COVID-19 related, such as new continuous cough, a high temperature/fever, or a loss of or change in your normal sense of taste or smell, stay home and get a COVID-19 test.

If you have an unexpected reaction to your COVID-19 vaccination, your vaccinator or health professional should report it to the Centre for Adverse Reactions Monitoring (CARM).

You can also report any unexpected reactions direct by emailing CARM or using their online reporting form on the CARM website otago.ac.nz/carm.

If you are unsure about your symptoms or they get worse, talk to your GP or call Healthline on **0800 358 5453**.

If you have an immediate concern about your safety, call 111 and make sure you tell them you've had a COVID-19 vaccination so that they can assess you properly.

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Privacy

All the information you provide today will be used to help run the COVID-19 vaccination programme. Information from the consent form and details of each immunisation given or turned down will be recorded by the Ministry of Health in the COVID-19 Immunisation Register.

This information will be treated with care to ensure the Ministry of Health meets its obligations under the Privacy Act 2020 and the Health Information Privacy Code 2020.

The information collected as part of the vaccination process may be used for:

- managing your health
- keeping you and others safe
- planning and funding health services
- carrying out authorised research
- training health care professionals
- preparing and publishing statistics
- improving government services.

Some information, such as information about reactions to the vaccine, will be shared with other organisations who provide health services such as the Centre for Adverse Reactions Monitoring.

Sharing information with employers

Your employer may request confirmation of you receiving a vaccine. They should email COVID-19.priv@xt.nz to request access.

Further information

For more information about how the Ministry of Health protects your information, visit the Ministry website at health.govt.nz/covid-vaccine-privacy or email COVID-19.privacy@health.govt.nz

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Information provided to vaccinators about obtaining informed consent

(over and above whatever is available in the Immunisation Handbook)

The vaccinator (or vaccinator support person) must obtain the consumer's informed consent to receive the vaccine prior to the administering of the vaccine.

Use the COVID-19 Vaccination form to obtain the consumer's written consent. Where appropriate, consent may be given by a proxy such as a guardian or person with power of attorney. See below for instructions on managing the written consent forms.

Written consent must be obtained for Tier 1 consumers.

Note: IPC guidance must be observed when dealing with hard-copy consent forms and obtaining consent. This may include, for example, the provision of single-use pens or encouraging consumers to bring along their own pen.

The vaccinator or an administrative support person must record the consumer's consent to receive the vaccine in COVID Immunisation Register (CIR). If the person does not wish to receive the vaccine, record their decline in CIR.

Information provided to vaccinators about reporting adverse events

1.1.1 Adverse Events During Observation Period

If the consumer has an adverse event during the 30-minute observation period at the vaccination site, appropriate medical attention must be provided. The on-site adverse event must be recorded in CIR to enable reporting on adverse reactions to the vaccine.

For more information on managing medical emergencies and anaphylaxis, please see section 2.3 of the [Immunisation Handbook](#).

Adverse events should be notified to the site clinical lead, who can then undertake a clinical review and determine appropriate actions with the site manager (e.g. pausing vaccinations for a time if needed).

The adverse event must be recorded in CIR. The Centre for Adverse Reaction Monitoring (CARM) will then undertake further investigation and provide any additional guidance to the consumer and site as appropriate.

1.1.2 Adverse Events After Observation Period

If the consumer has an adverse event after the observation period/when they've left the vaccination site, they will be advised (in the 'After your immunisation' flyer) to contact Healthline and submit an adverse reaction report to the Centre for Adverse Reaction Monitoring (CARM). A dedicated COVID-19 Vaccine Adverse Event Report is available on the [CARM website](#). This may be completed by the consumer or a health practitioner.