

9 May 2022

Debbie

By email: [fyi-request-19000-3fcd3239@requests.fyi.org.nz](mailto:fyi-request-19000-3fcd3239@requests.fyi.org.nz)  
Ref: H202205449

Tēnā koe Debbie

### Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) on 14 April 2022.  
You specifically requested:

*“a copy of the exact study/studies that the Prime Minister, Health Minister and the Director General of Health relied on in February 2021 to state unequivocally this "vaccine" is "safe and effective." For all of the New Zealand population, including children over 5 years of age, as well as pregnant woman. Not just the small group of at risk New Zealanders that Medsafe initially provisionally approved it for.”*

Please note, the Ministry of Health does not conduct scientific research or studies. However, information can be found in the *New Zealand Immunisation Handbook* at the following link: [www.health.govt.nz/our-work/immunisation-handbook-2020/5-coronavirus-disease-covid-19](http://www.health.govt.nz/our-work/immunisation-handbook-2020/5-coronavirus-disease-covid-19). Please refer to sections 5.22 and 5.5.6. This contains detailed information regarding your request. The Handbook is footnoted and cites more than 60 studies about COVID-19 and vaccination and provides links to a wide range of scientific studies.

The datasheet for Comirnaty also contains some information about fertility, pregnancy, and breast feeding: <https://www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf>. Datasheets contain information about the medicine, including the approved indication and information from clinical trials which have been run.

Pfizer is currently running a study on pregnant woman; some details can be found here - [www.clinicaltrials.gov/ct2/show/NCT04754594?term=NCT04754594&draw=2&rank=1](http://www.clinicaltrials.gov/ct2/show/NCT04754594?term=NCT04754594&draw=2&rank=1). There is limited data available about the as the trial is still underway.

It is important to remember that all medicines contain risk and benefits, however evidence of the use of the vaccine in pregnant woman to date suggests that the benefits are likely to outweigh the risks: [www.health.gov.au/resources/publications/covid-19-vaccination-shared-decision-making-guide-for-women-who-are-pregnant-breastfeeding-or-planning-pregnancy](http://www.health.gov.au/resources/publications/covid-19-vaccination-shared-decision-making-guide-for-women-who-are-pregnant-breastfeeding-or-planning-pregnancy).

You may also refer to the following references for further information:

1. Shimabukuro TT, Kim SY, Myers TR, et al. 2021. [Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons](https://doi.org/10.1056/NEJMoa2104983). *New England Journal of Medicine* 384(24): 2273-2282. DOI: 10.1056/NEJMoa2104983

2. Zauche LH, Wallace B, Smoots AN, et al. 2021. [Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion](#). *New England Journal of Medicine* 385(16): 1533-1535. DOI: 10.1056/NEJMc2113891
3. Bleicher I, Kadour-Peero E, Sagi-Dain L, et al. 2021. [Early exploration of COVID-19 vaccination safety and effectiveness during pregnancy: interim descriptive data from a prospective observational study](#). *Vaccine* 39(44): 6535-6538. DOI: [doi.org/10.1016/j.vaccine.2021.09.043](https://doi.org/10.1016/j.vaccine.2021.09.043).
4. Blakeway H, Prasad S, Kalafat E, et al. [COVID-19 Vaccination During Pregnancy: Coverage and Safety](#). *American Journal of Obstetrics & Gynecology* U [doi.org/10.1016/j.ajog.2021.08.007](https://doi.org/10.1016/j.ajog.2021.08.007), DOI:10.1016/j.ajog.2021.08.007
5. Trostle ME, Limaye MA, Avtushka V, et al. 2021. [COVID-19 vaccination in pregnancy: early experience from a single institution](#). *American Journal of Obstetrics & Gynecology* *MFM* 3(6): 100464. DOI: [doi.org/10.1016/j.ajogmf.2021.100464](https://doi.org/10.1016/j.ajogmf.2021.100464).

I trust this 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](mailto: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 of Health website at: [www.health.govt.nz/about-ministry/information-releases](http://www.health.govt.nz/about-ministry/information-releases).

Nāku noa, nā



Jan Torres  
**Acting Manager, OIA Services**  
**Office of the Director-General**