



COVID-19 VACCINATION CONSENT FORM

Purpose:

This form has been designed to support the Informed Consent process for Covid-19 vaccinations.

FOR THE LEGAL ADMINISTRATION OF ANY CV19 VACCINE, BOTH PARTIES MUST READ AND SIGN THIS DOCUMENT

Audience:

- Doctors (or their delegated Health Care Professionals)
- Patients receiving Covid-19 Vaccine

Background:

This document is based on the Montgomery Judgement and GMC Guidelines.

The Montgomery Judgement and Informed Consent

<https://www.themdu.com/guidance-and-advice/guides/montgomery-and-informed-consent>

This Supreme Court judgement of Montgomery v Lanarkshire (2015) changed the standards of consent. The key passages from Montgomery Judgement state:

*“...The doctor is therefore under a duty to **take reasonable care** to ensure that the patient is aware of any **material risks** involved in any recommended treatment, and of any **reasonable alternative** or variant treatments...”*

*“The test of materiality is whether, in the circumstances of the particular case, **a reasonable person in the patient's position would be likely to attach significance to the risk**, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.”*

Before Montgomery, a doctor's duty to warn patients of risks was based on whether they had acted in line with a responsible body of medical opinion - known as the “Bolam test”. Now, **doctors must provide information about all material risks** to which a reasonable person in the patient's position would attach significance. This puts the patient at the centre of consent process, as their understanding of material risk **must** be considered. Both patient and doctor need to sign this document.

If doctors fail to properly discuss the **risks and alternative treatments** with the patient, this renders them personally responsible for damages. This document therefore protects the patient and the doctor.

General Medical Council Guidance - Decision Making and Consent (2020)

<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent>

This states that doctors **MUST** attempt to find out what matters to patients, so they can share information about the benefits and harms of proposed options and reasonable alternatives.

Note the word MUST makes this a legally binding directive.

GMC Guidance states doctors **MUST** address the following information:

- a) Recognise risks of harm that you believe anyone in the patient's position would want to know. You'll know these already from your professional knowledge and experience.*
- b) The effect of the patient's individual clinical circumstances on the probability of a benefit or harm occurring. If you know the patient's medical history, you'll know some of what you need to share already, but the dialogue could reveal more.*
- c) Risks of harm and potential benefits that the patient would consider significant for any reason. These will be revealed during your discussion with the patient about what matters to them.*
- d) Any risk of serious harm, however unlikely it is to occur.*
- e) Expected harms, including common side effects and what to do if they occur.*

References

Vitamin D

1. <https://www.researchsquare.com/article/rs-21211/v1>
2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7513835>
3. <https://www.grassrootshealth.net/wp-content/uploads/2020/04/Grant-GRH-Covid-paper-2020.pdf>
4. <https://www.bmj.com/content/356/bmj.i6583>

Vitamin C

1. <http://orthomolecular.org/resources/omns/v16n25.s.html>
2. <https://orthomolecular.activehosted.com/index.php>
3. <https://ccforum.biomedcentral.com/articles/10.1186/s13054-020-03249-y>
4. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7592143/>

Iodine

1. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3563092
2. <https://www.medrxiv.org/content/10.1101/2020.05.25.20110239v1>
3. https://www.researchgate.net/publication/340769844_Iodine_Intake_to_Reduce_Covid-19_Transmission_and_Mortality
4. <https://www.medrxiv.org/content/10.1101/2020.09.07.20180448v1>

Vaccine development & testing timeframes:

“The discovery and research phase is normally two-to-five years, according to the Wellcome Trust. In total, a vaccine can take more than 10 years to fully develop”

<https://www.weforum.org/agenda/2020/06/vaccine-development-barriers-coronavirus/>

Vaccines trigger post viral syndromes:

“We present epidemiological, clinical and experimental evidence that ME/CFS constitutes a major type of adverse effect of vaccines” (2019 paper)

<https://www.sciencedirect.com/science/article/abs/pii/S1568997219301090>

Allergy and autoimmunity effects of vaccines:

1. Shoenfeld Y et al - *Vaccination and autoimmunity - Vaccinosis: A dangerous liaison?* J Autoimmun 2000;14:1-10.
2. Nossal GJV - *Vaccination and autoimmunity.* JAI 2000;14:15-22.
3. Shoenfeld Y et al - *Vaccination as an additional player in the mosaic of autoimmunity.* Clin Exp Rheumatol 2000;18 4.
4. Rogerson SJ, Nye FJ - *Hepatitis B vaccine associated with erythema nodosum and polyarthritis.* BMJ 1990;301:345.
5. Haschulla E et al - *Reactive arthritis after hepatitis B vaccination.* J Rheumatol 1990;17:1250-1251.
6. Biasi D et al - *A new case of reactive arthritis after hepatitis B vaccination.* Clin Exp Rheumatol 1993;11:215.
7. Gross K et al - *Arthritis after hepatitis B vaccination. Report of three cases.* Scand J Rheumatol 1995;24:50-52.
8. Maillefert JF et al - *Rheumatic disorders developed after hepatitis B vaccination.* Rheumatology (Oxford) 1999;38:978-983.
9. Grasland A et al - *Adult-onset Still's disease after hepatitis A and B vaccination* (article in French). Rev Med Interne 1998;19:134-136.
10. Pope JE et al - *The development of rheumatoid arthritis after recombinant hepatitis B vaccination.* J Rheumatol 1998;25:1687-1693.
11. Guiseriz J - *Systemic lupus erythematosus following hepatitis B vaccine.* Nephron 1996;74:441.
12. Grezard P et al - *Lupus erythematosus and buccal aphthosis after hepatitis B vaccination in a 6-year-old child.* Ann Dermatol Vener 1996;123:657-659.
13. Weibel RE et al - *Chronic arthropathy and musculoskeletal symptoms associated with rubella vaccines. A review of 124 claims submitted to the National Vaccine Injury Compensation Program.* Arthritis Rheum 1996;39:1529-1534.
14. Ray P et al - *Risk of chronic arthropathy among women after rubella vaccination.* Vaccine Safety Datalink Team. JAMA 1997;278:551-556.
15. Howson CP et al - *Adverse events following pertussis and rubella vaccines. Summary of a report of the Institute of Medicine.* JAMA 1992;267:392-396.
16. Howson CP et al - *Chronic arthritis after rubella vaccination.* Clin Infect Dis 1992;15:307-312.
17. Mitchell LA et al - *HLA-DR class II associations with rubella vaccine-induced joint manifestations.* J Infect Dis 1998;177:5-12.
18. Nussinovitch M, Harel L, Varsano I. *Arthritis after mumps and measles vaccination.* Arch Dis Child 1995;72:348-349.
19. Thurairajan G et al *Polyarthropathy, orbital myositis and posterior scleritis: an unusual adverse reaction to influenza vaccine.* Br J Rheumatol 1997;36:120-123.
20. Maillefert JF et al - *Arthritis following combined vaccine against diphtheria, polyomyelitis and tetanus toxoid.* Clin Exp Rheumatol 2000;18:255-256.
21. Adachi JA et al - *Reactive arthritis associated with typhoid vaccination in travelers: report of two cases with negative HLA-B27.* J Travel Med 2000;7:35-36.
22. Older SA et al - *Can immunization precipitate connective tissue disease? Report of five cases of systemic lupus erythematosus and review of the literature.* Sem Arthritis Rheum 1999;29:131-139.

With Respect to the new COVID-19 vaccinations the Doctor MUST inform the patient of the following and tick the box to indicate such:

Montgomery Judgement & GMC Guidance	Facts	Notes	Discussed
2015 Montgomery Judgement on Informed Consent	<i>The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any reasonable alternative or variant treatments.</i>	Vitamin D, 5,000iu daily has proven benefit to prevent and treat Covid-19 Vitamin C, 5 grams daily has proven benefit to prevent and treat Covid-19 Topical antiseptics (such as iodine) are of proven benefit to reduce the loading dose, and hence disease severity, of Covid-19	Yes/No
GMC Guidelines to Doctors	Facts	Notes	Discussed
a. Recognised risks of harm that you believe anyone in the patient's position would want to know. You'll know these already from your professional knowledge and experience.	Limited short-term safety data: NO long-term safety data available on current CV-19 vaccines, including potential impacts on fertility. mRNA vaccines are a completely novel technology - essentially experimental, with the possibility of unanticipated/unpredictable long-term/late onset health effects Risk of Antibody Dependent Enhancement causing more severe Covid-19 illness on exposure to virus post-vaccination	CV-19 vaccine development accelerated. Vaccine safety testing normally c.10 years. Current CV-19 vaccines trialled for a few months with little/no animal testing. PHASE 3 trials won't complete for 2 years https://www.bmj.com/content/370/bmj.m3096/r https://www.bulatlat.com/2020/08/21/hazards-of-the-covid-19-vaccine/ CV-19 vaccines may sensitize recipients to more severe disease https://doi.org/10.1111/ijcp.13795 Potential cross-reactivity of vaccine-induced antibodies to virus spike protein, with the placental protein syncytin-1, could cause infertility https://2020news.de/en/dr-wodarg-and-dr-yeardon-request-a-stop-of-all-corona-vaccination-studies-and-call-for-co-signing-the-petition/	Yes/No
	There have been reports of some serious side-effects including 2 cases of transverse myelitis and neurological conditions in the Astra Zeneca vaccine trial.	Astra Zeneca Transverse Myelitis report https://www.nature.com/articles/d41586-020-02594-w https://www.nytimes.com/2020/09/19/health/astrazeneca-vaccine-safety-blueprints.html?auth=login-email&login=email	Yes/No
	The CDC identified 6 case reports of anaphylaxis following Pfizer-BioNTech vaccine meeting Brighton Collaboration criteria for anaphylaxis CDC updated advice on equipment necessary at all vaccination sites to deal with anaphylaxis	Anaphylaxis reports: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-19/05-COVID-CLARK.pdf Preparations to manage anaphylaxis vaccine recipients: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html	Yes/No
b. The effect of the patient's individual clinical circumstances on the probability of a benefit or harm occurring. If you know the patient's medical history, you'll know some of what you need to share already, but the dialogue could reveal more.	It is known that vaccines can switch on allergy and autoimmunity May be contraindicated with pre-existing autoimmune conditions or CFS/ME, or previous vaccine injury/reactions. MHRA 09 December 2020: Any person with a history of anaphylaxis to a vaccine, medicine or food should not receive the Pfizer/BioNTech vaccine. A second dose should not be given to anyone who has experienced anaphylaxis	Any patient with a history or strong family history of allergies or autoimmune conditions may choose to refuse a CV-19 vaccine. Doctors working with CFS/ME patients already advise them to avoid vaccination as this may trigger a relapse. https://www.gov.uk/government/news/confirmation-of-guidance-to-vaccination-centres-on-managing-allergic-reactions-following-covid-19-vaccination-with-the-pfizer-biontech-vaccine	Yes/No

	following administration of the first dose of this vaccine.		
c. Risks of harm and potential benefits that the patient would consider significant for any reason. These will be revealed during your discussion with the patient about what matters to them.	<p>Patient's individual risk from Covid-19 MUST be discussed – IFR <0.05% for <70 years to weigh up against risk from vaccine.</p> <p>Patient expectation of vaccine benefit i.e. reducing risk of severe illness, hospitalisation and preventing infection with and transmission of SARS-Cov-2</p> <p>Patients MUST be made aware of the full list of vaccine ingredients</p>	<p>Covid-19 IFR estimate by age (Table 2): https://spiral.imperial.ac.uk:8443/bitstream/10044/1/83545/8/2020-10-29-COVID19-Report-34.pdf</p> <p>Make patient aware that current trials are not designed to show if CV-19 vaccine will reduce their risk of hospitalisation or death or will prevent infection and transmission of virus as may affect risk v benefit profile https://www.bmj.com/content/371/bmj.m4037</p> <p>Ethical/religious considerations e.g. animal products - vegetarianism/veganism, WI-38 human diploid cells (aborted fetus source) - pro-life/religious belief</p>	Yes/No
d. Any risk of serious harm, however unlikely it is to occur.	<p>The Doctor MUST consider the significance that the Patient may place on risk of material harm</p> <p>Patient MUST be made aware that the vaccine manufacturers have demanded and been granted immunity from liability for injury or death caused by the vaccines</p>	<p>One example may be if a patient has first-hand knowledge of a relative who has suffered serious harm following vaccination.</p> <p>https://www.gov.uk/government/consultations/distributing-vaccines-and-treatments-for-covid-19-and-flu/outcome/government-response-consultation-on-changes-to-the-human-medicines-regulations-to-support-the-rollout-of-covid-19-vaccines#extending-immunity-from-civil-liability</p>	Yes/No
e. Expected harms, including common side effects and what to do if they occur.	Full list of adverse reactions in insert to be shared. Common side-effects include chills, fever, myalgia, fatigue, arthralgia, headache, and pain at the injection site.	Moderna vaccine -100% of high-dose participants report systemic side effects after second dose, some severe https://www.nejm.org/doi/full/10.1056/NEJMoa2022483	Yes/No
	A reaction to the first dose increases risk of a major reaction to a second dose	Before a second dose, the patient must be asked about their reaction to the first dose.	Yes/No

To be signed by both parties and a copy held by both parties for at least 7 years.

Doctor confirmation:

I confirm that I have discussed the above issues at length with the patient below, in accordance with the 2015 Montgomery Judgement and GMC Guidelines. I understand that failure to correctly and fully inform my patient renders me personally and legally responsible for any damages

Date, time	Name of doctor or nurse administering	Professional number of doctor (GMC) or nurse (GNC)	Name of vaccine, batch number and date of administration	Signature

Patient consent:

I confirm that I have discussed the above issues at length with the doctor or health professional above. I accept that I have been correctly informed of possible side effects of the Covid-19 vaccine and the alternatives to vaccination. I choose and consent to receive the Covid-19 vaccination.

Date, time	Name of patient	Name of parent or guardian if consenting on behalf of a child	Contact phone number or email	Signature