



## 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:

- 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.*
- 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.*
- 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.*
- Any risk of serious harm, however unlikely it is to occur.*
- 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](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](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. Maillfert 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. Maillfert 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
<b>2017 Montgomery Judgement on Informed Consent</b>	<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 in doses of 5,000iu daily is of proven benefit to prevent and treat Covid-19 Vitamin C in doses of 5 grams daily is of 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
<b>GMC Guidelines to Doctors</b>	<b>Facts</b>	<b>Notes</b>	<b>Discussed</b>
<b>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.</b>	Limited short-term safety data: <b>NO</b> long-term safety data available on current CV-19 vaccines.  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/trials were accelerated for reasons of expediency. Vaccine safety testing normally takes about 10 years. Current CV-19 vaccines have been trialled for a few months, in relatively small numbers of volunteers and with little or no animal testing. Many PHASE 3 trials will not be completed for nearly 2 years. <a href="https://www.bmj.com/content/370/bmj.m3096/rr">https://www.bmj.com/content/370/bmj.m3096/rr</a> <a href="https://www.bulatlat.com/2020/08/21/hazards-of-the-covid-19-vaccine/">https://www.bulatlat.com/2020/08/21/hazards-of-the-covid-19-vaccine/</a>  COVID-19 vaccines may sensitize recipients to more severe disease. (wiley.com): <a href="https://doi.org/10.1111/ijcp.13795">https://doi.org/10.1111/ijcp.13795</a>	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 <a href="https://www.nature.com/articles/d41586-020-02594-w">https://www.nature.com/articles/d41586-020-02594-w</a> <a href="https://www.nytimes.com/2020/09/19/health/astrazeneca-vaccine-safety-blueprints.html?auth=login-email&amp;login=email">https://www.nytimes.com/2020/09/19/health/astrazeneca-vaccine-safety-blueprints.html?auth=login-email&amp;login=email</a>	Yes/No
<b>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.</b>	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.	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.	Yes/No
<b>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.</b>	Patient's individual risk from Covid-19 <b>MUST</b> be discussed – IFR <0.05% for <70 years to weigh up against risk from vaccine.  Patient expectation of vaccine benefit i.e. reducing risk of severe illness, hospitalisation and preventing infection with and transmission of SARS-Cov-2  Patients <b>MUST</b> be made aware of the full list of vaccine ingredients	Covid-19 IFR estimate by age (Table 2): <a href="https://spiral.imperial.ac.uk:8443/bitstream/10044/1/83545/8/2020-10-29-COVID19-Report-34.pdf">https://spiral.imperial.ac.uk:8443/bitstream/10044/1/83545/8/2020-10-29-COVID19-Report-34.pdf</a>  Make patient aware that current trials 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 <a href="https://www.bmj.com/content/371/bmj.m4037">https://www.bmj.com/content/371/bmj.m4037</a> Ethical/religious considerations e.g. animal products - vegetarianism/veganism, WI-38 human diploid cells (aborted fetus source) - pro-life/religious belief	Yes/No

<b>d. Any risk of serious harm, however unlikely it is to occur.</b>	The Doctor <b>MUST</b> consider the significance that the Patient may place on risk of material harm  Patient <b>MUST</b> be made aware that the vaccine manufacturers have demanded and been granted immunity from liability for injury or death caused by the vaccines	One example may be if a patient has first-hand knowledge of a relative who has suffered serious harm following vaccination.  <a href="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">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</a>	Yes/No
<b>e. Expected harms, including common side effects and what to do if they occur.</b>	Full list of adverse reactions in insert to be shared. Common side-effects include chills, fever, myalgia, fatigue, arthralgia, headache, and pain at the infection site.	Moderna vaccine -100% of high-dose participants report systemic side effects after second dose, some severe  <a href="https://www.nejm.org/doi/full/10.1056/NEJMoa2022483">https://www.nejm.org/doi/full/10.1056/NEJMoa2022483</a>	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 2017 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