



INFORMED CONSENT – LEGAL SUMMARY FOR THE COVID-19 VACCINE

We have set out below a summary of the current best medical practice and the law when it comes to providing your consent to any COVID-19 Vaccine. Please note the below is only a summary and only applies to those who have the mental capacity to consent. We would recommend that if you experience any issues with your healthcare provider that you seek legal advice.

What is informed consent?

In England and Wales, we currently operate a system of patient autonomy which means you have the right to give your consent prior to any medical treatment. For consent to be valid, your healthcare provider should abide by the following legal rights which are set out in the **NHS Constitution** that was last updated in 2015ⁱ, and the **guidance issued by the NHS**, updated on 29 March 2019ⁱⁱ:

1. You should be **free to accept or refuse treatment** that is offered
2. **You should not be given any treatment unless you have given valid consent**
3. You should be given information about the test and treatment options available, what they involve and their **risks and benefits**, and base your decision on that advice
4. **You should be involved in planning and making decisions about your health and care** with your care provider or providers
5. **Your decision should be voluntary** and must not be influenced by pressure from medical staff, friends, or family. **Your decision must be respected.**

The courts have also upheld the view that informed consent is now firmly part of **English Law**ⁱⁱⁱ. Informed consent means that the following steps must be undertaken prior to you consenting to any treatment:

1. It must be explained to you which, if any, **available forms of treatment** to undergo
2. Your doctor is under a duty to take reasonable care to ensure that you are aware of **any material risks** involved in any recommended treatment, and of **any reasonable alternative** or variant treatments
3. Where there are choices to be made, you should be presented **with arguments for and against each of the options**, and sufficient information must be given for you to decide.

In addition, healthcare providers are also required to adhere to additional requirements set out by the **United Nations** which further enshrines the right to informed consent^{iv}. This states that *“any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information.”*

Furthermore, the **United Nations** further states in relation to experimental treatment that *“Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned”*

What information should the doctor/healthcare provider give?

For your consent to be fully informed, you must have **all information available** to make a fully informed choice. We suggest that you should be provided with the following information to be able to make your choice:

1. The **outcome of the medical trials** leading to the emergency approval of any vaccine. This must be in easy-to-understand language and it should be explained that there are only a **few months of safety data** available for the trials, and that the **COVID-19 vaccine has been developed quickly**, compared to the average length of time taken to develop a vaccine, which is 10 years
2. It should be made clear that there is **no information available about potential late-onset side effects** resulting from a Covid-19 Vaccine, that may take years to become apparent.
3. The **age groups of those participating in the vaccine trials**, whether they had any pre-existing conditions and whether they were on any regular medications
4. A full list of **all adverse reactions reported in the vaccine trials** (mild, moderate, and serious)
5. Safety data must be presented in a way that allows you to **weigh up your individual risk** (age and comorbidity) from COVID-19 against the risk of side-effects (mild, moderate and severe) from a COVID-19 vaccine
6. **The alternatives to a Vaccine**, applicable to your age and any health-related issues
7. The doctor administering the vaccine must **keep a record of decisions made and actions agreed** in the patient's clinical records. This includes decisions to take no action.^v

Once you have been provided with the above, you are then entitled to **sufficient time to make your decision, without coercion** and without any further impacts on your choice. **Your choice must be respected by the healthcare provider.**

For more information, and to aid discussion with your healthcare provider, please refer to the UKMFA COVID-19 Vaccine Informed Consent Form^{vi}.

ⁱ <https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england>

ⁱⁱ <https://www.nhs.uk/conditions/consent-to-treatment/>

ⁱⁱⁱ Montgomery v Lanarkshire Health Board [2015] UKSC 11. <https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf>

^{iv} Universal Declaration on Bioethics and Human Rights http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

^v https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf

^{vi} [https://uploads-](https://uploads-ssl.webflow.com/5fa5866942937a4d73918723/5fcccc0fb2087f907e58ea30_UKMFA_CV19_vaccine_consent_form_v2.pdf)

[ssl.webflow.com/5fa5866942937a4d73918723/5fcccc0fb2087f907e58ea30_UKMFA_CV19_vaccine_consent_form_v2.pdf](https://uploads-ssl.webflow.com/5fa5866942937a4d73918723/5fcccc0fb2087f907e58ea30_UKMFA_CV19_vaccine_consent_form_v2.pdf)