

Date

Dear

This is a letter that you must read and must respond to. The word **MUST** is a legal imperative. Failure to comply is a criminal act.

- What you **MUST READ** is below in black
- **What you MUST DO** is below in red

The administration of any vaccine to a child in your school must comply with the following legal and ethical principles:

1. All children receiving a vaccine **MUST** (**MUST** is a legal imperative) give legally valid informed consent, usually obtained from a parent or legal guardian unless Gillick Competence is met.
2. Proper confidentiality must be observed to prevent peer pressure and coercion to vaccinate.

Whilst children are present in your school, you act in loco parentis. It is therefore your responsibility to ensure legally valid informed consent is obtained from either parents or older children before any vaccination. This requires a thorough understanding of the legalities of Gillick Competence, when older children are giving their own consent independent of parents.

### What is Informed Consent?

**Informed Consent is a legal imperative for ANY medical intervention e.g. physical and psychological examinations, prescription drugs, surgery, vaccines, medical trials etc. Failure to obtain proper informed consent is a criminal act.**

England and Wales healthcare system and legislation upholds the principle of patient autonomy, where everyone with capacity has the right to freely give or withhold consent prior to any medical treatment. For consent to be valid, a healthcare provider should abide by the following rules, set out in the NHS Constitution<sup>1</sup> (last updated in 2015) and NHS guidance<sup>2</sup> (updated on 29<sup>th</sup> March 2019):

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.

<sup>1</sup> <https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england>

<sup>2</sup> <https://www.nhs.uk/conditions/consent-to-treatment/>

## The Montgomery Judgement and Informed Consent<sup>3</sup>

The duty to obtain informed consent was enshrined in English Law in the Supreme Court judgement of *Montgomery v Lanarkshire Health Board [2015]* UKSC 11<sup>4</sup>, which changed the standards of consent. The following steps must be undertaken prior to any medical intervention or treatment:

1. It must be explained to you which, if any, available forms of treatment are available.
2. Your doctor has 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 is a choice to be made, you should be presented with arguments for and against each of the options, including the option to do nothing, and sufficient information must be given for you to decide, without duress.

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 the consent process, as their understanding of material risk must be considered. If a doctor fails to properly discuss risks and alternative treatments with the patient, they will be personally liable for damages.

In addition, healthcare providers are required to adhere to requirements set out by the United Nations in the Universal Declaration on Bioethics and Human Rights<sup>5</sup>, which further enshrine the right to uncoerced, informed consent:

*"...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."*

## General Medical Council Guidance - Decision Making and Consent (2020)<sup>6</sup>

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 when obtaining consent:

1. Recognise risks of harm that they believe anyone in the patient's position would want to know.
2. The effect of the patient's individual clinical circumstances on the probability of a benefit or harm occurring.
3. Risks of harm and potential benefits that the patient would consider significant for any reason - revealed during a discussion with the patient about what matters to them.
4. Any risk of serious harm, however unlikely it is to occur.
5. Expected harms, including common side effects and what to do if they occur.

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<sup>3</sup> <https://www.themdu.com/guidance-and-advice/guides/montgomery-and-informed-consent>

<sup>4</sup> <https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf>

<sup>5</sup> <https://www.unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights>

<sup>6</sup> <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent>

## Informed Consent and Application of Gillick Competence

As outlined above, informed consent is the cornerstone of good, ethical medical practice and is enshrined in UK and International Law and professional guidelines. Carrying out any medical procedure without informed consent is unlawful and amounts to medical negligence, which can lead to charges of misconduct.

It is not possible for anyone, let alone children, to give informed consent to any vaccination unless they are given factually accurate information, with full disclosure of risks (including long-term safety data) as well as benefits, and any other available treatments. The applicability of Gillick Competence cannot be assumed under current circumstances.

Gillick Competence is the principle deriving from the English and Welsh legal case of Gillick v West Norfolk and Wisbech Area Health Authority [1985] UKHL 7<sup>7</sup>, which provides that children under the age of 16 may be able to consent to their own treatment, if they are assessed and deemed to have enough intelligence, competence and understanding to fully appreciate what is involved in their treatment. The judgment in Gillick makes it clear it is to apply only in exceptional cases:

*“No reasonable person could read it as meaning that the doctor’s discretion could ordinarily override parental right. Illustrations are given in the text of exceptional cases in which the doctor may take the “most unusual” course of not consulting the parent. Only in exceptional cases does the guidance contemplate him exercising his clinical judgment without the parent’s knowledge and consent.”* (per Lord Scarman at paragraph 181)

It was stated in a subsequent case<sup>8</sup> that:

*“The right to decide on competence must not be used as a license to disregard the wishes of parents whenever the health professional finds it convenient to do so. Health professionals who behave in this way would be failing to discharge their professional responsibilities and could expect to be disciplined by their professional body.”*

For a child to even be considered Gillick Competent, they MUST have *“a sufficient understanding and intelligence to enable them to comprehend fully what is proposed”* and:

1. Understand the nature and implications of the decision and the process of implementing that decision.
2. Understand the implications of not pursuing the decision.
3. Retain the information long enough for the decision-making process to take place.
4. Be of sufficient intelligence and maturity to weigh up the information and arrive at a decision.
5. Be able to communicate that decision.

Determining Gillick Competence must be decision-specific, child-specific, made with the specific factual context in mind, and based on the available evidence. It can only be determined by a medical practitioner who knows the child, not just any personnel administering vaccines in schools.

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<sup>7</sup> <https://cirp.org/library/legal/UKlaw/gillickvwestnorfolk1985/>

<sup>8</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4962726/#cit0005>

Furthermore, following the High Court case of *An NHS Trust v A, B, C and A Local Authority* [2014] EWHC 1445<sup>9</sup>, Mr Justice Mosytn also stated the decision of the child must be given freely. He stated:

*“Dr Ganguly was also clear that the decision that was reached by A was hers alone and was not the product of influence by adults in her family. Dr Ganguly did not detect in her any sign of distress when she set out her position to her.”*

You will be well aware that children are often subject to peer pressure from their fellow pupils. Children also look up to their teachers and can be influenced by the media and celebrities. In the current cultural climate and discourse around vaccines, it certainly cannot be the case that any child could give legally valid informed consent, free from any coercion.

All teachers and school staff owe a Duty of Care to their pupils. We argue that this Duty of Care requires schools to ensure that the full legal requirements of Gillick Competency are properly adhered to when it comes to the administration of vaccines on school premises.

### What information should the doctor/healthcare provider give regarding vaccines?

We suggest that the following information is necessary to be able to make an informed decision:

1. **The outcome of the clinical trials** leading to the approval of any vaccine. This must be in easy-to-understand language. It should be explained that there may be only a few days or months of safety and efficacy data available for the trials and any limitation of assurance of short-, medium- or long-term safety or efficacy.
2. **Information about potential late-onset side-effects**, that may take months or years to become apparent.
3. **Key information about the vaccine trial participants** – age groups tested and whether they had any pre-existing conditions or were on any regular medications.
4. **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 **weighing up of individual risk from the illness against the risk of side-effects from the vaccine**.
6. **The alternatives to a vaccine**, applicable to age and any health-related issues.
7. The doctor or healthcare professional administering the vaccine must keep **a record of conversations, decisions made, and actions agreed, in the patient’s clinical records**<sup>10</sup>. This includes any decision to take no action.

Once the individual is provided with the above, they are then entitled to sufficient time to decide, without coercion and without any further impact on their circumstances. **Their choice must be respected and honoured by the healthcare provider.**

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<sup>9</sup> <http://www.bailii.org/ew/cases/EWHC/Fam/2014/1445.html>

<sup>10</sup> [https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english\\_pdf84191055.pdf](https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf84191055.pdf)

**FOR THE LEGAL ADMINISTRATION OF ANY MEDICAL TREATMENT OR INTERVENTION, ALL PARTIES MUST READ AND SIGN THIS DOCUMENT**

This form (in conjunction with the information in the letter above) has been designed to support the Informed Consent process for ANY medical intervention.

**GIVEN A FULL UNDERSTANDING OF THE ABOVE, before ANY medical intervention which may have adverse consequences, a proper consent form MUST be signed by both patient and doctor or healthcare professional and held by both parties for at least 7 years.**

**VACCINE CONSENT FORM - to be signed by Doctor/ Nurse AND Patient/Parent**

**Doctor/nurse 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 inform my patient fully and correctly renders me personally and legally responsible for any damages.

Date/Time	Name of Doctor or Nurse administering treatment	Professional Number of Doctor (GMC) or Nurse (NMC)	Vaccine(s) Details, Batch Number, Expiry Date	Signature of Healthcare Professional

**Patient/parent consent:**

I confirm that I have discussed the issues in this letter at length with the doctor or health professional named above. I believe that I have been correctly informed of possible side-effects of the vaccine(s) being offered, together with the alternatives to vaccination. I choose and consent to my child receiving the vaccine(s) listed above.

Date/Time	Name of Patient	Name of Parent or Guardian (if consenting on behalf of patient)	Contact Phone Number or Email	Signature of Patient

This information has been put together by [UK Medical Freedom Alliance](#) and [The Alliance for Natural Health](#).

It is available at [Professionals for Medical Informed Consent](#) (PROMIC).

We are committed to assist any parent or child who should demand informed consent.