LAWS REGARDING CLINICAL TRIALS

The law governing clinical trials involving "live human subjects" i.e. "live human experiments"

The use of face masks, testing equipment, and the so-called COVID-19 vaccines for children are entirely experimental and amount to a "live human experiment" on "live human subjects." The so-called COVID-19 vaccines are still in clinical trial stage until 2023 and is a "live human experiment" as is using the RT-PCR test and the wearing of face masks by children in school to combat the SARS-CoV-2 virus. As such, **conducting such a live human experiment using children as the live human subjects in these clinical trials, constitutes a prima facie breach** of International, European and UK civil and criminal laws and codes of medical ethics - **unless lawful, legal, moral and ethical informed consent - freely given - is provided by the individual child who has the competence and the capacity to provide their consent to be experimented upon,** having been informed of all the **material risks** of the experiment, including the material risk of **DEATH, SERIOUS INJURY, INJURY, HARM, INCONVENIENCE and the LONG TERM CONSEQUENCES to their health, fertility, immune system, heart, nervous system and major organs and to their well being**.; and

WHEREAS, you have a **duty of care and a legal statutory duty**, and **a moral and ethical duty to avoid all harm, loss, injury, suffering and death and all adverse events** associated with these NPIs and PIs.; and

The legal, lawful, ethical and moral requirement for Informed Consent - freely given - by the individual to medical treatment or procedures or live human experiments

WHEREAS, other than in exceptional circumstances, conducting a live human experiment on a living man, woman or child or conducting medical procedures or treatment on an individual living man, woman or child without obtaining their **informed consent - freely given** - to taking part in the live human experiment or to receiving medical treatment or procedures is a violation of their fundamental, inalienable lawful, legal and constitutional rights. Voluntary consent for any medical treatment is a fundamental part of the laws of the UK and international laws. **It is legally, lawfully, ethically, and morally wrong to coerce, threaten, intimidate, sanction, fine, punish, guilt-trip, shame, pressurise, or use any other form of means to obtain consent from a living man, woman or child to participate in a clinical trial** or to receive medical treatment and or medical procedures - see below; and

WHEREAS, the **duty to obtain an individual's informed consent freely given** to taking part in a live human experiment and or medical treatment or medical procedure is a **lawful, legal, moral and ethical duty, necessity and requirement** because individual living men, women and children have a **fundamental inalienable human right to bodily integrity**, that being autonomy and self - determination over their own body without unconsented physical or mental intrusion - **"Voluntas Aegroti Suprema Lex" - "Over his or her own mind and body, the individual is Sovereign**"- (John Stuart Mill, On Liberty, 1859).
- https://thegreatthinkers.org/mill/major-works/liberty-2/; and

WHEREAS, "Over his or her own mind or body the individual is sovereign" - Voluntas Aegroti Suprema Lex- is a **fundamental principle of law that binds you.** An individual has sovereignty

over their own mind and body i.e. they have the right to bodily integrity. This fundamental right cannot be limited or derogated from, other than in accordance with the law. **Salus populi suprema lex esto** (Latin: "**The health (welfare, good, salvation, felicity) of the people should be the supreme law", "Let the good (or safety) of the people be the supreme (or highest) law", or "The welfare of the people shall be the supreme law"**) is a maxim or principle found in Cicero's De Legibus (book III, part III, sub. VIII). - http://www.thelatinlibrary.com/cicero/leg3.shtml. Cicero (3 January 106 - 7 December 43 BC) was a Roman statesman, lawyer, scholar, philosopher. This evidences that this principle of law has been enshrined in our common law system and in our codes of medical ethics since at least pre-ancient and Roman times; and

WHEREAS, this right to bodily integrity includes the individual's **right to life,** and **the right not to be tortured or given inhumane, cruel or degrading treatment or punishment**, which includes **the right not to be experimented upon or to be given medical or other treatment without providing their informed consent - freely given**, (see below) and **the right not to have their psychiatric integrity breached** through psychological techniques or methods such as psychological warfare (see below), **the right to self determination** and **the right to privacy** (see below) ; and

Live human experiments

WHEREAS, there are extensive lawful, moral, ethical and legal obligations governing the participation of a live human subject in a live human experimental clinical trial, including the **duty to obtain fully informed consent, freely given** from the live human subject to participate in the live human experiment in accordance with the Rule of Law - **Informed Consent, freely given, is a legal, lawful, moral and ethical requirement for all individuals participating in a clinical trial.** It is unlawful to enrol anyone in a clinical trial without full and informed consent, freely given - see below and see Exhibit: Nuremburg Code [1947] which sets down 10 principles which must be followed by researchers in a clinical trial involving live human subjects. The British Medical Journal states the following in relation to the Nuremburg Code:

"*The judgment by the war crimes tribunal at Nuremberg laid down **10 standards to which physicians must conform when carrying out experiments on human subjects** in a new code that is now accepted worldwide.*

*This judgment established a new standard of ethical medical behaviour for the post World War II human rights era. Amongst other requirements, this document enunciates **the requirement of voluntary informed consent of the human subject. The principle of voluntary informed consent protects the right of the individual to control his own body.***

*This code also recognizes that the **risk must be weighed against the expected benefit, and that unnecessary pain and suffering must be avoided.***

*This code recognizes that **doctors should avoid actions that injure human patients.***

*The **principles established by this code for medical practice now have been extended into general codes of medical ethics**."* (emphasis added) ; and

http://www.cirp.org/library/ethics/nuremberg/

https://famous-trials.com/nuremberg/1903-doctortrial

https://crimeofaggression.info/documents/6/1946_Nuremberg_Judgement.pdf; and

WHEREAS, clinical trials involving live human subjects are defined as a "live human experiment" with "live human participants". Therefore the International obligations to protect the live human participants in a live human experiment must be upheld including those set out in, inter alia, the Nuremburg Code [1947], the Helsinki Declaration [1964], the Oviedo Convention [1997], the Universal Declaration on Bioethics and Human Rights [2005], applies. Under UK Statute law, clinical trials involving "medicines for human use" engage the Medicines for Human Use (Clinical Trials) Regulations 2004. All these governing codes, conventions, declarations and statutes require the **"informed consent, freely given**" of the live human subject to participate in a live human experiment and or clinical trial; and

WHEREAS, the Declaration of Helsinki [1964] is defined in Part 1 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as follows:

"SCHEDULE 1

CONDITIONS AND PRINCIPLES OF GOOD CLINICAL PRACTICE AND FOR THE PROTECTION OF CLINICAL TRIAL SUBJECTS

PART 1

APPLICATION AND INTERPRETATION

"2. In this Schedule—

"Declaration of Helsinki" means the Declaration of Helsinki adopted by the World Medical Assembly in June 1964, as amended by the General Assembly of the Association in October 1975, October 1983, September 1989 and October 1996."

https://www.legislation.gov.uk/uksi/2004/1031/schedule/1/made; and

WHEREAS, the Declaration of Helsinki [1964] is incorporated into PART 2 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as follows:

"PART 2

CONDITIONS AND PRINCIPLES WHICH APPLY TO ALL CLINICAL TRIALS

Principles based on International Conference on Harmonisation GCP Guideline

1. Clinical trials shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with good clinical practice and the requirements

of these Regulations."

https://www.legislation.gov.uk/uksi/2004/1031/schedule/1/made; and

Legal Statutory duty to apply the conditions and principles specified in Part 2 of the 2004 Regulations

WHEREAS, section 1 of PART 1 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 states as follows:

"1.— (1) **The conditions and principles specified in Part 2 apply to all clinical trials**.

(2) If any subject of a clinical trial is—

(a) an adult able to give informed consent, or
(b) an adult who has given informed consent to taking part in the clinical trial prior to the onset of incapacity,
the conditions and principles specified in Part 3 apply in relation to that subject.

(3) **If any subject of a clinical trial is a minor, the conditions and principles specified in Part 4 apply in relation to that subject.**
(emphasis added)

(4) If any subject—

(a) is an adult unable by virtue of physical or mental incapacity to give informed consent, and
(b) did not, prior to the onset of incapacity, give or refuse to give informed consent to taking part in the clinical trial,
the conditions and principles specified in Part 5 apply in relation to that subject.

(5) **If any person**—

(a) is an adult unable by virtue of physical or mental incapacity to give informed consent, and
(b) **has, prior to the onset of incapacity, refused to give informed consent to taking part in the clinical trial, that person cannot be included as a subject in the clinical trial."**

https://www.legislation.gov.uk/uksi/2004/1031/schedule/1/made; and

Legal statutory definition of Informed Consent which must be provided by an individual participant in a clinical trial

WHEREAS, the definition of **"informed consent**" which must be provided by the individual participant in a clinical trial in the UK is defined in the definitions section of Part 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as follows:

"informed consent" shall be construed in accordance with paragraph 3 of Part 1 of Schedule 1".

https://www.legislation.gov.uk/uksi/2004/1031/part/1/made; and

Legal statutory requirements for informed consent to participate in a clinical trial under the Medicines for Human Use (Clinical Trials) Regulations 2004

A person gives informed consent to take part in a clinical trial ONLY if his/her decision is

(a) given freely after that person is informed of

(i) the nature,
(ii) the implications, and
(iii) the risks

of the trial; and

(b) has either:

(i) provided evidence of their written consent, dated and signed, or

(ii) provided their consent orally in the presence of at least one witnesse and recorded in writing.

WHEREAS, paragraph 3 of Part 1 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 provides the definition of "informed consent" as follows:

"3.—(1) For the purposes of this Schedule, a person gives **informed consent** to take part, or that a subject is to take part, in a clinical trial only if his decision—

(a) is given **freely after that person is informed of the nature, significance, implications and risks of the trial**; and

(b) either—

(i) is **evidenced in writing**, dated and signed, or otherwise marked, by that person so as to indicate his consent, or

(ii) if the person is unable to sign or to mark a document so as to indicate his consent, is given orally in the presence of at least one witness and recorded in writing.

(2) For the purposes of this Schedule, references to informed consent—

(a) shall be construed in accordance with paragraph (1); and

(b) include references to informed consent given or refused by an adult unable by virtue of physical or mental incapacity to give

informed consent, prior to the onset of that incapacity."

https://www.legislation.gov.uk/uksi/2004/1031/schedule/1/made ; and

The legal statutory duty to conduct clinical trials in accordance with "Good Clinical Practice and Protection of Clinical Trial Subjects" - section 28 of Part 4 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004.

WHEREAS, Section 28, entitled "Good clinical practice and protection of clinical trial subjects" states:

> "Good clinical practice and protection of clinical trial subjects
> 28.—(1) No person shall—
>
> (a) conduct a clinical trial; or
>
> (b) perform the functions of the sponsor of a clinical trial (whether that person is the sponsor or is acting under arrangements made with that sponsor),otherwise than in **accordance with the conditions and principles of good clinical practice**.
>
> (2) Subject to paragraph (5), the sponsor of a clinical trial shall put and keep in place arrangements for the purpose of ensuring that with regard to that trial **the conditions and principles of good clinical practice are satisfied or adhered to**." (emphasis added)

- https://www.legislation.gov.uk/uksi/2004/1031/part/4/made; and

WHEREAS, Part 2 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 engages the conditions and principles which apply to all clinical trials, including ethics requirements for an ethics committee, as set out in the Declaration of Helsinki [1964] - https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/doh-jun1964/- for all subjects participating in clinical trials as follows:

> "PART 2
>
> CONDITIONS AND PRINCIPLES WHICH APPLY TO ALL CLINICAL TRIALS
>
> Principles based on International Conference on Harmonisation GCP Guideline - https://ichgcp.net/
>
> 1. **Clinical trials shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with good clinical practice and the requirements of these Regulations.**
>
> 2. Before the trial is initiated, **foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients**.

A trial should be initiated and continued only if the anticipated benefits justify the risks.

3. The **rights, safety, and well-being of the trial subjects are the most important considerations and shall prevail over interests of science and society .**

4. The available non-clinical and clinical information on an investigational medicinal product shall be adequate to support the clinical trial.

5. Clinical trials shall be scientifically sound, and described in a clear, detailed protocol.

6. A **trial shall be conducted in compliance with the protocol that has a favourable opinion from an ethics committee.**

7. The medical care given to, and medical decisions made on behalf of, subjects shall always be the **responsibility of an appropriately qualified doctor** or, when appropriate, of a qualified dentist.

8. **Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his or her respective task**(s).

9. Subject to the other provisions of this Schedule relating to consent, **freely given informed consent shall be obtained from every subject prior to clinical trial participation.**

10. All clinical trial information shall be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.

11. The confidentiality of records that could identify subjects shall be protected, **respecting the privacy and confidentiality rules in accordance with the requirements of the Data Protection Act 1998 and the law relating to confidentiality**.

12. Investigational medicinal products used in the trial shall be—

(a) manufactured or imported, and handled and stored, in accordance with the principles and guidelines of good manufacturing practice, and

(b) used in accordance with the approved protocol.

13. Systems with procedures that assure the quality of every aspect of

the trial shall be implemented." (emphasis added)

https://www.legislation.gov.uk/uksi/2004/1031/schedule/1/made; and

MINORS PARTICIPATING IN CLINICAL TRIALS – VACCINATION OF MINORS

Legal statutory duties in relation to conditions and principles which apply in relation to a Minor participating in a clinical trial and to obtain Parental Consent for a Child under 16 years old -

WHEREAS, Part 4 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 which sets the minimum of providing a more exacting test of informed consent for minors, which must apply to emergency approval treatments that have not completed clinical trials, and sets the minimum of **requiring parental consent for a minor aged under 16 - in accordance with "Good clinical practice" -** see Condition number 4 in Part 4 of the 2004 Regulations (below)**. ;** and

WHEREAS, under Schedule 1, Part 4 of the Medicines for Human Use (Clinical Trials) Regulations 2004, it states, inter alia:

"PART 4

CONDITIONS AND PRINCIPLES WHICH APPLY IN RELATION TO A MINOR

Conditions

1. Subject to paragraph 6, **a person with parental responsibility for the minor** or, if by reason of the emergency nature of the treatment provided as part of the trial no such person can be contacted prior to the proposed inclusion of the subject in the trial, a legal representative for the minor has had an interview with the investigator, or another member of the investigating team, in which he **has been given the opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.**

2. That person or legal representative has been **provided with a contact point where he may obtain further information** about the trial.

3. That person or legal representative has been **informed of the right to withdraw the minor from the trial** at any time.

4. That person or legal representative has **given his informed consent to the minor taking part in the trial**.

5. That person with parental responsibility or the legal representative **may, without the minor being subject to any resulting detriment, withdraw the minor from the trial at any time by revoking his informed consent**.

6. The **minor has received information according to his**

capacity of understanding, from staff with experience with minors, regarding the trial, its risks and its benefits.

7. The **explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in the previous paragraph to refuse participation in, or to be withdrawn from, the clinical trial at any time** is considered by the investigator.

8. No **incentives or financial inducements are given**—

   (a) to the minor; or
   (b) to a person with parental responsibility for that minor or, as the case may be, the minor's legal representative,

   except provision for compensation in the event of injury or loss.

9. The clinical trial relates directly to a clinical condition from which the minor suffers or is of such a nature that it can only be carried out on minors.

10. Some direct benefit for the group of patients involved in the clinical trial is to be obtained from that trial.

11. The clinical trial is necessary to validate data obtained—

   (a) in other clinical trials involving persons able to give informed consent, or
   (b) by other research methods.

12. The corresponding scientific guidelines of the European Medicines Agency are followed.

Principles

13. **Informed consent given by a person with parental responsibility or a legal representative to a minor taking part in a clinical trial shall represent the minor's presumed will**.

14. The clinical trial has been designed to **minimise pain, discomfort, fear and any other foreseeable risk i**n relation to the disease and the minor's stage of development.

15. The **risk threshold and the degree of distress have to be specially defined and constantly monitored**.

16. The **interests of the patient always prevail over those of science and society**. (emphasis added).

https://www.legislation.gov.uk/uksi/2004/1031/schedule/1/made; and

WHEREAS, no other person such as a family member, friend or carer and no organisation can give or refuse consent to a health or social care service on behalf of an individual living man, woman or child **who lacks capacity to consent** unless they have specific legal authority to do so - https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/national-consent-policy-hse-v1-3-june-2019.pdf; and

Legal statutory definition of "Parental Responsibility"

WHEREAS, "parental responsibility" is defined in PART 1 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as follows:

> "(a) in relation to England and Wales, has **the same meaning as in the Children Act 1989,**
>
> (b) in relation to Scotland, has the same meaning as in the Children (Scotland) Act 1985, and
>
> (c) in relation to Northern Ireland, has the same meaning as in the Children (Northern Ireland) Order 1995"

https://www.legislation.gov.uk/uksi/2004/1031/schedule/1/made; and

WHEREAS, the legal statutory definition of "parental responsibility" is defined in section 3 of the Children Act 1989, which states:

> "3 Meaning of "parental responsibility".
>
> (1) In this Act "**parental responsibility" means all the rights, duties, powers, responsibilities and authority which by law a parent of a child has in relation to the child and his property.**
>
> (2) It also includes the rights, powers and duties which a guardian of the child's estate (appointed, before the commencement of section 5, to act generally) would have had in relation to the child and his property.
>
> (3) The rights referred to in subsection (2) include, in particular, the right of the guardian to receive or recover in his own name, for the benefit of the child, property of whatever description and wherever situated which the child is entitled to receive or recover.
>
> (4) The fact that a person has, or does not have, parental responsibility for a child shall not affect—

(a) any obligation which he may have in relation to the child (such as a statutory duty to maintain the child);

or

(b) any rights which, in the event of the child's death, he (or any other person) may have in relation to the child's property.

(5) A person who—

(a) does not have parental responsibility for a particular child; but

(b) has care of the child, may (subject to the provisions of this Act) do what is reasonable in all the circumstances of the case for the purpose of safeguarding or promoting the child's welfare."

https://www.legislation.gov.uk/ukpga/1989/41/section/3; and

Competence and Capacity to provide Informed Consent

WHEREAS, consent to medical treatment or to participation in a live human experiment **cannot be provided** by a living man, woman or child who **lacks the competence or the capacity to provide their informed consent, freely given** to such medical treatment or participation in a live human experiment.; and

WHEREAS, capacity and competency of an adult or child to consent to or refuse medical treatment is **decision-specific, child-specific and made on the specific factual context in mind, and based on the available evidence**.; and

WHEREAS, the law in the UK, states that a "minor" is a child under the age of 18 for the purposes of capacity to consent to or to refuse medical treatment. A "minor" is deemed to lack the capacity to consent to or refuse medical treatment unless the child is found to be "Gillick competent" in accordance with the "Fraser Guidelines" set out in the UK case of Gillick v West Norfolk and Wisbech Health Authority [1986] https://www.casemine.com/judgement/uk/5a8ff8c960d03e7f57ecd66a; and

WHEREAS, a child's competence and capacity to consent MUST be formally assessed PRIOR to the medical treatment and PRIOR to their participation in a live human experiment- as required by the law - see the UK case law of the House of Lords in the case of Gillick v West Norfolk and Wisbech AHA (1986). This test for a child's competence to consent to medical treatment is known as "Gillick competence" after the case of Gillick cited.

- https://www.casemine.com/judgement/uk/5a8ff8c960d03e7f57ecd66a; and

WHEREAS, the General Medical Council (the "GMC"), and Department of Health and Social Care (the "DHSC") provide guidance on informed consent. The government's Green Book on vaccination opines that **Gillick Competency is not automatic**. It states in Chapter 2 that

*"Where immunisations are routinely offered in the school setting, consent differs depending on the age and competence of the **individual** child or young person.";* and

ETHICS COMMITTEE

Legal requirement for authorisation and ethics committee opinion

WHEREAS, under Part 3 of the Medicines for Human Use (Clinical Trials) Regulations 2004, it states, inter alia:

> "Requirement for authorisation and ethics committee opinion
>
> 12.— (1) **No person shall—**
>
> **(a) start a clinical trial or cause a clinical trial to be started; or**
> **(b) conduct a clinical trial, unless the conditions specified in paragraph (3) are satisfied.**
>
> (2) **No person shall—**
>
> **(a) recruit an individual to be a subject in a trial;**
> **(b) issue an advertisement for the purpose of recruiting individuals to be subjects in a trial, unless the condition specified in paragraph (3)(a) has been satisfied**.
>
> (3) The conditions referred to in paragraphs (1) and (2) are—
>
> (a) **an ethics committee or an appeal panel appointed under Schedule 4 has given a favourable opinion in relation to the clinical trial**; and
>
> (b) the clinical trial has been authorised by the licensing authority." (emphasis added)

- https://www.legislation.gov.uk/uksi/2004/1031/part/3/made; and

GENERAL CLINICAL TRIAL

Legal requirement for "urgent safety measures" to be taken to protect the subjects of a clinical trial against any "immediate hazard to their health or safety".

WHEREAS, section 30 of PART 4 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 entitled "Urgent safety measures" states that:

> "30.—(1) The sponsor and investigator may take appropriate urgent safety measures in order to **protect the subjects of a clinical trial against any immediate hazard to their health or safety**. (emphasis added)
>
> (2) If measures are taken pursuant to paragraph (1), the sponsor shall immediately, and in any event no later than 3 days from the date the measures are taken, give written notice to the licensing authority and the relevant ethics committee of the measures taken and the circumstances giving rise to those measures."

https://www.legislation.gov.uk/uksi/2004/1031/part/4/made; ; and

REPORTING OF SERIOUS ADVERSE EVENTS

Legal requirement to notify/report any "serious adverse event" which occurs in a subject at a trial site.

WHEREAS, PART 5 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 entitled "PHARMACOVIGILANCE", section 32 requires reporting any "serious adverse event" as stated:

> "Notification of adverse events
>
> 32.—(1) An investigator shall report any serious adverse event which occurs in a subject at a trial site at which he is responsible for the conduct of a clinical trial immediately to the sponsor.
>
> (2) An immediate report under paragraph (1) may be made orally or in writing.
>
> (3) Following the immediate report of a serious adverse event, the investigator shall make a detailed written report on the event."

https://www.legislation.gov.uk/uksi/2004/1031/part/5/made; and

Legal requirement to record and notify/report "suspected unexpected serious adverse reactions" which is "fatal or life-threatening"

WHEREAS, PART 5 of Schedule 1 of the Medicines for Human Use (Clinical Trials) Regulations 2004 entitled "PHARMACOVIGILANCE", section 33 requires "Notification of suspected unexpected serious adverse reactions" as stated:

> "**Notification of suspected unexpected serious adverse reactions"**
>
> 33.—(1) A sponsor shall ensure that **all relevant information about a suspected unexpected serious adverse reaction** which occurs during the course of a clinical trial in the United Kingdom and is fatal or life-threatening is—
>
> (a) **recorded**; and
>
> (b) **reported as soon as possible** to—
>
> (i) the licensing authority,
> (ii) the competent authorities of any EEA State, other than the United Kingdom, in which the trial is being conducted, and
> (iii) the relevant ethics committee, and in any event not later that 7 days after the sponsor was first aware of the reaction." (emphasis added)

https://www.legislation.gov.uk/uksi/2004/1031/part/5/made; and