Informed Consent:

The process of informed consent occurs when <u>communication between a patient</u> and <u>physician</u> results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:

- 1. Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.
- 2. Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:
- 3. The diagnosis (when known)
- 4. The nature and purpose of recommended interventions
- 5. The burdens, risks, and expected benefits of all options, including forgoing treatment

6.

Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record.

Informed Consent occurs between a patient and a doctor.

<u>Informed Consent | American Medical Association (ama-assn.org)</u>

VAERS COVID Vaccine Data (Vaccine Adverse Events Reporting System, USA) 438,440 Reports as of July 7, 2021 3,324 985 Heart Attacks Miscarriages 2,226 7,823 Thrombocytopenia/ Life Threatening Low Platelet 2.200 **7,463**Disabled Myocarditis/Pericarditis 19.105 5.118 Severe Allergic Tinnitus Reaction 26,818 56,970 2,152 2,486

Know Your Constitutional and Lawful Rights



Who's that knocking on my front door?

Solicit:

To appeal for something; to apply to for obtaining something; to ask earnestly; to ask for the purpose of receiving; to endeavor to obtain by asking or pleading; to entreat, implore, or importune; to make petition to; to plead for; to try to obtain; and through word implies a serious request, it requires no particular degree of importunity, entreaty, imploration, or supplication. People v. Phillips, 70 Cal. App.2d 449, 160 P.2d 872, 874 To awake or excite to action, or to invite. The term implies personal petition and importunity addressed to a particular individual to do some particular thing.

Solicitation:

Asking; enticing; urgent request. Any action which the relation of the parties justifies in construing into a serious request.

Black's Law Dictionary 5th edition Pgs1248-1249

Virginia Constitution

ARTICLE 1 SECTIONS 1-3, 15, 17

Section 1: Equality and Rights of Men

That all men are by nature equally free and independent and have certain inherent rights, of which, when they enter into a state of society, they cannot, by any compact, deprive or divest their posterity; namely, the enjoyment of life and liberty, with the means of acquiring and possessing property, and pursuing and obtaining happiness and safety.

Section 2: People the Source of Power

That all power is vested in, and consequently derived from, the people, that magistrates are their trustees and servants, and at all times amenable to them.

Section 3: Government Instituted for Common Benefit

That government is, or ought to be, instituted for the common benefit, protection, and security of the people, nation, or community: of all the various modes and forms of government, that is best which is capable of producing the greatest degree of happiness and safety, and is most effectually secured against the danger of maladministration: and. whenever any government shall be found inadequate or contrary to these purposes, a majority of the community hath an indubitable, inalienable, and indefeasible right to reform, alter, or abolish it, in such manner as shall be judged most conducive to the public weal.

Section 15:

Qualities Necessary to Preservation of Free Government That no free government, nor the blessings of liberty, can be preserved to any people, but by a firm adherence to justice, moderation, temperance, frugality, and virtue: by frequent recurrence to fundamental principles; and by the recognition by all citizens that they have duties as well as rights. and that such rights cannot be enjoyed save in a society where law is respected and due process is observed. That free government rests, as does all progress, upon the broadest possible diffusion of knowledge, and that the Commonwealth should avail itself of those talents which nature has sown so liberally among its people by assuring the opportunity for their fullest development by an effective system of education throughout the Commonwealth.

Section 17:

Construction of the Bill of Rights The rights enumerated in this Bill of Rights shall not be construed to limit other rights of the people not therein expressed.





<u>Informed consent disclosure to</u>

vaccine trial subjects of risk of COVID-19 vaccines worsening

clinical disease

www.pubmed.ncbi.nim.nih.gov

Abstract

Aims of the study: Patient comprehension is a critical part of meeting medical ethics standards of informed consent in study designs. The aim of the study was to determine if sufficient literature exists to require clinicians to disclose the specific risk that COVID-19 vaccines could worsen disease upon exposure to challenge or circulating virus.

Methods used to conduct the

study: Published literature was reviewed to identify preclinical and clinical evidence that COVID-19 vaccines could worsen disease upon exposure to challenge or circulating virus. Clinical trial protocols for COVID-19 vaccines were reviewed to determine if risks were properly disclosed.

Results of the study: COVID-19 vaccines designed to elicit neutralising antibodies may sensitise vaccine recipients to more severe disease than if they were not vaccinated. Vaccines for SARS, MERS and RSV have never been approved, and the data generated in the development and testing of these vaccines suggest a serious mechanistic concern: that vaccines designed empirically using the traditional approach (consisting of the unmodified or minimally modified coronavirus viral spike to elicit neutralising antibodies), be they composed of protein, viral vector, DNA or RNA and irrespective of delivery method, may worsen COVID-19 disease via antibody -dependent enhancement (ADE). This risk is sufficiently obscured in clinical trial protocols and consent forms for ongoing COVID-19 vaccine trials that adequate patient comprehension of this risk is unlikely to occur, obviating truly informed consent by subjects in these trials.

Conclusions drawn from the study and clinical implications: The specific and significant COVID-19 risk of ADE should have been and should be prominently and independently disclosed to research subjects currently in vaccine trials, as well as those being recruited for the trials and future patients after vaccine approval, in order to meet the medical ethics standard of patient comprehension for informed consent.