

Informed Consent:

The process of informed consent occurs when **communication between a patient and physician** 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.

Informed Consent | American Medical Association (ama-assn.org)

VAERS COVID

Vaccine Data

(Vaccine Adverse Events Reporting System, USA)

463,456 Reports Through

July 9th 2021

2,487
ANAPHYLAXIS

2,885
BELL'S PALSY

10,991
DEATHS

30,781
HOSPITALIZATIONS

82,535
OFFICE VISITS

59,402
URGENT CARE

3,906
Heart Attacks

2,466
Myocarditis/Pericarditis

8,832
Life Threatening

19,814
Severe Allergic Reaction

1,073
Miscarriages

9,274
Disabled

2,552
Thrombocytopenia/
Low Platelet

5,422
Tinnitus

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

Maine Constitution

ARTICLE 1
SECTIONS 1-4



Section 1: Natural Rights

Natural rights. All people are born equally free and independent, and have certain natural, inherent and unalienable rights, among which are those of enjoying and defending life and liberty, acquiring, possessing and protecting property, and of pursuing and obtaining safety and happiness.

Section 2: Power Inherent in People

All power is inherent in the people; all free governments are founded in their authority and instituted for their benefit; they have therefore an unalienable and infeasible right to institute government, and to alter, reform, or totally change the same, when their safety and happiness require it.

Section 3: Religious Freedom; Sects Equal; Religious Tests Prohibited; Religious Teachers

All individuals have a natural and unalienable right to worship Almighty God according to the dictates of their own consciences, and no person shall be hurt, molested or restrained in that person's liberty or estate for worshipping God in the manner and season most agreeable to the dictates of that person's own conscience, nor for that person's religious professions or sentiments, provided that that person does not disturb the public peace, nor obstruct others in their religious worship; -- and all persons demeaning themselves peaceably, as good members of the State, shall be equally under the protection of the laws, and no subordination nor preference of any one sect or denomination to another shall ever be established by law, nor shall any religious test be required as a qualification for any office or trust, under this State; and all religious societies in this State, whether incorporate or unincorporate, shall at all times have the exclusive right of electing their public teachers, and contracting with them for their support and maintenance.

Section 4: Freedom of Speech and Publication; Libel; Truth Given in Evidence; Jury Determines Law and Fact

Every citizen may freely speak, write and publish sentiments on any subject, being responsible for the abuse of this liberty; no laws shall be passed regulating or restraining the freedom of the press; and in prosecutions for any publication respecting the official conduct of people in public capacity, or the qualifications of those who are candidates for the suffrages of the people, or where the matter published is proper for public information, the truth thereof may be given in evidence, and in all indictments for libels, the jury, after having received the direction of the court, shall have a right to determine, at their discretion, the law and the fact.



Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease

www.pubmed.ncbi.nlm.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.

