

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)

545,337 Reports
through August 6, 2021*

12,366

DEATHS

46,036

HOSPITALIZATIONS

4,759

ANAPHYLAXIS

4,044

BELL'S PALSY

68,040

URGENT CARE

92,527

OFFICE VISITS

5,236

Heart Attacks

3,728

Myocarditis/Pericarditis

12,194

Life Threatening

23,354

Severe Allergic Reaction

14,251

Permanently Disabled

1,381

Miscarriages

7,509

Shingles

2,269

Thrombocytopenia/
Low Platelet

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

Massachusetts Constitution

DECLARATION OF RIGHTS

ARTICLES 1, 4, 5, 7, 8 & 18

Article I: All men are born free and equal, and have certain natural, essential, and unalienable rights; among which may be reckoned the right of enjoying and defending their lives and liberties; that of acquiring, possessing, and protecting property; in fine, that of seeking and obtaining their safety and happiness.

Article IV: The people of this commonwealth have the sole and exclusive right of governing themselves, as a free, sovereign, and independent state; and do, and forever hereafter shall, exercise and enjoy every power, jurisdiction, and right, which is not, or may not hereafter, be by them expressly delegated to the United States of America in Congress assembled.

Article V: All power residing originally in the people, and being derived from them, the several magistrates and officers of government, vested with authority, whether legislative, executive, or judicial, are their substitutes and agents, and are at all times accountable to them.

Article VII: Government is instituted for the common good; for the protection, safety, prosperity and happiness of the people; and not for the profit, honor, or private interest of any one man, family, or class of men: Therefore the people alone have an incontestable, unalienable, and indefeasible right to institute government; and to reform, alter, or totally change the same, when their protection, safety, prosperity and happiness require it.

Article VIII: In order to prevent those, who are vested with authority, from becoming oppressors, the people have a right, at such periods and in such manner as they shall establish by their frame of government, to cause their public officers to return to private life; and to fill up vacant places by certain and regular elections and appointments.

Article XVIII: A frequent recurrence to the fundamental principles of the constitution, and a constant adherence to those of piety, justice, moderation, temperance, industry, and frugality, are absolutely necessary to preserve the advantages of liberty, and to maintain a free government. The people ought, consequently, to have a particular attention to all those principles, in the choice of their officers and representatives: and they have a right to require of their lawgivers and magistrates, an exact and constant observance of them, in the formation and execution of the laws necessary for the good administration of the commonwealth.



Informed consent

disclosure to

vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease

www.pubmed.ncbi.nlm.nih.gov/33113270

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 pre-clinical 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.

ADE: Occurs when the anti-bodies generated during an immune response recognize and bind to a pathogen, but are unable to prevent infection. Instead, these antibodies act as a “Trojan Horse”, allowing the pathogen to get into cells and exacerbate the immune response.