

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



Ohio Constitution

ARTICLE 1 SECTIONS 1-3, 7 & 20

Section 1:

Inalienable Rights *All men are, by nature, free and independent, and have certain inalienable rights, among which are those of enjoying and defending life and liberty, acquiring, possessing, and protecting property, and seeking and obtaining happiness and safety.*

Section 2:

Right to Alter, Reform, or Abolish Government, and Repeal Special Privileges

All political power is inherent in the people. Government is instituted for their equal protection and benefit, and they have the right to alter, reform, or abolish the same, whenever they may deem it necessary; and no special privileges or immunities shall ever be granted, that may not be altered, revoked, or repealed by the General Assembly.

Section 3:

Right to Assemble The people have the right to assemble together, in a peaceable manner, to consult for the common good; to instruct their representatives; and to petition the General Assembly for the redress of grievances.

Section 20:

Powers Reserved to the People This enumeration of rights shall not be construed to impair or deny others retained by the people, and all powers, not herein delegated, remain with the people.

Section 7:

Rights of Conscience; Education; the Necessity of Religion and Knowledge All men have a natural and inalienable right to worship Almighty God according to the dictates of their own conscience. No person shall be compelled to attend, erect, or support any place of worship, or maintain any form of worship, against his consent; and no preference shall be given, by law, to any religious society; **nor shall any interference with the rights of conscience be permitted.** No religious test shall be required, as a qualification for office, nor shall any person be incompetent to be a witness on account of his religious belief; but nothing herein shall be construed to dispense with oaths and affirmations. Religion, morality, and knowledge, however, being essential to good government, it shall be the duty of the General Assembly to pass suitable laws, to protect every religious denomination in the peaceable enjoyment of its own mode of public worship, and to encourage schools and the means of instruction.



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.