

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 July 30, 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



Indiana Constitution

ARTICLE 1 SECTIONS 1, 3, 9 & 31

Section 1: Inherent Rights

WE DECLARE, That **all people** are created equal; that they are endowed by their CREATOR with certain **inalienable rights**; that among these are **life, liberty, and the pursuit of happiness**; *that all power is inherent in the people; and that all free governments are, and of right ought to be, founded on their authority, and instituted for their peace, safety, and well-being. For the advancement of these ends, the people have, at all times, an indefeasible right to alter and reform their government.*

Section 3: Freedom of Religious Opinions

No law shall, in any case whatever, control the free exercise and enjoyment of religious opinions, or interfere with the rights of conscience.

Section 9: Freedom of Thought and Speech

No law shall be passed, restraining the free interchange of thought and opinion, or restricting the right to speak, write, or print, freely, on any subject whatever: but for the abuse of that right, every person shall be responsible.

Section 31:

Right of Assemblage and Petition No law shall restrain any of the inhabitants of the State from assembling together in a peaceable manner, to consult for their common good; nor from instructing their representatives; nor from applying to the General Assembly for redress of grievances.

Informed Consent:

n. agreement to do something or to allow something to happen only after all the relevant facts are known.



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 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.*

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.