

## 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*

# Florida Constitution

## ARTICLE 1 SECTIONS 1, 2, 4 & 5

**Section 1: Political Power** *All political power is inherent in the people. The enunciation herein of certain rights shall not be construed to deny or impair others retained by the people.*

**Section 2: Basic rights** *All natural persons, female and male alike, are equal before the law and have inalienable rights, among which are the right to enjoy and defend life and liberty, to pursue happiness, to be rewarded for industry, and to acquire, possess and protect property. No person shall be deprived of any right because of race, religion, national origin, or physical disability.*

**Section 4: Freedom of Speech and Press** *Every person may speak, write and publish sentiments on all subjects but shall be responsible for the abuse of that right. No law shall be passed to restrain or abridge the liberty of speech or of the press. In all criminal prosecutions and civil actions for defamation the truth may be given in evidence. If the matter charged as defamatory is true and was published with good motives, the party shall be acquitted or exonerated.*

**Section 5: Right to Assemble** *The people shall have the right peaceably to assemble, to instruct their representatives, and to petition for redress of grievances.*

**Section 23: Right of Privacy** *Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law.*



### **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](http://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.*