

## 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**

[www.openvaers.com/covid-data](http://www.openvaers.com/covid-data)

**571,830 Reports  
through August 06, 2021**

**12,791**

DEATHS

**51,242**

HOSPITALIZATIONS

**95,887**

OFFICE VISITS

**70,666**

URGENT CARE

**4,461**

BELL'S PALSY

**5,282**

ANAPHYLAXIS

**5,590**

Heart Attacks

**4,371**

Myocarditis/  
Pericarditis

**13,140**

Life Threatening

**24,305**

Severe Allergic  
Reaction

**16,044**

Permanently  
Disabled

**1,505**

Miscarriages

**6,784**

Shingles

**2,554**

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*

# Rhode Island Constitution

## ARTICLE 1 SECTIONS 1-3 & 20, 21

**Section 1: Right to Make and Alter Constitution - Constitution Obligatory upon All** In the words of the Father of his Country, we declare that "the basis of our political systems is the right of the people to make and alter their constitutions of government; but that the constitution which at any time exists, till changed by an explicit and authentic act of the whole people, is sacredly obligatory upon all."

**Section 2: Laws for Good of Whole -- Burdens to Be Equally Distributed -- Due Process -- Equal Protection -- Discrimination -- No Right to Abortion Granted** All free governments are instituted for the protection, safety, and happiness of the people. All laws, therefore, should be made for the good of the whole; and the burdens of the state ought to be fairly distributed among its citizens. No person shall be deprived of life, liberty or property without due process of law, nor shall any person be denied equal protection of the laws. No otherwise qualified person shall, solely by reason of race, gender or handicap be subject to discrimination by the state, its agents or any person or entity doing business with the state. Nothing in this section shall be construed to grant or secure any right relating to abortion or the funding thereof.

**Section 3: Freedom of Religion** Whereas Almighty God hath created the mind free; and all attempts to influence it by temporal punishments or burdens, or by civil incapacitations, tend to beget habits of hypocrisy and meanness; and whereas a principal object of our venerable ancestors, in their migration to this country and their settlement of this state, was, as they expressed it, to hold forth a lively experiment that a flourishing civil state may stand and be best maintained with full liberty in religious concerns; we, therefore, declare that no person shall be compelled to frequent or to support any religious worship, place, or ministry whatever, except in fulfillment of such person's voluntary contract; nor enforced, restrained, molested, or burdened in body or goods; nor disqualified from holding any office; nor otherwise suffer on account of such person's religious belief; and that every person shall be free to worship God according to the dictates of such person's conscience, and to profess and by argument to maintain such person's opinion in matters of religion; and that the same shall in no wise diminish, enlarge, or affect the civil capacity of any person.

**Section 20: Freedom of Press** The liberty of the press being essential to the security of freedom in a state, any person may publish sentiments on any subject, being responsible for the abuse of that liberty; and in all trials for libel, both civil and criminal, the truth, unless published from malicious motives, shall be sufficient defense to the person charged.

**Section 21: Right to Assembly -- Redress of Grievances - Freedom of Speech** The citizens have a right in a peaceable manner to assembly for their common good, and to apply to those invested with the powers of government, for redress of grievances, or for other purposes, by petition, address, or remonstrance. No law abridging the freedom of speech shall be enacted.



### 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 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.*