

## 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*

# New York Constitution

ARTICLE 1 SECTIONS 3, 8, 9, 11 & 14

## Section 3: Freedom of Worship; Religious Liberty

*The free exercise and enjoyment of religious profession and worship, without discrimination or preference, shall forever be allowed in this state to all humankind;* and no person shall be rendered incompetent to be a witness on account of his or her opinions on matters of religious belief; but *the liberty of conscience hereby secured* shall not be so construed as to excuse acts of licentiousness, or justify practices inconsistent with the peace or safety of this state.

## Section 8: Freedom of Speech and Press; Criminal Prosecutions for Libel

Every citizen may freely speak, write and publish his or her sentiments on all subjects, being responsible for the abuse of that right; and no law shall be passed to restrain or abridge the liberty of speech or of the press. In all criminal prosecutions or indictments for libels, the truth may be given in evidence to the jury; and if it shall appear to the jury that the matter charged as libelous is true, and was published with good motives and for justifiable ends, the party shall be acquitted; and the jury shall have the right to determine the law and the fact.

### Text of Section 9:

**Right to Assemble and Petition;** Divorce; Lotteries; Pool-Selling and Gambling; Laws to Prevent; Pari-Mutual Betting on Horse Races Permitted; Games of Chance, Bingo or Lotto Authorized under Certain Restrictions

**1. No law shall be passed abridging the rights of the people peaceably to assemble and to petition the government, or any department thereof;...**

## Section 14: Common Law and Acts of the Colonial and State Legislatures

Such parts of the common law, and of the acts of the legislature of the colony of New York, as together did form the law of the said colony, on the nineteenth day of April, one thousand seven hundred seventy-five, and the resolutions of the congress of the said colony, and of the convention of the State of New York, in force on the twentieth day of April, one thousand seven hundred seventy-seven, *which have not since expired, or been repealed or altered; and such acts of the legislature of this state as are now in force, shall be and continue the law of this state, subject* to such alterations as the legislature shall make concerning the same. *But all such parts of the common law, and such of the said acts, or parts thereof, as are repugnant to this constitution, are hereby abrogated.*



**Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease**

**[www.pubmed.ncbi.nlm.nih.gov](http://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.*