

## 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*

# Kentucky Constitution

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

### **Section 1:**

All men are, by nature, free and equal, and have certain inherent and inalienable rights, among which may be reckoned:

**First:** The right of enjoying and defending their lives and liberties.

**Second:** The right of worshipping Almighty God according to the dictates of their consciences.

**Third:** The right of seeking and pursuing their safety and happiness.

**Fourth:** The right of freely communicating their thoughts and opinions.

**Fifth:** The right of acquiring and protecting property.

**Sixth:** The right of assembling together in a peaceable manner for their common good, and of applying to those invested with the power of government for redress of grievances or other proper purposes, by petition, address or remonstrance.

**Seventh:** The right to bear arms in defense of themselves and of the State, subject to the power of the General Assembly to enact laws to prevent persons from carrying concealed weapons.

### **Section 2:**

Absolute and arbitrary power over the lives, liberty and property of freemen exists nowhere in a republic, not even in the largest majority.

### **Section 4:**

All power is inherent in the people, and all free governments are founded on their authority and instituted for their peace, safety, happiness and the protection of property. For the advancement of these ends, they have at all times an inalienable and indefeasible right to alter, reform or abolish their government in such manner as they may deem proper.

### **Section 5:**

No preference shall ever be given by law to any religious sect, society or denomination; nor to any particular creed, mode of worship or system of ecclesiastical polity; nor shall any person be compelled to attend any place of worship, to contribute to the erection or maintenance of any such place, or to the salary or support of any minister of religion; nor shall any man be compelled to send his child to any school to which he may be conscientiously opposed; and the civil rights, privileges or capacities of no person shall be taken away, or in anywise diminished or enlarged, on account of his belief or disbelief of any religious tenet, dogma or teaching. No human authority shall, in any case whatever, control or interfere with the rights of conscience.

### **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.