

## 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)**



## 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*



## Georgia Constitution **ARTICLE 1, SECTION 1,**

### Paragraph I: Life, Liberty, and Property

*No person shall be deprived of life, liberty, or property except by due process of law.*

### Paragraph III: Freedom of Conscience

*Each person has the natural and inalienable right to worship God, each according to the dictates of that person's own conscience; and no human authority should, in any case, control or interfere with such right of conscience.*

### Paragraph VII: Citizens, Protection of

*All citizens of the United States, resident in this state, are hereby declared citizens of this state; and it shall be the duty of the General Assembly to enact such laws as will protect them in the full enjoyment of the rights, privileges, and immunities due to such citizenship.*

### Section 2, Paragraph I: Origin and Foundation of Government

*All government, of right, originates with the people, is founded upon their will only, and is instituted solely for the good of the whole. Public officers are the trustees and servants of the people and are at all times amenable to them.*

### Section 2, Paragraph II: Constitutional Provisions Mandatory

*The people of this state have the inherent right of regulating their internal government. Government is instituted for the protection, security, and benefit of the people; and at all times they have the right to alter or reform the same whenever the public good may require it.*



## 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.*