## 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)

438,440 Reports as of July 7, 2021

| | |
|---|---|
| 985 Miscarriages | 3,324 Heart Attacks |
| 2,226 Thrombocytopenia/ Low Platelet | 7,823 Life Threatening |
| 2,200 Myocarditis/Pericarditis | 7,463 Disabled |
| 19,105 Severe Allergic Reaction | 5,118 Tinnitus |
| 56,970 URGENT CARE | 26,818 HOSPITALIZATIONS |
| 2,152 ANAPHYLAXIS | 2,486 BELL'S PALSY |
| 9,048 DEATHS | |

# Know Your Constitutional and Lawful Rights

## ***Who's that knocking on my front door?***

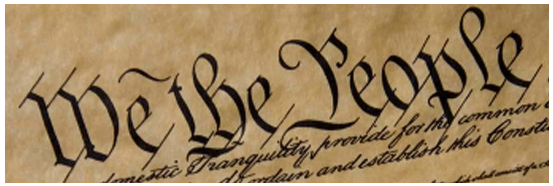
## Solicit:

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*




# North Carolina Constitution

ARTICLE 1 SECTIONS 1-3

**Section 1:**
**The Equality and Rights of Persons**
We hold it to be self-evident that all persons are created equal; that they are endowed by their Creator with certain inalienable rights; that among these are life, liberty, the enjoyment of the fruits of their own labor, and the pursuit of happiness.

**Section 2:**
**Sovereignty of the People** *All political power is vested in and derived from the people; all government of right originates from the people, is founded upon their will only, and is instituted solely for the good of the whole*

**Section 3:**
**Internal Government of the State** *The people of this State have the inherent, sole, and exclusive right of regulating the internal government and police thereof,* and of altering or abolishing their Constitution and form of government whenever it may be necessary to their safety and happiness; but every such right shall be exercised in pursuance of law and consistently with the Constitution of the United States.

**Section 13:**
**Religious Liberty** All persons have a natural and inalienable right to worship Almighty God according to the dictates of their own consciences, *and no human authority shall, in any case whatever, control or interfere with the rights of conscience.*

**Section 14:**
**Freedom of Speech and Press**

Freedom of speech and of the press are two of the great bulwarks of liberty and *therefore shall never be restrained,* but every person shall be held responsible for their abuse.

**Section 35:**
**Recurrence to Fundamental Principles**

***A frequent recurrence to fundamental principles is absolutely necessary to preserve the blessings of liberty.***

**Section 36:**
**Other Rights of the People**

The enumeration of rights in this Article shall not be construed to impair or deny others retained by the

PubMed.gov

NIH National Library of Medicine
National Center for Biotechnology Information

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

www.pubmed.ncbi.nim.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.**