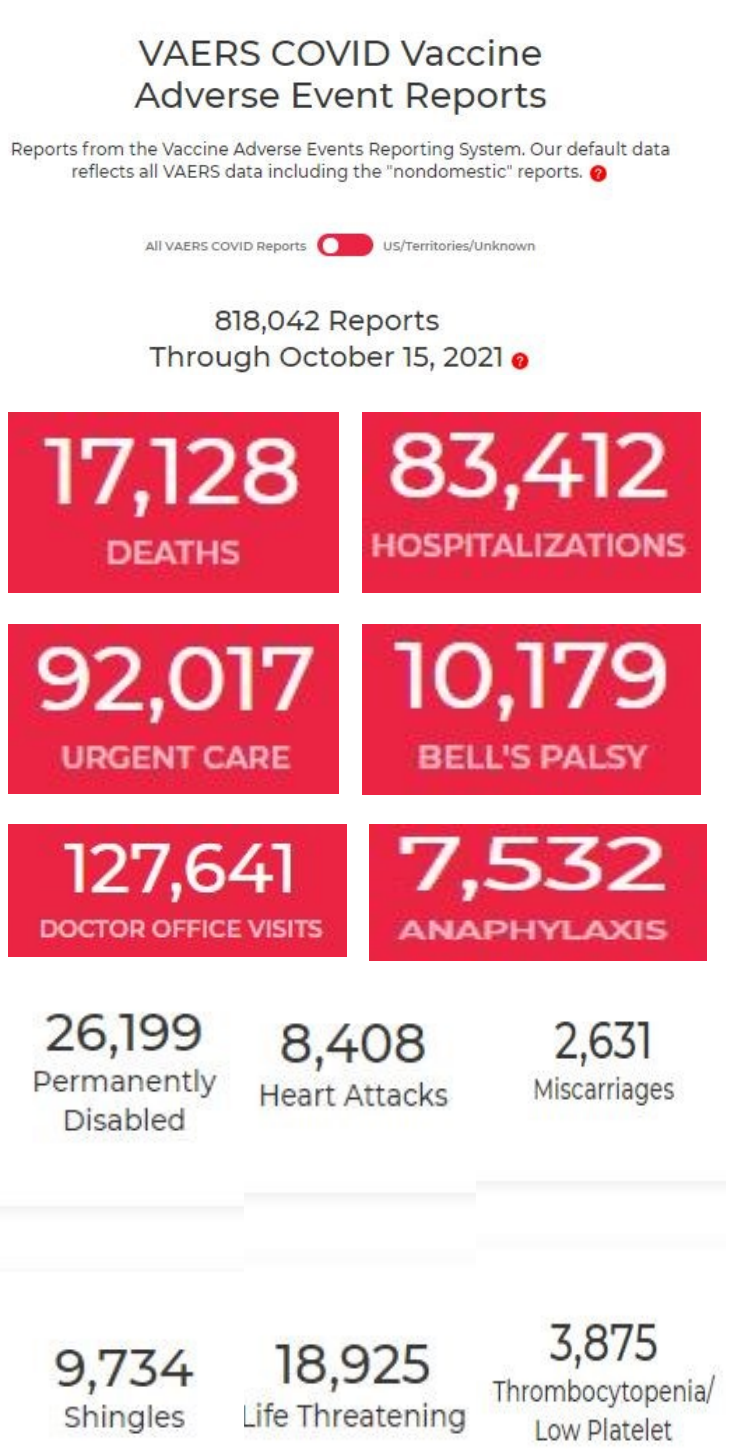
## Informed Consent:

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*


# Montana Constitution

Article 2 Sections 1, 3, 6-8, 10, 11, & 34

**Section 1: Popular Sovereignty** *All political power is vested in and derived from the people. All government of right originates with the people, is founded upon their will only, and is instituted solely for the good of the whole.*

***Section 3: Inalienable Rights*** *All persons are born free and have certain inalienable rights. They include the right to a clean and healthful environment and the rights of pursuing life's basic necessities, enjoying and defending their lives and liberties, acquiring, possessing and protecting property, and seeking their safety, health and happiness in all lawful ways. In enjoying these rights, all persons recognize corresponding responsibilities.*

**Section 6: Freedom of Assembly** The people shall have the right peaceably to assemble, petition for redress or peaceably protest governmental action.

**Section 7: Freedom of Speech, Expression, and Press** No law shall be passed impairing the freedom of speech or expression. *Every person shall be free to speak or publish whatever he will on any subject,* being responsible for all abuse of that liberty. In all suits and prosecutions for libel or slander the truth thereof may be given in evidence; and the jury, under the direction of the court, shall determine the law and the facts.

**Section 8: Right of Participation** The public has the right to expect governmental agencies to afford such reasonable opportunity for citizen participation in the operation of the agencies prior to the final decision as may be provided by law.

**Section 10: Right of Privacy** *The right of individual privacy is essential to the well-being of a free society and shall not be infringed without the showing of a compelling state interest.*

**Section 11: Searches and Seizures** The people shall be secure in their persons, papers, homes and effects from unreasonable searches and seizures. No warrant to search any place, or seize any person or thing shall issue without describing the place to be searched or the person or thing to be seized, or without probable cause, supported by oath or affirmation reduced to writing.

**Section 34: Unenumerated Rights**
*The enumeration in this constitution of certain rights shall not be construed to deny, impair, or disparage others retained by the people.*

NIH National Library of Medicine
National Center for Biotechnology Information

PubMed.gov

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

www.pubmed.ncbi.nim.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.*