



114TH CONGRESS
2nd SESSION
S. _____

5 IN THE SENATE OF THE UNITED STATES

[Date]

10 [Sponsors] introduced the following bill; which was referred to the Committee on _____,
for a period to be subsequently determined by the President of the Senate, for consideration of such
provisions as fall within the jurisdiction of the committee concerned.

A BILL

15 To ensure the internationally recognized individual right of Informed Consent with regard to any
medical intervention.

*Be it enacted by the Senate and House of Representatives of the United States of America in
Congress assembled,*

20 **SECTION 1. SHORT TITLE.**

This Act may be cited as the “**Informed Consent Protection Act of 2016**”.

25 **SECTION 2. CONGRESSIONAL FINDINGS**

The Congress of the United States finds:

- 30 (1) Individuals in the United States have been subjected to medical experimentation and
medical intervention without Informed Consent in violation of fundamental rights.
- (2) Informed Consent may not be assumed, deemed, or implied. Informed Consent must be
actual and individual, and may be conveyed by a signed, notarized Advanced Medical
(or Health Care) Directive or any other verifiable written communication.
- 35 (3) Informed Consent may only be given by the individual involved, or, in the case of any
child under the age of 18 or non-competent person, his or her natural guardian and no
guardian may be appointed without full judicial process and only in cases of *non-compos
mentis*.
- (4) A conscious individual is always deemed capable of making an Informed Consent
decision.



- 40 (5) Valid Informed Consent may only be obtained after full disclosure of All Risk,
memorialized with a written document signed by the consenting individual or natural
guardian.
- (6) The requirement for prior Informed Consent applies to all medical interventions, and
- 45 (7) Informed Consent is subject to International Humanitarian Law: “The voluntary consent
of the human... is absolutely essential. This means that the person involved should have
legal capacity to give consent; should be so situated as to be able to exercise free power
of choice, without the intervention of any element of force, fraud, deceit, duress, over-
reaching, or other ulterior form of constraint or coercion; and should have sufficient
50 knowledge and comprehension of the elements of the subject matter involved, as to
enable him to make an understanding and enlightened decision.” -
<http://www.hhs.gov/ohrp/archive/nurcode.html>

SECTION 3. DEFINITIONS.

55 In this Act—

- (1) The term “Informed Consent” means a conscious decision to exercise free power of choice,
without the intervention of any element of force, fraud, deceit, duress, over-reaching, or
other ulterior form of constraint or coercion.
- 60 (2) The term “Violation of Informed Consent” means any element of force, fraud, deceit,
duress, over-reaching, or other ulterior form of constraint or coercion which prevents or
forces an Informed Consent decision as set forth in the Findings Section of this Act.
- (3) The Term “Medical Intervention” includes any preventative, palliative, curative treatment
or therapy, whether or not experimental.
- 65 (4) The term “Order Protecting Informed Consent” means an Order issued by a United States
District Court authorized by this Act to redress a violation of Informed Consent.

SECTION 4. PROHIBITED ACTS.

- 70 (1) No United States citizen or person under the jurisdiction of the United States may be
subjected to a violation of Informed Consent.
- (2) No federal funds may be expended for any medical intervention whenever a violation of
Informed Consent occurs, except to remediate any injury caused by, or adverse event
75 resulting from, the aforesaid medical intervention.



- (3) No federal funds may be expended to communicate in favor of restrictions on Informed Consent or to mandate any medical intervention in violation of Informed Consent.

SECTION 5. CAUSE OF ACTION.

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- (1) Any person aggrieved by any violation of informed consent may sue in any United States District Court in the District where the person resides or in the District where any defendant resides or is located for redress of grievances, including injunctive relief, damages and punitive damages.
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- (2) The United States District Courts are empowered to issue preliminary, temporary or permanent Orders Protecting Informed Consent whenever it shall appear by the preponderance of the evidence that a violation of informed consent has occurred or is at immanent risk of occurring.

SECTION 6. EFFECTIVE DATE.

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- (1) This Act is effective immediately.