COVID-19 FORCED TESTING AND VACCINATION – AUTHORITIES CITED

***Health Care Consent Act*, 1996, SO 1996, c 2, Sch A**

Purposes

1 The purposes of this Act are,

(a) to provide rules with respect to consent to treatment that apply consistently in all settings;

(b) to facilitate treatment, admission to care facilities, and personal assistance services, for persons lacking the capacity to make decisions about such matters;

(c) to enhance the autonomy of persons for whom treatment is proposed, persons for whom admission to a care facility is proposed and persons who are to receive personal assistance services by,

(i) allowing those who have been found to be incapable to apply to a tribunal for a review of the finding,

(ii) allowing incapable persons to request that a representative of their choice be appointed by the tribunal for the purpose of making decisions on their behalf concerning treatment, admission to a care facility or personal assistance services, and

(iii) requiring that wishes with respect to treatment, admission to a care facility or personal assistance services, expressed by persons while capable and after attaining 16 years of age, be adhered to

Consent to Treatment

No treatment without consent

10 (1) A health practitioner who proposes a treatment for a person shall not administer the treatment, and shall take reasonable steps to ensure that it is not administered, unless,

(a) he or she is of the opinion that the person is capable with respect to the treatment, and the person has given consent; or

(b) he or she is of the opinion that the person is incapable with respect to the treatment, and the person's substitute decision-maker has given consent on the person's behalf in accordance with this Act. 1996, c. 2, Sched. A, s. 10 (1).

Elements of consent

11 (1) The following are the elements required for consent to treatment:

1. The consent must relate to the treatment.
2. The consent must be informed.
3. The consent must be given voluntarily.
4. The consent must not be obtained through misrepresentation or fraud. 1996, c. 2, Sched. A, s. 11 (1).

Informed consent

(2) A consent to treatment is informed if, before giving it,

(a) the person received the information about the matters set out in subsection (3) that a reasonable person in the same circumstances would require in order to make a decision about the treatment; and

(b) the person received responses to his or her requests for additional information about those matters. 1996, c. 2, Sched. A, s. 11 (2).

Same

(3) The matters referred to in subsection (2) are:

1. The nature of the treatment.
2. The expected benefits of the treatment.
3. The material risks of the treatment.
4. The material side effects of the treatment.

5. Alternative courses of action.

6. The likely consequences of not having the treatment. 1996, c. 2, Sched. A, s. 11 (3).

Express or implied

(4) Consent to treatment may be express or implied. 1996, c. 2, Sched. A, s. 11 (4).

Included consent

12 Unless it is not reasonable to do so in the circumstances, a health practitioner is entitled to presume that consent to a treatment includes,

(a) consent to variations or adjustments in the treatment, if the nature, expected benefits, material risks and material side effects of the changed treatment are not significantly different from the nature, expected benefits, material risks and material side effects of the original treatment; and

(b) consent to the continuation of the same treatment in a different setting, if there is no significant change in the expected benefits, material risks or material side effects of the treatment as a result of the change in the setting in which it is administered. 1996, c. 2, Sched. A, s. 12.

Withdrawal of consent

14 A consent that has been given by or on behalf of the person for whom the treatment was proposed may be withdrawn at any time,

(a) by the person, if the person is capable with respect to the treatment at the time of the withdrawal;

(b) by the person's substitute decision-maker, if the person is incapable with respect to the treatment at the time of the withdrawal. 1996, c. 2, Sched. A, s. 14.

Consent on Incapable Person's Behalf

Consent

List of persons who may give or refuse consent

20 (1) If a person is incapable with respect to a treatment, consent may be given or refused on his or her behalf by a person described in one of the following paragraphs:

1. The incapable person's guardian of the person, if the guardian has authority to give or refuse consent to the treatment.

2. The incapable person's attorney for personal care, if the power of attorney confers authority to give or refuse consent to the treatment.

3. The incapable person's representative appointed by the Board under section 33, if the representative has authority to give or refuse consent to the treatment.

4. The incapable person's spouse or partner.

5. A child or parent of the incapable person, or a children's aid society or other person who is lawfully entitled to give or refuse consent to the treatment in the place of the parent. This

paragraph does not include a parent who has only a right of access. If a children's aid society or other person is lawfully entitled to give or refuse consent to the treatment in the place of the parent, this paragraph does not include the parent.

6. A parent of the incapable person who has only a right of access.

7. A brother or sister of the incapable person.

8. Any other relative of the incapable person. 1996, c. 2, Sched. A, s. 20 (1); 2016, c. 23, s. 51 (1); 2021, c. 4, Sched. 11, s. 14 (1, 2).

Requirements

(2) A person described in subsection (1) may give or refuse consent only if he or she,

(a) is capable with respect to the treatment;

(b) is at least 16 years old, unless he or she is the incapable person's parent;

(c) is not prohibited by court order or separation agreement from having access to the incapable person or giving or refusing consent on his or her behalf;

(d) is available; and

(e) is willing to assume the responsibility of giving or refusing consent. 1996, c. 2, Sched. A, s. 20 (2); 2021, c. 4, Sched. 11, s. 14 (3).

Principles for giving or refusing consent

21 (1) A person who gives or refuses consent to a treatment on an incapable person's behalf shall do so in accordance with the following principles:

1. If the person knows of a wish applicable to the circumstances that the incapable person expressed while capable and after attaining 16 years of age, the person shall give or refuse consent in accordance with the wish.

2. If the person does not know of a wish applicable to the circumstances that the incapable person expressed while capable and after attaining 16 years of age, or if it is impossible to comply with the wish, the person shall act in the incapable person's best interests. 1996, c. 2, Sched. A, s. 21 (1).

Best interests

(2) In deciding what the incapable person's best interests are, the person who gives or refuses consent on his or her behalf shall take into consideration,

(a) the values and beliefs that the person knows the incapable person held when capable and believes he or she would still act on if capable;

(b) any wishes expressed by the incapable person with respect to the treatment that are not required to be followed under paragraph 1 of subsection (1); and

(c) the following factors:

1. Whether the treatment is likely to,

i. improve the incapable person's condition or well-being,

ii. prevent the incapable person's condition or well-being from deteriorating, or

iii. reduce the extent to which, or the rate at which, the incapable person's condition or well-being is likely to deteriorate.

2. Whether the incapable person's condition or well-being is likely to improve, remain the same or deteriorate without the treatment.

3. Whether the benefit the incapable person is expected to obtain from the treatment outweighs the risk of harm to him or her.

4. Whether a less restrictive or less intrusive treatment would be as beneficial as the treatment that is proposed. 1996, c. 2, Sched. A, s. 21 (2).

Offence: decision contrary to wishes

84 (1) A person who knowingly contravenes paragraph 1 of subsection 21 (1), paragraph 1 of subsection 42 (1) or paragraph 1 of subsection 59 (1) is guilty of an offence and is liable, on conviction, to a fine not exceeding $10,000. 1996, c. 2, Sched. A, s. 84 (1).

***Freedom of Information and Protection of Privacy Act*, RSO 1990, c F.31**

Definitions

2 (1) In this Act,

...

"personal information" means recorded information about an identifiable individual, including,

(a) information relating to the race, national or ethnic origin, colour, religion, age, sex, sexual orientation or marital or family status of the individual,

(b) information relating to the education or the medical, psychiatric, psychological, criminal or employment history of the individual or information relating to financial transactions in which the individual has been involved,

(c) any identifying number, symbol or other particular assigned to the individual,

(d) the address, telephone number, fingerprints or blood type of the individual,

(e) the personal opinions or views of the individual except where they relate to another individual,

(f) correspondence sent to an institution by the individual that is implicitly or explicitly of a private or confidential nature, and replies to that correspondence that would reveal the contents of the original correspondence,

(g) the views or opinions of another individual about the individual, and

(h) the individual's name where it appears with other personal information relating to the individual or where the disclosure of the name would reveal other personal information about the individual; ("renseignements personnels")

Personal information

38 (1) In this section and in section 39,

"personal information" includes information that is not recorded and that is otherwise defined as

"personal information" under this Act. R.S.O. 1990, c. F.31, s. 38 (1).

Collection of personal information

(2) No person shall collect personal information on behalf of an institution unless the collection is expressly authorized by statute, used for the purposes of law enforcement or necessary to the proper administration of a lawfully authorized activity. R.S.O. 1990, c. F.31, s. 38 (2).

Manner of collection

39 (1) Personal information shall only be collected by an institution directly from the individual to whom the information relates unless,

(a) the individual authorizes another manner of collection;

(b) the personal information may be disclosed to the institution concerned under section 42 or under section 32 of the *Municipal Freedom of Information and Protection of Privacy Act*;

(c) the Commissioner has authorized the manner of collection under clause 59 (c);

(d) the information is in a report from a reporting agency in accordance with the *Consumer Reporting Act*;

(e) the information is collected for the purpose of determining suitability for an honour or award to recognize outstanding achievement or distinguished service;

(f) the information is collected for the purpose of the conduct of a proceeding or a possible proceeding before a court or tribunal;

(g) the information is collected for the purpose of law enforcement; or

(h) another manner of collection is authorized by or under a statute. R.S.O. 1990, c. F.31, s. 39 (1).

Notice to individual

(2) Where personal information is collected on behalf of an institution, the head shall, unless notice is waived by the responsible minister, inform the individual to whom the information relates of,

(a) the legal authority for the collection;

(b) the principal purpose or purposes for which the personal information is intended to be used; and

(c) the title, business address and business telephone number of a public official who can answer the individual's questions about the collection. R.S.O. 1990, c. F.31, s. 39 (2).

Offences

61 (1) No person shall,

(a) wilfully disclose personal information in contravention of this Act;

(b) wilfully maintain a personal information bank that contravenes this Act;

(b.1) wilfully contravene section 49.8;

(c) make a request under this Act for access to or correction of personal information under false pretenses;

(c.1) alter, conceal or destroy a record, or cause any other person to do so, with the intention of

denying a right under this Act to access the record or the information contained in the record;

(d) wilfully obstruct the Commissioner in the performance of his or her functions under this Act;

(e) wilfully make a false statement to, mislead or attempt to mislead the Commissioner in the performance of his or her functions under this Act; or

(f) wilfully fail to comply with an order of the Commissioner. R.S.O. 1990, c. F.31, s. 61 (1); 2014, c. 13, Sched. 6, s. 2 (1); 2019, c. 7, Sched. 31, s. 8.

Penalty

(2) Every person who contravenes subsection (1) is guilty of an offence and on conviction is liable to a fine not exceeding $5,000. R.S.O. 1990, c. F.31, s. 61 (2).

Consent of Attorney General

(3) A prosecution shall not be commenced under clause (1) (c.1), (d), (e) or (f) without the consent of the Attorney General. R.S.O. 1990, c. F.31, s. 61 (3); 2014, c. 13, Sched. 6, s. 2 (2).

Personal Health Information Protection Act, 2004, SO 2004, c 3, Sch A

Personal health information

4 (1) In this Act,

"personal health information", subject to subsections (3) and (4), means identifying information about an individual in oral or recorded form, if the information,

(a) relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family,

(b) relates to the providing of health care to the individual, including the identification of a person as a provider of health care to the individual,

(c) is a plan of service within the meaning of the *Home Care and Community Services Act, 1994* for the individual,

(d) relates to payments or eligibility for health care, or eligibility for coverage for health care, in respect of the individual,

(e) relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance,

(f) is the individual's health number, or

(g) identifies an individual's substitute decision-maker. 2004, c. 3, Sched. A, s. 4 (1); 2007, c. 8, s. 224 (6); 2007, c. 10, Sched. H, s. 2.

Identifying information

(2) In this section,

"identifying information" means information that identifies an individual or for which it is reasonably foreseeable in the circumstances that it could be utilized, either alone or with other information, to identify an individual. 2004, c. 3, Sched. A, s. 4 (2).

Elements of consent

18 (1) If this Act or any other Act requires the consent of an individual for the collection, use or disclosure of personal health information by a health information custodian, the consent,

(a) must be a consent of the individual;

(b) must be knowledgeable;

(c) must relate to the information; and

(d) must not be obtained through deception or coercion. 2004, c. 3, Sched. A, s. 18 (1).

Implied consent

(2) Subject to subsection (3), a consent to the collection, use or disclosure of personal health information about an individual may be express or implied. 2004, c. 3, Sched. A, s. 18 (2).

Exception

(3) A consent to the disclosure of personal health information about an individual must be express, and not implied, if,

(a) a health information custodian makes the disclosure to a person that is not a health information custodian; or

(b) a health information custodian makes the disclosure to another health information custodian and the disclosure is not for the purposes of providing health care or assisting in providing health care. 2004, c. 3, Sched. A, s. 18 (3).

Same

(4) Subsection (3) does not apply to,

(a) a disclosure pursuant to an implied consent described in subsection 20 (4);

(b) a disclosure pursuant to clause 32 (1) (b); or

(c) a prescribed type of disclosure that does not include information about an individual's state of health. 2004, c. 3, Sched. A, s. 18 (4).

Knowledgeable consent

(5) A consent to the collection, use or disclosure of personal health information about an individual is knowledgeable if it is reasonable in the circumstances to believe that the individual knows,

(a) the purposes of the collection, use or disclosure, as the case may be; and

(b) that the individual may give or withhold consent. 2004, c. 3, Sched. A, s. 18 (5).

Notice of purposes

(6) Unless it is not reasonable in the circumstances, it is reasonable to believe that an individual knows the purposes of the collection, use or disclosure of personal health information about the individual by a health information custodian if the custodian posts or makes readily available a notice describing the purposes where it is likely to come to the individual's attention or provides the individual with such a notice. 2004, c. 3, Sched. A, s. 18 (6).

Transition

(7) A consent that an individual gives, before the day that subsection (1) comes into force, to a collection, use or disclosure of information that is personal health information is a valid consent if it

meets the requirements of this Act for consent. 2004, c. 3, Sched. A, s. 18 (7).

Withdrawal of consent

19 (1) If an individual consents to have a health information custodian collect, use or disclose personal health information about the individual, the individual may withdraw the consent, whether the consent is express or implied, by providing notice to the health information custodian, but the withdrawal of the consent shall not have retroactive effect. 2004, c. 3, Sched. A, s. 19 (1).

Conditional consent

(2) If an individual places a condition on his or her consent to have a health information custodian collect, use or disclose personal health information about the individual, the condition is not effective to the extent that it purports to prohibit or restrict any recording of personal health information by a health information custodian that is required by law or by established standards of professional practice or institutional practice. 2004, c. 3, Sched. A, s. 19 (2).

Persons who may consent

23 (1) If this Act or any other Act refers to a consent required of an individual to a collection, use or disclosure by a health information custodian of personal health information about the individual, a person described in one of the following paragraphs may give, withhold or withdraw the consent:

1. If the individual is capable of consenting to the collection, use or disclosure of the information,

    i. the individual, or

    ii. if the individual is at least 16 years of age, any person who is capable of consenting, whom the individual has authorized in writing to act on his or her behalf and who, if a natural person, is at least 16 years of age.

2. If the individual is a child who is less than 16 years of age, a parent of the child or a children's aid society or other person who is lawfully entitled to give or refuse consent in the place of the parent unless the information relates to,

    i. treatment within the meaning of the *Health Care Consent Act, 1996*, about which the child has made a decision on his or her own in accordance with that Act, or

    ii. counselling in which the child has participated on his or her own under the *Child, Youth and Family Services Act, 2017*.

3. If the individual is incapable of consenting to the collection, use or disclosure of the information, a person who is authorized under subsection 5 (2), (3) or (4) or section 26 to consent on behalf of the individual.

Incapable individual: persons who may consent

26 (1) If an individual is determined to be incapable of consenting to the collection, use or disclosure of personal health information by a health information custodian, a person described in one of the following paragraphs may, on the individual's behalf and in the place of the individual, give, withhold or withdraw the consent:

1. The individual's guardian of the person or guardian of property, if the consent relates to the guardian's authority to make a decision on behalf of the individual.

2. The individual's attorney for personal care or attorney for property, if the consent relates to the attorney's authority to make a decision on behalf of the individual.

3. The individual's representative appointed by the Board under section 27, if the representative has authority to give the consent.

4. The individual's spouse or partner.

5. A child or parent of the individual, or a children's aid society or other person who is lawfully entitled to give or refuse consent in the place of the parent. This paragraph does not include a parent who has only a right of access to the individual. If a children's aid society or other person is lawfully entitled to consent in the place of the parent, this paragraph does not include the parent.

6. A parent of the individual with only a right of access to the individual.

7. A brother or sister of the individual.

8. Any other relative of the individual. 2004, c. 3, Sched. A, s. 26 (1); 2016, c. 23, s. 64 (2); 2021, c. 4, Sched. 11, s. 27 (5, 6).

Requirements

(2) A person described in subsection (1) may consent only if the person,

(a) is capable of consenting to the collection, use or disclosure of personal health information by a health information custodian;

(b) in the case of an individual, is at least 16 years old or is the parent of the individual to whom the personal health information relates;

(c) is not prohibited by court order or separation agreement from having access to the individual to whom the personal health information relates or from giving or refusing consent on the individual's behalf;

(d) is available; and

(e) is willing to assume the responsibility of making a decision on whether or not to consent. 2004, c. 3, Sched. A, s. 26 (2); 2021, c. 4, Sched. 11, s. 27 (7).

Offences

72 (1) A person is guilty of an offence if the person,

(a) wilfully collects, uses or discloses personal health information in contravention of this Act or its regulations;

(b) makes a request under this Act, under false pretences, for access to or correction of a record of personal health information;

(b.1) wilfully contravenes section 11.2;

(c) in connection with the collection, use or disclosure of personal health information or access to a record of personal health information, makes an assertion, knowing that it is untrue, to the effect that the person,

(i) is a person who is entitled to consent to the collection, use or disclosure of personal health information about another individual,

(ii) meets the requirement of clauses 26 (2) (b) and (c),

(iii) holds the beliefs described in subsection 26 (5), or

(iv) is a person entitled to access to a record of personal health information under section 52;

(d) disposes of a record of personal health information in the custody or under the control of the custodian with an intent to evade a request for access to the record that the custodian has received under subsection 53 (1);

(e) wilfully disposes of a record of personal health information in contravention of section 13;

(f) contravenes subsection 34 (2), (3) or (4) or clause 47 (15) (a), (e) or (f);

(g) wilfully obstructs the Commissioner or a person known to be acting under the authority of the Commissioner in the performance of his or her functions under this Act;

(h) wilfully makes a false statement to mislead or attempt to mislead the Commissioner or a person known to be acting under the authority of the Commissioner in the performance of his or her functions under this Act;

(i) wilfully fails to comply with an order made by the Commissioner or a person known to be acting under the authority of the Commissioner under this Act; or

(j) contravenes section 70. 2004, c. 3, Sched. A, s. 72 (1); 2019, c. 15, Sched. 30, s. 7 (1).

Penalty

(2) A person who is guilty of an offence under subsection (1) is liable, on conviction,

(a) if the person is a natural person, to a fine of not more than $200,000 or to a term of imprisonment of not more than 1 year, or to both; or

(b) if the person is not a natural person, to a fine of not more than $1,000,000. 2004, c. 3, Sched. A, s. 72 (2); 2016, c. 6, Sched. 1, s. 1 (26); 2020, c. 5, Sched. 6, s. 23.

Officers, etc.

(3) If a corporation commits an offence under this Act, every officer, member, employee or other agent of the corporation who authorized the offence, or who had the authority to prevent the offence from being committed but knowingly refrained from doing so, is a party to and guilty of the offence and is liable, on conviction, to the penalty for the offence, whether or not the corporation has been prosecuted or convicted. 2004, c. 3, Sched. A, s. 72 (3).

Human Rights Code, RSO 1990, c H.19

Preamble

Whereas recognition of the inherent dignity and the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world and is in accord with the Universal Declaration of Human Rights as proclaimed by the United Nations;

And Whereas it is public policy in Ontario to recognize the dignity and worth of every person and to

provide for equal rights and opportunities without discrimination that is contrary to law, and having as its aim the creation of a climate of understanding and mutual respect for the dignity and worth of each person so that each person feels a part of the community and able to contribute fully to the development and well-being of the community and the Province;

And Whereas these principles have been confirmed in Ontario by a number of enactments of the Legislature and it is desirable to revise and extend the protection of human rights in Ontario;

Therefore, Her Majesty, by and with the advice and consent of the Legislative Assembly of the Province of Ontario, enacts as follows:

PART I
FREEDOM FROM DISCRIMINATION

Services

1 Every person has a right to equal treatment with respect to services, goods and facilities, without discrimination because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, gender identity, gender expression, age, marital status, family status or disability. R.S.O. 1990, c. H.19, s. 1; 1999, c. 6, s. 28 (1); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (1); 2012, c. 7, s. 1.

Accommodation

2 (1) Every person has a right to equal treatment with respect to the occupancy of accommodation, without discrimination because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, gender identity, gender expression, age, marital status, family status, disability or the receipt of public assistance. R.S.O. 1990, c. H.19, s. 2 (1); 1999, c. 6, s. 28 (2); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (2); 2012, c. 7, s. 2 (1).

Harassment in accommodation

(2) Every person who occupies accommodation has a right to freedom from harassment by the landlord or agent of the landlord or by an occupant of the same building because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sexual orientation, gender identity, gender expression, age, marital status, family status, disability or the receipt of public assistance. R.S.O. 1990, c. H.19, s. 2 (2); 1999, c. 6, s. 28 (3); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (3); 2012, c. 7, s. 2 (2).

Contracts

3 Every person having legal capacity has a right to contract on equal terms without discrimination because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, gender identity, gender expression, age, marital status, family status or disability. R.S.O. 1990, c. H.19, s. 3; 1999, c. 6, s. 28 (4); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (4); 2012, c. 7, s. 3.

Employment

5 (1) Every person has a right to equal treatment with respect to employment without discrimination because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sex, sexual orientation, gender identity, gender expression, age, record of offences, marital status, family status or disability. R.S.O. 1990, c. H.19, s. 5 (1); 1999, c. 6, s. 28 (5); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (5); 2012, c. 7, s. 4 (1).

Harassment in employment

(2) Every person who is an employee has a right to freedom from harassment in the workplace by the employer or agent of the employer or by another employee because of race, ancestry, place of origin, colour, ethnic origin, citizenship, creed, sexual orientation, gender identity, gender expression, age, record of offences, marital status, family status or disability. R.S.O. 1990, c. H.19, s. 5 (2); 1999, c. 6, s. 28 (6); 2001, c. 32, s. 27 (1); 2005, c. 5, s. 32 (6); 2012, c. 7, s. 4 (2).

Announced intention to discriminate

13 (1) A right under Part I is infringed by a person who publishes or displays before the public or causes the publication or display before the public of any notice, sign, symbol, emblem, or other similar representation that indicates the intention of the person to infringe a right under Part I or that is intended by the person to incite the infringement of a right under Part I. R.S.O. 1990, c. H.19, s. 13 (1).

Opinion

(2) Subsection (1) shall not interfere with freedom of expression of opinion. R.S.O. 1990, c. H.19, s. 13 (2).

***Hopp v. Lepp*, 1980 CanLII 14 (SCC), [1980] 2 SCR 192**

Informed consent:

Whether there was informed consent was the main issue argued in this Court. It is an issue that comes before this Court for the first time. The

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term "informed consent", frequently used in American cases, reflects the fact that although there is, generally, prior consent by a patient to proposed surgery or therapy, this does not immunize a surgeon or physician from liability for battery or for negligence if he has failed in a duty to disclose risks of the surgery or treatment, known or which should be known to him, and which are unknown to the patient. The underlying principle is the right of a patient to decide what, if anything, should be done with his body: see Parmley v. Parmley and Yule[2], at pp. 645-46. (I leave aside any question of emergency or of mental incompetency and, also, situations where the operation or treatment performed or given is different from that to which the patient consented.) It follows, therefore, that a patient's consent, whether to surgery or to therapy, will give protection to his surgeon or physician only if the patient has been sufficiently informed to enable him to make a choice whether or not to submit to the surgery or therapy. The issue of informed consent is at bottom a question whether there is a duty of disclosure, a duty by the surgeon or physician to provide information and, if so, the extent or scope of the duty.

***Parmley v. Parmley*, 1945 CanLII 13 (SCC), [1945] SCR 635**

Consent and assault:

Force to the person is rendered lawful by consent in such matters as surgical operations. The

> fact is common enough; indeed authorities are silent or nearly so, because it is common and obvious. Taking out a man's tooth without his consent would be an aggravated assault and battery. With consent it is lawfully done every day. [Pollock on Torts, 14th ed., p. 124.]

...

The conclusion appears unavoidable that both of the parties hereto, particularly in the operating room, failed to recognize the right of a patient, when consulting a pro-

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fessional man in the practice of his profession, to have an examination, a diagnosis, advice and consultations, and that thereafter it is for the patient to determine what, if any, operation or treatment shall be proceeded with.

...

It may be that in the operating room the parties hereto were of the opinion that they were acting in the best interests of Mrs. Yule in extracting the teeth, but that is not the point. That would have been very important in their consultation with and their advising of Mrs. Yule, but it does not justify their proceeding without her consent. As was said by Garrison J., "No amount of professional skill can justify the substitution of the will of the surgeon for that of his patient." *Bennan* v. *Parsonnet[7]*

***Fleming v. Reid*, 1991 CanLII 2728 (ON CA)**

Informed consent and bodily autonomy:

Part IV:

The right to determine what shall, or shall not, be done with one's own body, and to be free from non-consensual medical treatment, is a right deeply rooted in our common law. This right underlies the doctrine of informed consent. With very limited exceptions, every person's body is considered inviolate, and, accordingly, every competent adult has the right to be free from unwanted medical treatment. The fact that serious risks or consequences may result from a refusal of medical treatment does not vitiate the right of medical self- determination. The doctrine of informed consent ensures the freedom of individuals to make choices about their medical care. It is the patient, not the doctor, who ultimately must decide if treatment -- any treatment -- is to be administered.

Part V:

On the first branch of the analysis, it is manifest that the impugned provisions of the Act operate so as to deprive the appellants of their right to "security of the person" as guaranteed by s. 7. The common law right to bodily integrity and personal autonomy is so entrenched in the traditions of our law as to be ranked as fundamental and deserving of the highest order of protection. This right forms an essential part of an individual's security of the person and must be included in the liberty interests protected by s. 7. Indeed, in my view, the common law right to determine what shall be done with one's own body and the constitutional right to security of the person, both of which are founded on the belief in the dignity

and autonomy of each individual, can be treated as co-extensive.

Few medical procedures can be more intrusive than the forcible injection of powerful mind-altering drugs which are often accompanied by severe and sometimes irreversible adverse side effects. To deprive involuntary patients of any right to make competent decisions with respect to such treatment when they become incompetent, and force them to submit to such medication, against their competent wishes and without the consent of their legally appointed substitute decision-makers, clearly infringes their Charter right to security of the person.

R. v. Ewanchuk, 1999 CanLII 711 (SCC), [1999] 1 SCR 330

Bodily autonomy, consent, fear and assault:

28 The rationale underlying the criminalization of assault explains this. Society is committed to protecting the personal integrity, both physical and psychological, of every individual. Having control over who touches one's body, and how, lies at the core of human dignity and autonomy. The inclusion of assault and sexual assault in the *Code* expresses society's determination to protect the security of the person from any non-consensual contact or threats of force. The common law has recognized for centuries that the individual's right to physical integrity is a fundamental principle, "every man's person being sacred, and no other having a right to meddle with it, in any the slightest manner": see Blackstone's *Commentaries on the Laws of England* (4th ed. 1770), Book III, at p. 120. It follows that any intentional but unwanted touching is criminal.

36 To be legally effective, consent must be freely given. Therefore, even if the complainant consented, or her conduct raises a reasonable doubt about her non-consent, circumstances may arise which call into question what factors prompted her apparent consent. The *Code* defines a series of conditions under which the law will deem an absence of consent in cases of assault, notwithstanding the complainant's ostensible consent or participation. As enumerated in s. 265(3), these include submission by reason of force, fear, threats, fraud or the exercise of authority, and codify the longstanding common law rule that consent given under fear or duress is ineffective: see G. Williams, *Textbook of Criminal Law* (2nd ed. 1983), at pp. 551-61.

...

37 The words of Fish J.A. in *Saint-Laurent v. Hétu*, 1993 CanLII 4380 (QC CA), [1994] R.J.Q. 69 (C.A.), at p. 82, aptly describe the concern which the trier of fact must bear in mind when evaluating the actions of a complainant who claims to have been under fear, fraud or duress:

> "Consent" is . . . stripped of its defining characteristics when it is applied to the submission, non-resistance, non-objection, or even the apparent agreement, of a deceived, unconscious or compelled will.

***Bruno Appliance and Furniture, Inc. v. Hryniak*, 2014 SCC 8 (CanLII), [2014] 1 SCR 126**

Civil fraud:

[18] The classic statement of the elements of civil fraud stems from an 1889 decision of the House of Lords, *Derry v. Peek* (1889), 14 App. Cas. 337, where Lord Herschell conducted a thorough review of the history of the tort of deceit and put forward the following three propositions, at p. 374:

> First, in order to sustain an action of deceit, there must be proof of fraud, and nothing short of that will suffice. Secondly, fraud is proved when it is shewn that a false representation has been made (1) knowingly, or (2) without belief in its truth, or (3) recklessly, careless whether it be true or false. . . . Thirdly, if fraud be proved, the motive of the person guilty of it is immaterial. It matters not that there was no intention to cheat or injure the person to whom the statement was made.

[19] This Court adopted Lord Herschell's formulation in *Parna v. G. & S. Properties Ltd.*, 1970 CanLII 25 (SCC), [1971] S.C.R. 306, adding that the false statement must "actually [induce the plaintiff] to act upon it" (p. 316, quoting *Anson on Contract*). Requiring the plaintiff to prove inducement is consistent with this Court's later recognition in *Snell v. Farrell*, 1990 CanLII 70 (SCC), [1990] 2 S.C.R. 311, at pp. 319-20, that tort law requires proof that "but for the tortious conduct of the defendant, the plaintiff would not have sustained the injury complained of".

[20] Finally, this Court has recognized that proof of loss is also required. As Taschereau C.J. held in *Angers v. Mutual Reserve Fund Life Assn.* (1904), 1904 CanLII 44 (SCC), 35 S.C.R. 330, "fraud without damage gives . . . no cause of action" (p. 340).

[21] From this jurisprudential history, I summarize the following four elements of the tort of civil fraud: (1) a false representation made by the defendant; (2) some level of knowledge of the falsehood of the representation on the part of the defendant (whether through knowledge or recklessness); (3) the false representation caused the plaintiff to act; and (4) the plaintiff's actions resulted in a loss.

***Queen v. Cognos Inc.*, 1993 CanLII 146 (SCC), [1993] 1 SCR 87**

Negligence and negligent misrepresentation:

Page 110:

The required elements for a successful *Hedley Byrne* claim have been stated in many authorities, sometimes in varying forms. The decisions of this Court cited above suggest five general requirements: (1) there must be a duty of care based on a "special relationship" between the representor and the representee; (2) the representation in question must be untrue, inaccurate, or misleading; (3) the representor must have acted negligently in making said misrepresentation; (4) the representee must have relied, in a reasonable manner, on said negligent misrepresentation; and (5) the reliance must have been detrimental to the representee in the sense that damages resulted.

Page 120:

In my view, the relevant standard of care is neither the one advanced by the respondent and the Court of Appeal nor the one proposed by the appellant. The former is too low as it equates, in essence, a duty

of care with a duty of common honesty. On the other hand, the standard of care proposed by the appellant is too onerous as it is tantamount to requiring full disclosure from employers during pre-employment interviews. This Court has been presented with no compelling reasons to treat representations made in an employment context differently from representations made in any other context. It is unfortunate that the appellant has spent considerable time in his argument trying to convince this Court to recognize a fundamentally new standard of care, specific to the employment context. Clearly, the standard of care normally required by law is sufficient to dispose of this appeal in the appellant's favour. Upholding the trial judge's finding of negligence does not require an expansion of tort law into previously uncharted and hence unknown waters. Rather, it simply requires an application of well established principles of the law of negligence.

The applicable standard of care should be the one used in every negligence case, namely the universally accepted, albeit hypothetical, "reasonable person". The standard of care required by a person making representations is an objective one. It is a duty to exercise such reasonable care as the circumstances require to ensure that representations made are accurate and not misleading

Page 125:

A duty of care with respect to representations made during pre-contractual negotiations is over and above a duty to be honest in making those representations. It requires not just that the representor be truthful and honest in his or her representations. It also requires that the representor exercise such reasonable care as the circumstances require to ensure that the representations made are accurate and not misleading.

Although the representor's subjective belief in the accuracy of the representations and his moral blameworthiness, or lack thereof, are highly relevant when considering whether or not a misrepresentation was fraudulently made, they serve little, if any, purpose in an inquiry into negligence. As noted above, the applicable standard of care is that of the objective reasonable person. The representor's belief in the truth of his or her representations is irrelevant to that standard of care. The position adopted by the Court of Appeal seems to absolve those who make negligent misrepresentations from liability if they believe that their representations are true. Such a position would virtually eliminate liability for negligent misrepresentation as liability would result only where there is actual knowledge that the representation made is not true; the basis of fraudulent misrepresentation.

McCulloch v. Murray, 1942 CanLII 44 (SCC), [1942] SCR 141

Gross negligence:

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All these phrases, gross negligence, wilful misconduct, wanton misconduct, imply conduct in which, if there is not conscious wrong doing, there is a very marked departure from the standards by which responsible and competent people in charge of motor cars habitually govern themselves. Subject to that, I think it is entirely a question of fact for the jury whether conduct falls within the category of gross negligence, or wilful misconduct, or wanton misconduct.

Interpretation

Definitions

2 The following definitions apply in this Act.

disclose includes to authorize disclosure. (communiquer)

genetic test means a test that analyzes DNA, RNA or chromosomes for purposes such as the prediction of disease or vertical transmission risks, or monitoring, diagnosis or prognosis. (test génétique)

health care practitioner means a person lawfully entitled under the law of a province to provide health services in the place in which the services are provided by that person. (professionnel de la santé)

Prohibitions

Genetic test

3 (1) It is prohibited for any person to require an individual to undergo a genetic test as a condition of

(a) providing goods or services to that individual;

(b) entering into or continuing a contract or agreement with that individual; or

(c) offering or continuing specific terms or conditions in a contract or agreement with that individual.

Refusal to undergo genetic test

(2) It is prohibited for any person to refuse to engage in an activity described in any of paragraphs (1)(a) to (c) in respect of an individual on the grounds that the individual has refused to undergo a genetic test.

Disclosure of results

4 (1) It is prohibited for any person to require an individual to disclose the results of a genetic test as a condition of engaging in an activity described in any of paragraphs 3(1)(a) to (c).

Refusal to disclose results

(2) It is prohibited for any person to refuse to engage in an activity described in any of paragraphs 3(1)(a) to (c) in respect of an individual on the grounds that the individual has refused to disclose the results of a genetic test.

Written consent

5 It is prohibited for any person who is engaged in an activity described in any of paragraphs 3(1)(a) to (c) in respect of an individual to collect, use or disclose the results of a genetic test of the individual without the individual's written consent.

Offences and Punishment

Contravention of sections 3 to 5

7 Every person who contravenes any of sections 3 to 5 is guilty of an offence and is liable

(a) on conviction on indictment, to a fine not exceeding $1,000,000 or to imprisonment for a term not exceeding five years, or to both; or

(b) on summary conviction, to a fine not exceeding $300,000 or to imprisonment for a term not exceeding twelve months, or to both.

***Criminal Code*, RSC 1985, c C-46**

Parties to Offences

Parties to offence

21 (1) Every one is a party to an offence who

(a) actually commits it;

(b) does or omits to do anything for the purpose of aiding any person to commit it; or

(c) abets any person in committing it.

Common intention

(2) Where two or more persons form an intention in common to carry out an unlawful purpose and to assist each other therein and any one of them, in carrying out the common purpose, commits an offence, each of them who knew or ought to have known that the commission of the offence would be a probable consequence of carrying out the common purpose is a party to that offence.

Person counselling offence

22 (1) Where a person counsels another person to be a party to an offence and that other person is afterwards a party to that offence, the person who counselled is a party to that offence, notwithstanding that the offence was committed in a way different from that which was counselled.

Idem

(2) Every one who counsels another person to be a party to an offence is a party to every offence that the other commits in consequence of the counselling that the person who counselled knew or ought to have known was likely to be committed in consequence of the counselling.

Definition of counsel

(3) For the purposes of this Act, counsel includes procure, solicit or incite.

Offences of negligence — organizations

22.1 In respect of an offence that requires the prosecution to prove negligence, an organization is a

party to the offence if

(a) acting within the scope of their authority

(i) one of its representatives is a party to the offence, or

(ii) two or more of its representatives engage in conduct, whether by act or omission, such that, if it had been the conduct of only one representative, that representative would have been a party to the offence; and

(b) the senior officer who is responsible for the aspect of the organization's activities that is relevant to the offence departs — or the senior officers, collectively, depart — markedly from the standard of care that, in the circumstances, could reasonably be expected to prevent a representative of the organization from being a party to the offence.

Other offences — organizations

22.2 In respect of an offence that requires the prosecution to prove fault — other than negligence — an organization is a party to the offence if, with the intent at least in part to benefit the organization, one of its senior officers

(a) acting within the scope of their authority, is a party to the offence;

(b) having the mental state required to be a party to the offence and acting within the scope of their authority, directs the work of other representatives of the organization so that they do the act or make the omission specified in the offence; or

(c) knowing that a representative of the organization is or is about to be a party to the offence, does not take all reasonable measures to stop them from being a party to the offence.

Accessory after the fact

23 (1) An accessory after the fact to an offence is one who, knowing that a person has been a party to the offence, receives, comforts or assists that person for the purpose of enabling that person to escape.

(2) [Repealed, 2000, c. 12, s. 92]

Where one party cannot be convicted

23.1 For greater certainty, sections 21 to 23 apply in respect of an accused notwithstanding the fact that the person whom the accused aids or abets, counsels or procures or receives, comforts or assists cannot be convicted of the offence.

Assault

265 (1) A person commits an assault when

(a) without the consent of another person, he applies force intentionally to that other person, directly or indirectly;

...

Consent

(3) For the purposes of this section, no consent is obtained where the complainant submits or does not resist by reason of

(a) the application of force to the complainant or to a person other than the complainant;

(b) threats or fear of the application of force to the complainant or to a person other than the complainant;

(c) fraud; or

(d) the exercise of authority.

Assault

266 Every one who commits an assault is guilty of

(a) an indictable offence and is liable to imprisonment for a term not exceeding five years; or

(b) an offence punishable on summary conviction.

Unlawfully causing bodily harm

269 Every one who unlawfully causes bodily harm to any person is guilty of

(a) an indictable offence and liable to imprisonment for a term not exceeding ten years; or

(b) an offence punishable on summary conviction.

Torture

269.1 (1) Every official, or every person acting at the instigation of or with the consent or acquiescence of an official, who inflicts torture on any other person is guilty of an indictable offence and liable to imprisonment for a term not exceeding fourteen years.

Definitions

(2) For the purposes of this section,

official means

(a) a peace officer,

(b) a public officer,

(c) a member of the Canadian Forces, or

(d) any person who may exercise powers, pursuant to a law in force in a foreign state, that would, in Canada, be exercised by a person referred to in paragraph (a), (b), or (c),

whether the person exercises powers in Canada or outside Canada; (fonctionnaire)

torture means any act or omission by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person

(a) for a purpose including

(i) obtaining from the person or from a third person information or a statement,

(ii) punishing the person for an act that the person or a third person has committed or is suspected of having committed, and

(iii) intimidating or coercing the person or a third person, or

(b) for any reason based on discrimination of any kind,

but does not include any act or omission arising only from, inherent in or incidental to lawful sanctions. (torture)

No defence

(3) It is no defence to a charge under this section that the accused was ordered by a superior or a public authority to perform the act or omission that forms the subject-matter of the charge or that the act or omission is alleged to have been justified by exceptional circumstances, including a state of war, a threat of war, internal political instability or any other public emergency.

Fraud

380 (1) Every one who, by deceit, falsehood or other fraudulent means, whether or not it is a false pretence within the meaning of this Act, defrauds the public or any person, whether ascertained or not, of any property, money or valuable security or any service,

(a) is guilty of an indictable offence and liable to a term of imprisonment not exceeding fourteen years, where the subject-matter of the offence is a testamentary instrument or the value of the subject-matter of the offence exceeds five thousand dollars; or

(b) is guilty

(i) of an indictable offence and is liable to imprisonment for a term not exceeding two years, or

(ii) of an offence punishable on summary conviction,

where the value of the subject-matter of the offence does not exceed five thousand dollars.

Minimum punishment

(1.1) When a person is prosecuted on indictment and convicted of one or more offences referred to in subsection (1), the court that imposes the sentence shall impose a minimum punishment of imprisonment for a term of two years if the total value of the subject-matter of the offences exceeds one million dollars.

...

Sentencing — aggravating circumstances

380.1 (1) Without limiting the generality of section 718.2, where a court imposes a sentence for an offence referred to in section 380, 382, 382.1 or 400, it shall consider the following as aggravating circumstances:

(a) the magnitude, complexity, duration or degree of planning of the fraud committed was significant;

(b) the offence adversely affected, or had the potential to adversely affect, the stability of the Canadian economy or financial system or any financial market in Canada or investor confidence in such a financial market;

(c) the offence involved a large number of victims;

(c.1) the offence had a significant impact on the victims given their personal circumstances including their age, health and financial situation;

(d) in committing the offence, the offender took advantage of the high regard in which the offender was held in the community;

(e) the offender did not comply with a licensing requirement, or professional standard, that is normally applicable to the activity or conduct that forms the subject-matter of the offence; and

(f) the offender concealed or destroyed records related to the fraud or to the disbursement of the proceeds of the fraud.

Intimidation

423 (1) Every one is guilty of an indictable offence and liable to imprisonment for a term of not more than five years or is guilty of an offence punishable on summary conviction who, wrongfully and without lawful authority, for the purpose of compelling another person to abstain from doing anything that he or she has a lawful right to do, or to do anything that he or she has a lawful right to abstain from doing,

(a) uses violence or threats of violence to that person or their intimate partner or children, or injures the person's property;

(b) intimidates or attempts to intimidate that person or a relative of that person by threats that, in Canada or elsewhere, violence or other injury will be done to or punishment inflicted on him or her or a relative of his or hers, or that the property of any of them will be damaged;

...

Punishment

(3) Every person who contravenes this section is guilty of an indictable offence and is liable to imprisonment for a term of not more than fourteen years.

Appendix A

1. United States: Emergency Use Authorization for Vaccines Explained

"An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives."

2. List of FDA Phase III Clinical Trials for COVID-19 Vaccine Candidates

https://clinicaltrials.gov/ct2/show/NCT04470427
Actual Study Start Date : July 27, 2020
Estimated Study Completion Date : October 27, 2022
Moderna: A Study to Evaluate Efficacy, Safety, and Immunogenicity of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19

https://clinicaltrials.gov/ct2/show/NCT04848584
Estimated Study Start Date : May 15, 2021
Estimated Study Completion Date : July 30, 2023
Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California

https://clinicaltrials.gov/ct2/show/NCT04505722
Actual Study Start Date : September 7, 2020
Estimated Study Completion Date : January 2, 2023
Janssen: A Study of Ad26.COV2.S for the Prevention of SARS-CoV-2-Mediated COVID-19 in Adult Participants (ENSEMBLE)

https://clinicaltrials.gov/ct2/show/NCT04516746
Actual Study Start Date : August 28, 2020
Estimated Study Completion Date : February 14, 2023
Astrazeneca: Phase III Double-blind, Placebo-controlled Study of AZD1222 for the Prevention of COVID-19 in Adults

3. Canada: Food and Drugs Act, RSC 1985, c F-27

Interim orders

30.1 (1) The Minister may make an interim order that contains any provision that may be contained in a regulation made under this Act if the Minister believes that immediate action is required to deal with a

significant risk, direct or indirect, to health, safety or the environment.

4. Drug and vaccine authorizations for COVID-19: List of applications received

Date published: 2021-07-09

Under the interim order, a company can submit an application for a drug or vaccine for use in COVID-19 that:

- has never been approved in Canada
- was previously approved in Canada for another use
- has been approved by a trusted foreign regulatory authority

An applicant can also file a new drug submission under the *Food and Drug Regulations*.

The list below includes all applications received by Health Canada for drugs and vaccines used for the COVID-19 pandemic. This list includes applications received under the interim order and those received under the *Food and Drug Regulations*. The current status of each application is also noted.

...

https://covid-vaccine.canada.ca/moderna-covid-19-vaccine/product-details

COVID-19 Vaccine Moderna (mRNA-1273 SARS-CoV-2)

https://covid-vaccine.canada.ca/pfizer-biontech-covid-19-vaccine/product-details

Pfizer-BioNTech COVID-19 Vaccine (tozinameran)

https://covid-vaccine.canada.ca/janssen-covid-19-vaccine/product-details

Janssen COVID-19 Vaccine

https://covid-vaccine.canada.ca/astrazeneca-covid-19-vaccine/product-details

AstraZeneca COVID-19 Vaccine (ChAdOx1-S [recombinant])

5. Cardozo T, Veazey R. Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease. International Journal of Clinical Practice, 04 Dec 2020, 75(3):e13795.

https://onlinelibrary.wiley.com/doi/full/10.1111/ijcp.13795

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.

...

The elicitation of antibodies, specifically neutralising antibodies, is the goal of nearly every current SARS-CoV-2 vaccine candidate. The prior evidence that vaccine-elicited, antibody-dependent enhancement (ADE) of disease is likely to occur to some degree with COVID-19 vaccines is vertically consistent from controlled SARS studies in primates to clinical observations in SARS and COVID-19. Thus, a finite, non-theoretical risk is evident in the medical literature that vaccine candidates composed of the SARS-CoV-2 viral spike and eliciting anti-SARS-CoV-2 antibodies, be they neutralising or not, place vaccinees at higher risk for more severe COVID-19 disease when they encounter circulating viruses.

...

In all, the evidence from the Pfizer, Moderna and Johnson & Johnson protocols for their COVID-19 vaccine trials and the sample consent forms, when contrasted with the evidence for antibody-dependent enhancement of disease presented by this report and widely available to any skilled practitioner in the field, establishes that patient comprehension of the specific risk that receiving the COVID-19 vaccine could convert a subject from someone who experiences mild disease to someone who experiences severe disease, lasting morbidity or even death is unlikely to be achieved by the informed consent procedures planned for these clinical trials.

Medical ethics standards required that, given the extent of evidence in the medical literature reviewed above, the risk of ADE should be clearly and emphatically distinguished in the informed consent from risks observed *rarely* as well as the more obvious risk of lack of efficacy, which is unrelated to the specific risk of ADE. Based on the published literature, it should have been obvious to any skilled medical practitioner in 2019 that there is a significant risk to vaccine research subjects that they may experience severe disease once vaccinated, while they might only have experienced a mild, self-limited disease if not vaccinated. The consent should also clearly distinguish the specific risk of worsened COVID-19 disease from generic statements about risk of death and generic risk of lack of efficacy of the vaccine.

...

Given the strong evidence that ADE is a non-theoretical and compelling risk for COVID-19 vaccines and the "laundry list" nature of informed consents, disclosure of the specific risk of worsened COVID-19 disease from vaccination calls for a specific, separate, informed consent form and demonstration of patient comprehension in order to meet medical ethics standards. The informed consent process for ongoing COVID-19 vaccine trials does not appear to meet this standard.