

**RIGHT TO REFUSE TO ACCEPT TREATMENT FOR MINOR CHILDREN**

Please print all information

I, \_\_\_\_\_, parent or legal guardian of \_\_\_\_\_, **DO NOT CONSENT** to any medical care **IN REGARDS TO COVID TESTING** and/or the **Administration of COVID Immunizations/ vaccines/ or experimental treatments related to COVID19 and all variants.** determined by a physician and or school board to be necessary for the welfare of my child while said child is under the care of \_\_\_\_\_ (School), to include all school staff.

I attest that my child is a minor having been born on, \_\_\_\_\_, and under the

***CODE OF FEDERAL REGULATIONS, TITLE 16- COMMERCIAL PRACTICES- CHAPTER II- CONSUMER PRODUCT SAFETY COMMISSION, SUBCHAPTER A- GENERAL PART 1028- PROTECTION OF HUMAN SUBJECTS, 1028.116 GENERAL REQUIREMENTS FOR INFORMED CONSENT***

**My child CANNOT provide informed consent** in my physical absence and without my informed permission. **Failure to comply with this refusal could lead to criminal charges against** \_\_\_\_\_ (School) **and participating staff members.** Criminal charges could include “False Imprisonment, Kidnapping, Assault, Battery, Menacing, and all applicable others evaluated on a case-by-case basis.”

This authorization is effective from \_\_\_\_\_ to \_\_\_\_\_

Signature of Parent or Legal Guardian \_\_\_\_\_

Witness Signature Witness Name (please print) \_\_\_\_\_

## § 1028.116 General requirements for informed consent.

(a) **General.** General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary [research](#) uses of [identifiable private information](#) and identifiable biospecimens. Waiver or alteration of consent in [research](#) involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in [paragraph \(e\)](#) of this section. General waiver or alteration of informed consent is described in [paragraph \(f\)](#) of this section. Except as provided elsewhere in this policy:

- (1) Before involving a human subject in [research](#) covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's [legally authorized representative](#).
- (2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the [legally authorized representative](#) sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- (3) The information that is given to the subject or the [legally authorized representative](#) shall be in language understandable to the subject or the [legally authorized representative](#).
- (4) The prospective subject or the [legally authorized representative](#) must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- (5) Except for broad consent obtained in accordance with [paragraph \(d\)](#) of this section:
  - (i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or [legally authorized representative](#) in understanding the reasons why one might or might not want to participate in the [research](#). This part of the informed consent must be organized and presented in a way that facilitates comprehension.
  - (ii) Informed consent as a whole must present information in sufficient detail relating to the [research](#), and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or [legally authorized representative](#)'s understanding of the reasons why one might or might not want to participate.
- (6) No informed consent may include any exculpatory language through which the subject or the [legally authorized representative](#) is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the [institution](#), or its agents from liability for negligence.

**(b) Basic elements of informed consent.** Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

- (1) A statement that the study involves [research](#), an explanation of the purposes of the [research](#) and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others that may reasonably be expected from the [research](#);
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For [research](#) involving more than [minimal risk](#), an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the [research](#) and [research](#) subjects' rights, and whom to contact in the event of a [research](#)-related injury to the subject;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any [research](#) that involves the collection of [identifiable private information](#) or identifiable biospecimens:

(i) A statement that identifiers might be removed from the [identifiable private information](#) or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future [research](#) studies or distributed to another investigator for future [research](#) studies without additional informed consent from the subject or the [legally authorized representative](#), if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the [research](#), even if identifiers are removed, will not be used or distributed for future [research](#) studies.

**(c) Additional elements of informed consent.** Except as provided in paragraphs (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the [legally authorized representative](#)'s consent;

(3) Any additional costs to the subject that may result from participation in the [research](#);

(4) The consequences of a subject's decision to withdraw from the [research](#) and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the [research](#) that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant [research](#) results, including individual [research](#) results, will be disclosed to subjects, and if so, under what conditions; and

(9) For [research](#) involving biospecimens, whether the [research](#) will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**(d) Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.** Broad consent for the storage, maintenance, and secondary [research](#) use of [identifiable private information](#) or identifiable biospecimens (collected for either [research](#) studies other than the proposed [research](#) or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this paragraph. If the subject or the [legally](#)

[authorized representative](#) is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

- (1) The information required in paragraphs (b)(2), (3), (5), and (8) and, when appropriate, (c)(7) and (9) of this section;
- (2) A general description of the types of [research](#) that may be conducted with the [identifiable private information](#) or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of [research](#) conducted;
- (3) A description of the [identifiable private information](#) or identifiable biospecimens that might be used in [research](#), whether sharing of [identifiable private information](#) or identifiable biospecimens might occur, and the types of [institutions](#) or researchers that might conduct [research](#) with the [identifiable private information](#) or identifiable biospecimens;
- (4) A description of the period of time that the [identifiable private information](#) or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the [identifiable private information](#) or identifiable biospecimens may be used for [research](#) purposes (which period of time could be indefinite);
- (5) Unless the subject or [legally authorized representative](#) will be provided details about specific [research](#) studies, a statement that they will not be informed of the details of any specific [research](#) studies that might be conducted using the subject's [identifiable private information](#) or identifiable biospecimens, including the purposes of the [research](#), and that they might have chosen not to consent to some of those specific [research](#) studies;
- (6) Unless it is known that clinically relevant [research](#) results, including individual [research](#) results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
- (7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's [identifiable private information](#) or identifiable biospecimens, and whom to contact in the event of a [research](#)-related harm.

**(e) Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials -**

- (1) **Waiver.** An [IRB](#) may waive the requirement to obtain informed consent for [research](#) under paragraphs (a), (b), and (c) of this section, provided the [IRB](#) satisfies the requirements of [paragraph \(e\)\(3\)](#) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary [research](#) use of [identifiable private information](#) or identifiable biospecimens in accordance with the requirements at [paragraph \(d\)](#) of this section, and refused to consent, an [IRB](#) cannot waive consent for the storage, maintenance, or secondary [research](#) use of the [identifiable private information](#) or identifiable biospecimens.
- (2) **Alteration.** An [IRB](#) may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the [IRB](#) satisfies the requirements of [paragraph \(e\)\(3\)](#) of this section. An [IRB](#) may not omit or alter any of the requirements described in [paragraph \(a\)](#) of this section. If a broad consent procedure is used, an [IRB](#) may not omit or alter any of the elements required under [paragraph \(d\)](#) of this section.
- (3) **Requirements for waiver and alteration.** In order for an [IRB](#) to waive or alter consent as described in this subsection, the [IRB](#) must find and document that:
  - (i) The [research](#) or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    - (A) Public benefit or service programs;

- (B) Procedures for obtaining benefits or services under those programs;
  - (C) Possible changes in or alternatives to those programs or procedures; or
  - (D) Possible changes in methods or levels of payment for benefits or services under those programs; and
- (ii) The [research](#) could not practicably be carried out without the waiver or alteration.

**(f) General waiver or alteration of consent -**

**(1) Waiver.** An [IRB](#) may waive the requirement to obtain informed consent for [research](#) under paragraphs (a), (b), and (c) of this section, provided the [IRB](#) satisfies the requirements of [paragraph \(f\)\(3\)](#) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary [research](#) use of [identifiable private information](#) or identifiable biospecimens in accordance with the requirements at [paragraph \(d\)](#) of this section, and refused to consent, an [IRB](#) cannot waive consent for the storage, maintenance, or secondary [research](#) use of the [identifiable private information](#) or identifiable biospecimens.

**(2) Alteration.** An [IRB](#) may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the [IRB](#) satisfies the requirements of [paragraph \(f\)\(3\)](#) of this section. An [IRB](#) may not omit or alter any of the requirements described in [paragraph \(a\)](#) of this section. If a broad consent procedure is used, an [IRB](#) may not omit or alter any of the elements required under [paragraph \(d\)](#) of this section.

**(3) Requirements for waiver and alteration.** In order for an [IRB](#) to waive or alter consent as described in this subsection, the [IRB](#) must find and document that:

- (i) The [research](#) involves no more than [minimal risk](#) to the subjects;
- (ii) The [research](#) could not practicably be carried out without the requested waiver or alteration;
- (iii) If the [research](#) involves using [identifiable private information](#) or identifiable biospecimens, the [research](#) could not practicably be carried out without using such information or biospecimens in an identifiable format;
- (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

**(g) Screening, recruiting, or determining eligibility.** An [IRB](#) may approve a [research](#) proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's [legally authorized representative](#), if either of the following conditions are met:

- (1) The investigator will obtain information through oral or written communication with the prospective subject or [legally authorized representative](#), or
- (2) The investigator will obtain [identifiable private information](#) or identifiable biospecimens by accessing records or stored identifiable biospecimens.

**(h) Posting of clinical trial consent form.**

(1) For each [clinical trial](#) conducted or supported by a [Federal department or agency](#), one [IRB](#)-approved informed consent form used to enroll subjects must be posted by the awardee or the [Federal department or agency](#) component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the [Federal department or agency](#) supporting or conducting the [clinical trial](#) determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such [Federal department or agency](#) may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web site after the [clinical trial](#) is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

**(i) Preemption.** The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

**(j) Emergency medical care.** Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).