

Montclair Policy on Passive Consent as permitted under NJ A5597: Permits school districts to administer health surveys after prior written notification to parents and guardians.

Background:

NJ A5597 allows school districts to administer anonymous, voluntary surveys regarding student health after prior written notification has been provided to parents and legal guardians. School districts would be able to administer surveys concerning topics affecting students including the use of alcohol, tobacco, drugs, and vaping; sexual behavior and attitudes; behaviors that may contribute to intentional or unintentional injuries or violence; or physical activity and nutrition-related behaviors.

Written notification to parents or legal guardians can be delivered by regular mail, electronic mail, or a written acknowledgement form to be delivered by the student at least two weeks prior to administration of the survey. Information obtained through the survey would be submitted to the Department of Education and the Department of Health. Information may be used to develop public health initiatives and prevention programs. The bill forbids the use of the data for marketing or other commercial purposes unrelated to student health.

This bill was drafted in response to the low participation rates seen across NJ without follow up measures to attain active consent. Passive parental permission presumes a parent or legal guardian has consented to the student's participation in a survey if written notice and an opportunity for the parent or legal guardian to deny permission (opt out) is provided.

IRB Guidance of Studies Referencing Passive Consent legislation (NJ A5597):

Although the HHS regulations do not reference passive or implied consent, OHRP recognizes that this terminology is used to describe a process in which consent or parental permission requirements have been altered or waived, or for which the requirement to document consent or parental permission has been waived. Under the conditions specified in the regulations at 45 CFR 46.116(c) or (d), an IRB may approve a consent procedure that does not include, or that alters some or all of the elements of informed consent.

Therefore, when reviewing research that seeks to utilize the Passive Consent model outlined in NJ A5597, the IRB will ensure the researcher has answered all questions relevant to an alteration or waiver of informed consent. The research will specify when the parental notification will take place according to the provisions outlined in NJ A5597. Those provisions include:

- Method of parental notification (mail, email, flyer sent home)
- Written notice of the proposed research (must contain the elements of informed consent)

It will be the responsibility of the researcher to ensure that their study meets the requirements for passive consent as outlined by the school district(s) involved in the research.

If the IRB determines that the criteria is satisfied, the alteration of the informed consent can be approved as per 45 CFR 46.116.

FOR REFERENCE

IRB Review as permitted under the 2018 Common Rule:

(1) Waiver. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (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.

Please also note that the regulations at [45 CFR 46.408\(c\)](#) also permit an IRB to waive parental permission.