

December 30, 2020

Interim Guidance: Use of an Informed Consent Committee for Consent to the COVID-19 Vaccine

I. Background

As vaccines for COVID-19 become available, individuals with intellectual and developmental disabilities who live in congregate residential facilities certified or operated by the New York State Office for People With Developmental Disabilities (OPWDD) (referred to herein as “residential facilities”), have been designated by the Governor and the New York State Department of Health as phase one recipients of the vaccine, subject to availability.

II. Informed Consent for the COVID-19 Vaccine

The administration of the COVID-19 vaccine will require informed consent. A COVID-19 Immunization Screening and Consent Form will be required for each person who receives the vaccine from a designated vaccine distribution location. Vaccines received through community providers may also require their own consent form prior to administration.

Like other types of medical treatment, the list of surrogate consent-givers provided in 14 NYCRR 633.11 will be available for individuals living in OPWDD certified residential facilities. Unlike other medical procedures that require informed consent, however, 14 NYCRR § 633.11 (as amended by emergency regulation on December 29, 2020) temporarily authorizes Informed Consent Committees (ICCs), as originally described in 14 NYCRR § 633.16, to provide informed consent for the administration of the COVID-19 vaccine for individuals who (a) lack the capacity to provide informed consent and (b) do not have another authorized surrogate decision-maker, as listed in 14 NYCRR § 633.11. Allowing ICCs to provide informed consent for the vaccine will allow for a timelier consent process for the vaccine than would otherwise be available, in recognition of the necessity of the vaccine to curb the spread of the COVID-19 pandemic.

Most individuals residing in residential facilities, however, should not require use of the ICC.

III. COVID-19 Vaccine: Informed Consent for Individuals 18 Years of Age or Older

If the individual is 18 years of age or older and has the capacity to provide informed consent, the individual shall provide their own consent for the COVID-19 vaccine.

If the individual is 18 years of age or older and does not have the capacity to provide their own consent, informed consent for the COVID-19 vaccine shall be provided by one of the surrogates identified in 14 NYCRR § 633.11(a)(1)(iii)(b). Specifically, informed consent for the COVID-19 vaccine shall be obtained from one of the following surrogates, in the order stated:

- (1) a guardian lawfully empowered to give such consent or the person's duly appointed health care agent or alternative agent;
- (2) an actively involved spouse;
- (3) an actively involved parent;
- (4) an actively involved adult child;
- (5) an actively involved adult sibling;
- (6) an actively involved adult family member;
- (7) the Consumer Advisory Board for the Willowbrook Class;
- (8) the Informed Consent Committee (ICC); or
- (9) a surrogate decision-making committee (SDMC) or a court of competent jurisdiction.

IV. COVID-19 Vaccine: Informed Consent for Individuals Under the Age of 18

When vaccines are available for individuals under the age of 18, informed consent for the COVID-19 vaccine shall be provided, for the duration of the emergency declaration, by one of the surrogates identified in 14 NYCRR § 633.11(a)(1)(iii)(a), as amended by emergency regulation.

V. Determination of Capacity to Provide Informed Consent

A determination of capacity to provide informed consent for individuals, who have not been determined by a court to be incapable of providing consent, shall be made by the individual's program planning team. In most cases, program planning teams will determine capacity to provide informed consent without the need for a formal assessment by a mental/behavioral health professional. Individuals who have historically provided their own consent, as determined by the treatment team, will likely be able to provide their own informed consent for the COVID-19 vaccine. Individuals who have historically not been able to provide informed consent, as determined by the treatment team, and who

have utilized a surrogate consent-giver will likely not be able to provide informed consent for the COVID-19 vaccine.

In making capacity determinations, the individual's program planning team should consider the individual's history of consenting for themselves, ability to demonstrate general understandings of the COVID-19 illness and purpose of vaccines, and ability to express a reasonably informed choice in this regard. Such a determination by the treatment team should be documented.

Only when there is a question about an individual's ability to provide informed consent is a formal capacity assessment by a mental/behavioral health professional necessary to make such a determination. Of those individuals formally assessed by a mental/behavioral health professional, only those who are determined by the assessment to be unable to provide informed consent shall be referred to the ICC when another authorized surrogate consent provider is not available. Additional materials related to capacity to consent, specific to the COVID-19 vaccine, are available on the Statewide Learning Management System (SMLS).

VI. Use of Informed Consent Committee for the COVID-19 Vaccine

The ICC may be utilized to obtain informed consent for the COVID-19 vaccine solely for those individuals who: (1) lack the capacity to provide their own consent and (2) do not have another surrogate authorized to act on their behalf. Providers may also consider requesting a patient-specific prescription for the COVID-19 from a medical professional, particularly if there is any concern regarding an individual's medical history or status.

The requirements related to the composition of the ICC and the procedures of the committee are outlined in 14 NYCRR § 633.16 and shall continue to apply. However, for the emergency utilization of an ICC to obtain informed consent for the COVID-19 vaccine, the following requirement is waived, as consent to a vaccine is unrelated to an individual's behavior plan:

14 NYCRR § 633.16(g)(8)(iii)(c): requirement that the ICC must include at least one person who does not serve on the behavior plan/human rights committee which reviewed the individual's behavior support plan.

Given the urgency for allowing access to the COVID-19 vaccine, the ICC is encouraged, but not required, to complete its review and render a determination within five (5) days of the receipt of a referral. A referral packet should include:

- (1) Any forms already required by agency protocol for an ICC referral except for a Behavior Support Plan or other documentation about behavioral rights restrictions;
- (2) Patient-specific prescription, if applicable;
- (3) An information factsheet from the manufacturer of the vaccine being distributed (e.g. Moderna or Pfizer, or both, if manufacturer unknown);
- (4) A COVID-19 Immunization Screening and Consent Form; and
- (5) Documentation that the person has been determined to be incapable of providing informed consent on their own behalf. Such a determination can be based upon either:
 - a. The program planning team's review of the individual's record; or
 - b. A formal assessment completed by a licensed psychologist, licensed clinical social worker, or licensed physician OR by another mental/behavioral health professional and cosigned by a licensed psychologist, licensed clinical social worker, or licensed physician.

Questions about this guidance or this process may be directed to Dr. Paul Partridge, Chief Psychologist, OPWDD Statewide Services, at Paul.Partridge@opwdd.ny.gov.