

Frequently Asked Questions (FAQ) September 30, 2011
On Informed Consent for Willowbrook Class Members Fully Represented by the Consumer
Advisory Board

➤ *What is the Consumer Advisory Board (CAB)?*

The CAB is a seven-member board that provides necessary and appropriate representation and advocacy services on an individual basis for all Willowbrook class members who do not have correspondents, as long as any class member lives, and may also act as co-representative or advocate for class members who are not non-correspondent class members. There are also local representatives who are assigned throughout the state to carry out the mission of the CAB. These local CAB representatives perform their day-to-day functions under the direction of an Executive Director and three regional Assistant Directors. The CAB was established in 1975 on consent of the parties to litigation on behalf of approximately 5,400 current and former residents of the Willowbrook Developmental Center.

➤ *What is the CAB's role in providing informed consent for class members?*

Following revisions to 14 NYCRR 633.11 that took effect November 23, 2005, the CAB is authorized to provide informed consent for Willowbrook class members who are not able to give informed consent on their own behalf, and for whom there is no legal guardian, health care agent or other actively involved family member to act as surrogate decision maker. If a family member is available and willing to give consent on behalf of a class member **or has objected to the proposed treatment**, the CAB will not review a request for informed consent.

➤ *For what type of professional medical treatment may the CAB provide informed consent?*

As defined by Section 633.99, informed consent is needed for medical, surgical, dental or diagnostic interventions or procedures that involve:

- the use of a general anesthetic;
- any significant invasion of bodily integrity requiring an incision or producing discomfort, debilitation or having a significant recovery period;
- treatment with a significant risk.

➤ *What is the role of the local representative?*

The local CAB representative **must** be contacted immediately when professional medical treatment is recommended, and involved throughout the review process. The local CAB representative **must** also be notified when an expedited decision is needed, defined as within eight business days of submission. Advance notice should be given to the local CAB representative of related appointments so that, if possible, they can make arrangements to attend. If Ms. Ferguson and the Board have no questions, the signed or declined consent will be forwarded via regular mail directly to the originating requestor as reflected on the *CAB Informed Consent Submission Checklist* along with the local CAB representative. In expedited situations, the CAB will fax the signed consent to the designated person. All inquiries on the status of a request for informed consent are to be made to the local CAB representative.

➤ *When is informed consent not required?*

Informed consent is not required for routine diagnosis or treatment including administration of routine medications, and dental care performed under a local anesthetic. Emergency medical, dental, health and hospital services may be rendered without informed consent when in the physician's judgment an emergency exists creating an immediate need for medical attention.

➤ *What happens in an emergency?*

For emergency medical treatment, Section 633.11 provides that “Medical, dental, health and hospital services may be rendered to a person of any age without seeking informed consent when, in the physician’s judgment, an emergency exists creating an immediate need for medical attention.” In such cases, the supplier of treatment may accept the authorization of the chief executive officer of the person’s residential facility to render treatment. Public health law defines “emergency” as when a person is in immediate need of medical attention and an attempt to secure consent would result in delay of treatment that would increase the risk of the person’s life or health.

Before declaring an “emergency,” the hospital/physician will attempt to reach out to the appropriate surrogate to obtain informed consent. For a class member fully represented by the CAB, the hospital/physician would reach out to CAB Central Office in Staten Island at (718) 477-8800, to give notice of the situation. If the CAB cannot be reached or provide consent given the circumstances, the treatment should be provided on an “emergency” basis. Some hospitals/physicians will simply provide such treatment; others will seek the director’s authorization pursuant to Section 633.11.

➤ *What happens when a situation is not an emergency but urgent care is needed?*

Urgent care may be needed for a condition that occurs suddenly and unexpectedly; requires prompt diagnosis or treatment; and in the absence of immediate care, the individual could reasonably be expected to suffer chronic illness, prolonged impairment or require a more hazardous treatment.

For a class member fully represented by CAB is in the hospital and requires urgent care, the following are the steps to be taken:

- ✓ Contact should be made to the CAB Staten Island Office directly by telephone at 718-477-8800.
- ✓ The primary health contact should complete the *Medical Consent Overview* form and fax to the CAB Office in Staten Island at 718-477-8805
- ✓ While all questions on the *Medical Consent Overview* form are to be answered to prevent delays, responses to some questions will be abbreviated since the CAB will obtain supplemental information directly from the physician via telephone

➤ *What are the expectations for review and follow up by requesting agencies?*

Agencies must implement a review protocol for requests for informed consent that includes sign off from administrative or medical supervisory staff. This signoff is reflected on the *CAB Informed Consent Submission Checklist* and *Medical/Dental Consent Overview*. This review is critical since incomplete packets or the use of forms from the Surrogate Decision Making

Committee (SDMC) **are unacceptable** when seeking informed consent from the CAB for a class member and **will be returned to the originating requestor**. In addition, agencies are to maintain a chronology of contacts following submission of its request for informed consent, with local CAB representatives and CAB Central Office in SI. This chronology is to include all dates of verbal or phone contact, questions from CAB and follow up actions taken by the agency. Written correspondence should be utilized to confirm multiple verbal or phone contacts.

- *What forms are utilized when submitting a request for informed consent from CAB?*

When CAB is the identified surrogate for a class member, the CAB Informed Consent Submission Checklist and either the Dental Consent Overview or Medical Consent Overview are utilized. Please continue to use the current version, which is dated April 15, 2009. These forms may be accessed on the OPWDD website at the following address:
http://www.opwdd.ny.gov/hp_cabconsent_index.jsp.

- *What are the expected timeframes for receipt of a decision on informed consent from CAB?*

As a general rule, the CAB will complete a regular review, when all required documentation is submitted, within 21 business days. An expedited decision will be made within eight business days of submission. Piecemeal submissions will delay the review process.

- *What are the expectations for participation by the DDSO?*

The agency is to fax the *CAB Informed Consent Submission Checklist (Revised 4/15/09)* to the DDSO Director immediately after mailing. The DDSO will enter date of receipt in Box 1. The agency immediately notifies the DDSO Director should the information packet be returned for resubmission, or when the signed or declined consent form is received from CAB on behalf of the class member ~ DDSO will enter date consent confirmed in Box 3. The DDSO contacts the originating requestor as reflected on the *CAB Informed Consent Submission Checklist (Revised 4/15/09)* for any informed consent submission still pending after 30 business days. If signed or declined consent has already been secured, the DDSO notes this on its copy of the *CAB Informed Consent Submission Checklist*. If the request is still outstanding, the DDSO Director contacts Ms. Ferguson to ascertain the status of the submission.

- *How will requesting agencies hear from CAB?*

Once all questions are fully addressed and information received, the signed or declined consent will be forwarded via regular mail directly to the originating requestor as reflected on the CAB Informed Consent Submission Checklist along with the local CAB representative. In expedited situations, the CAB will fax the signed consent to the designated person. On an exception basis only, CAB will fax the copy of the consent directly to a provider if a faxed consent is accepted by the health care provider, i.e., hospital, clinic, physician, etc.

- *When should a person be assessed for ability to provide informed consent for professional medical treatment?*

It is the responsibility of the person's program planning team to determine on a situation specific basis whether a person is able to understand the nature and implications of professional medical treatment. Whenever there is doubt on the part of any party interested in the welfare of the

person as to that person's ability to make a specific decision, prior to the submission of the request to CAB, a determination of capability should be made by a psychiatrist or psychologist.

- *What if there is a known family member who is not the correspondent on behalf of the class member and has not been active in the care and treatment issues?*

A non-correspondent family member may be initially passed over in the chain of surrogate decision makers if they do not meet the definition of "actively involved" in 633.99. However, the provider **MUST** include the name, address and telephone number of any known family member in its request to CAB for informed consent.

- *What if an alternate surrogate exists?*

The requesting agency must document its efforts to determine that such a person is "not reasonably available and willing, and is not expected to become reasonably available and willing to make a timely decision given the person's medical circumstances" before requesting a decision from an alternate surrogate. If an alternative surrogate consent decision maker is available and objects to the proposed treatment, the proposed treatment over objection must proceed as a court application.

- *What if there is a family member who has served as correspondent for a class member with CAB co-representation; however, the family is no longer involved and no other family is immediately available to serve as correspondent?*

Immediately complete a request for full representation from the CAB. CAB is unable to give informed consent until it serves as the full representative. If an alternate family member subsequently indicates a willingness to serve as correspondent, the issue of co-representation would be revisited.

- *What if the class member has served as his/her own correspondent with no CAB involvement; however, the individual is no longer able to provide his/her own informed consent and no other family is immediately available to serve as correspondent?*

If the class member has not executed a health care proxy, a request should be made for full representation from the CAB. CAB is unable to give informed consent until it serves as the full representative. If an alternate family member subsequently indicates a willingness to serve as correspondent, the issue would be revisited.

- *Is it possible for the consent form to be faxed?*

The signed or declined consent will be forwarded via regular mail directly to the originating requestor, with a copy to the local CAB representative. In expedited situations, the CAB will fax the signed consent to the designated person. On an exception basis, the CAB will fax the copy directly to a provider if a faxed consent is accepted by the health care provider, i.e., hospital, clinic, physician, etc.

➤ *Who is the secondary contact?*

The secondary contact is designated by the requesting provider as the service coordinator/case manager, residential director or other agency designee. It is never the local CAB representative. All communication with the secondary contact must be reflected in the chronology maintained by the agency requesting informed consent.

➤ *Please provide some differentiation between routine care and professional medical treatment.*

The following are examples of the difference between routine care and professional medical treatment, and are not an all inclusive list.

- Venipuncture, suturing of lacerations and catheterization of the bladder are seen as routine.
- Radiology procedures not involving contrast are seen as routine; however, radiology procedures involving contrast with radiopaque would require informed consent due to the risk of allergic reaction.
- Sigmoidoscopies would require informed consent due to the risk of perforation. This is also the case for colonoscopy and endometrial biopsies.
- Biopsies of suspicious skin lesions that involve scraping are seen as routine; however, those involving excision procedures would require informed consent due to the risk of bleeding and infection, and due to the cuts that compromise body integrity.
- Reduction and casting of fractures depends on the situation. If considered an emergency, care would be covered under Public Health Law 2504. However, informed consent would be recommended if a break has not healed well and recasting procedures were needed, or if the skin must be broken in order to do an internal fixation.
- Aspiration or injection of joints, tendons, or cysts that involve a fine needle biopsy do not require informed consent. An excision biopsy requires informed consent.
- Insertion of a central venous catheter for venous access would require informed consent due to the risk of infection, bleeding and the intrusive nature of the catheter.

➤ *Is informed consent required for sedation when it is required in order to perform a proposed medical or dental treatment?*

Informed consent for sedation is included in CAB's informed consent for the underlying professional medical treatment.

- *Is informed consent required for IV sedation for dental services?*

The local representative on behalf of CAB is able to provide consent for routine dental procedures when IV sedation is required. Dental procedures performed under general anesthesia must go before the CAB for informed consent.

- *Does the primary health services contact have to be available during evening hours?*

Agencies must ensure the availability of the primary health services contact (RN or MD) to respond to CAB questions, and take steps promptly to facilitate CAB's communication directly with the health care provider who is proposing the treatment, for explanation and clarification of the request. These telephone calls will be scheduled with notice during day or evening hours. All communication with the primary health services contact must be reflected in the chronology maintained by the agency requesting informed consent.

- *Once the procedure has been completed on behalf of the class member, are there any other steps to be taken to finalize documentation?*

The primary health services contact should forward the results of the procedure to the Executive Director of the CAB at the Staten Island Office of the CAB, located at 1050 Forest Hill Road, Staten Island, NY 10314.