NYS Office For People With Developmental Disabilities
Putting People First

# Informed Consent for "Professional Medical Treatment"

## for Willowbrook class members fully represented by the Consumer Advisory Board (CAB)

Updated 2/1/2012

## CAB's Authority to give informed consent

OPWDD's regulation on informed consent for "professional medical treatment" 14 NYCRR 633.11 was amended effective November 23, 2005, to include the Consumer Advisory Board (CAB) on the list of surrogate decision makers. As a result, the CAB is authorized to make informed consent decisions for a Willowbrook class member who is not able to make the informed medical decision for herself or himself, has no other identified surrogate, and has full representation from the CAB.

Per the regulation, informed consent for a proposed medical treatment should be sought from this list in the order stated: a legal guardian or health care agent; an actively involved spouse; an actively involved parent; an actively involved adult child; an actively involved adult sibling; or any other actively involved adult family member; the CAB for class members for whom it provides full representation; or a surrogate decision making committee (SDMC) or a court.

If there is a family member 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.

When CAB is the identified surrogate for a class member, the *CAB Informed Consent Submission Checklist (Revised 4/15/09)* should be utilized, along with the *Dental Consent Overview (Revised 4/15/09)* or *Medical Consent Overview (Revised 4/15/09)*, depending on the procedure.

The compiled information is submitted to Antonia Ferguson, Executive Director of the CAB, at the CAB Central Office, located at 1050 Forest Hill Road, Staten Island, NY 10314.

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.

All inquiries on the status of a request for informed consent are to be made to the local CAB representative. A message for the representative should be left at the CAB Central Office in Staten Island at (718) 477-8800.

## When is informed consent necessary?

14 NYCRR 633.11 contains procedures for obtaining informed consent for professional medical treatment, which is defined in Section 633.99 as follows:

- *A medical, dental, surgical or diagnostic intervention or procedure in which a general anesthetic is used or which involves a significant invasion of bodily integrity requiring an incision or producing substantial pain, discomfort, debilitation or having a significant recovery period or any professional diagnosis or treatment to which informed consent is required by law.*

Informed consent is not required for medical treatment that

- *does not meet the 633.99 definition ~ generally routine care or emergency treatment.*

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WHAT IF AN ALTERNATE SURROGATE EXISTS?

633.11 allows the requesting agency to seek consent from the next highest surrogate if the authorized surrogate 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." However, the agency must document the efforts made to contact the surrogate.

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Note:
IF a surrogate refuses to provide the requested consent and the agency believes the proposed treatment would be in the person's best interest, the agency should apply for court authorization for the proposed treatment.

## WHAT IS THE CAB?

- The CAB was established in 1975 on consent of the parties to litigation on behalf of the approximately 5400 residents of the Willowbrook Developmental Center. This seven-member board is comprised of parents, siblings and advocates, who provide 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.
- Local representatives are also 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 local CAB representatives play a critical role in the informed consent process. The provider must contact the representative immediately when any professional medical treatment is recommended, and communicate with him or her throughout the review process. Advance notice should be given to the representative of related appointments so that, if possible, they can make arrangements to attend.

## OVERVIEW OF WILLOWBROOK ACTIVE REPRESENTATION…

A class member who self-advocates:

- Acts as his or her own correspondent.
- May also have co-representation from a family member or CAB.

In either instance, the class member gives his or her own consent for movements, release of information, participation in activities, routine medical/dental care, professional medical treatment, etc.

When a class member does not self-advocate, the correspondent would be a parent/legal guardian, alternate family member or CAB.

A family member may…

- Fully represent a class member;
- Have CAB co-representation; or
- Designate CAB to be the full representative.

When CAB provides co-representation along with family:

- CAB staff attend team meetings and visit programs.
- The family retains its responsibility as correspondent, to review and respond to issues that require written consent, including informed consent.

When CAB fully represents a class member…

- The Board acts as correspondent for the class member.
- The Board provides informed consent for surgery or other invasive treatments.
- On behalf of the Board, local CAB staff:
  - ✓ Visit/attend meetings/advocate for the class member;
  - ✓ Ensure that appropriate services are provided as per his/her plans; and
  - ✓ Report findings/ make recommendations to the Board.

CAB is not authorized to give informed consent for class members who are able to give informed consent on their own behalf; who have a legal guardian, health care agent [person appointed pursuant to a health care proxy executed by the individual] or other actively involved family member; or when CAB provides co-representation.

## EXPECTATIONS FOR REQUESTING AGENCIES

- Implement a review protocol for requests for informed consent, which includes sign off from administrative or medical supervisory staff. Sign-off must be reflected on the *CAB Informed Consent Submission Checklist* and *Medical/Dental Consent Overview*.
- Maintain a detailed chronology of contacts following submission of the request for informed consent with local CAB representatives and CAB Central Office in Staten Island, including all dates of verbal/phone contact, questions from CAB and follow-up actions taken.
- Respond timely to all questions and requests for information from CAB.
- Notify CAB of date of procedure/treatment AND forward results/findings to the Executive Director of CAB.
- Notify DDSOs of all requests for informed consent:
  - ✓ Fax the *CAB Informed Consent Submission Checklist* to the DDSO Director immediately after mailing ~ DDSO enters date received in Box 1.
  - ✓ Notify the DDSO Director immediately when the information packet is returned for resubmission, or when the signed or declined consent form is received from CAB ~ DDSO enters date consent confirmed in Box 3.
- Keep the DDSO informed of the status of request. If the request is still outstanding after 8 business days for expedited requests or 30 business days for all other requests, the DDSO Director or his/her designee will contact Ms. Ferguson to ascertain the status of the submission.

## COMMUNICATION PROTOCOL

- The requesting agency identifies a primary health services contact; this contact is generally an RN or MD.
  - ✓ The primary health services contact must be available by telephone to respond to CAB questions, and 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.
- The requesting agency also designates a secondary contact, which may be the service coordinator/case manager, residential director or other agency designee. The secondary contact should be aware and knowledgeable of the submission.
  - ✓ The local CAB representative is NEVER the secondary contact.
- All communication with the primary health services contact and secondary contact must be reflected in the chronology maintained by the requesting agency.
- Inquiries on the status of a request for informed consent are to be directed to the local CAB representative. A message for the representative should be left at the CAB Central Office in Staten Island at (718) 477-8800. Remember that these contacts must be reflected in the chronology maintained by the agency requesting informed consent.
- The health services contact should forward the results/findings to the Executive Director of the CAB, 1050 Forest Hill Road, Staten Island, NY 10314.

THE MEMORANDUM, "*UPDATE ~ INFORMED CONSENT FOR WILLOWBROOK CLASS MEMBERS FULLY REPRESENTED BY THE CONSUMER ADVISORY BOARD (CAB),*" DATED SEPTEMBER 30, 2011 AND ALL ATTACHMENTS CAN BE ACCESSED ON THE OPWDD WEBSITE, AS FOLLOWS:

Go to http://www.omr.state.ny.us/

Select "News & Publications"

Select "Publications"

See "CAB Informed Consent"

IS INFORMED CONSENT NEEDED FOR IV SEDATION?

Procedures performed under general anesthesia require CAB informed consent.

For procedures that require informed consent in which IV sedation is required, the informed consent provided by CAB will cover both the procedure and the IV sedation.

The local CAB representative is able to provide consent for routine dental/medical procedures when IV sedation is required.

When presedation is required for a proposed medical/dental treatment, informed consent for presedation is included in CAB's informed consent for the underlying professional medical treatment.

## WHEN COMPLETING THE REQUEST...

- Use the appropriate forms: the *CAB Informed Consent Submission Checklist* along with the *Dental Consent Overview* or *Medical Consent Overview* depending on the procedure, all dated 4/15/2009.
- Remember ~ the CAB review process does not include a formal hearing. Use the *CAB Informed Consent Submission Checklist* to guide the compilation of required information. Submit ALL items on the list unless marked optional.
- Seek a second opinion for medical/dental treatment when questions can be anticipated.
- Always include recent annual medical assessment and laboratory reports to facilitate CAB review.
- If sedation or anesthesia is required, include an explanation including type of anesthesia and risk/benefit information. Note: the revised forms detail the possible types of anesthesia for your reference.
- Provide a listing of current medication ~ remember name and dosage.
- Provide any known medication or food allergies.
- Do not forget weight information for the past year.
- Do not use SDMC forms ~ they will be returned to the originating requestor.
- Include a statement from the plan of services, i.e., the ISP/CFA, or a recent assessment by a qualified examiner that confirms:
  - ✓ The class member lacks capacity to give informed consent for the proposed medical treatment and the basis for the statement.
  - ✓ No health care agent, legal guardian, or actively involved family member is available to grant consent.
  - ✓ The class member is fully represented by the CAB.

## HOW & WHEN 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*.
- On an exception basis only, CAB will fax the consent directly to a provider if the faxed consent is accepted by the health care provider, i.e., hospital, clinic, physician, etc.
- As a general rule, CAB will complete a regular review, when all requested documentation is submitted, within 21 business days. Expedited decisions will be made within 8 business days when all requested documentation is submitted.

## WHEN AN EXPEDITED DECISION IS NEEDED...

- [within 8 business days of submission], inform the local CAB representative, and reflect on the *CAB Informed Consent Submission Checklist* and cover letter.
- Remember to provide the medical recommendation/justification for the expedited review.
- For expedited requests only, fax submissions will be accepted. However, the sender must confirm that all pages are received by CAB and are legible.

## IS IT ROUTINE CARE OR PROFESSIONAL MEDICAL TREATMENT?

- Venipuncture, suturing of lacerations and catheterization of the bladder are routine.
- Radiology procedures not involving contrast are routine. Radiology procedures involving contrast with radiopaque dyes or contrast media require informed consent due to the risk of allergic reaction.
- Sigmoidoscopy, colonoscopy and endometrial biopsies require informed consent due to the risk of perforation.
- Biopsies of suspicious skin lesions that involve scraping are routine. Those involving excision require informed consent due to the risk of bleeding and infection, and due to the cuts that compromise bodily integrity.
- Reduction and casting of fractures depends on the situation. If considered an emergency, care would be covered under Public Health Law 2504. Routine recasting does not require informed consent. If a break has not healed well and internal fixation is needed, informed consent is needed for this surgical procedure.
- Aspiration or injection of joints, tendons or cysts that involve a fine needle biopsy do not require informed consent.
- Surgical biopsies; fine/core needle biopsies. i.e., breast, liver; and transurethral biopsies of the bladder require informed consent due to the invasive nature of the procedures.
- Insertion of a central venous catheter for venous access requires informed consent due to the intrusive nature of the catheter.

## WHAT IF....

*...there is known family who is not the correspondent for the class member and has not been active in care and treatment?*

- A non-correspondent family member may be initially passed over the chain of surrogate decision maker. However, the provider must include the name, address and telephone number of any known family member in its request to CAB for informed consent.

*...there is a family member who has served as correspondent for the 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 submit a written request for full representation to the Executive Director of the CAB. CAB is unable to give informed consent until it serves as the full representative.*****

*...the class member has served as his/her own correspondent with no CAB involvement but is no longer able to do so and no other family member is immediately available to serve as correspondent?*

- If the class member has not executed a health care proxy, immediately submit a written request for full representation to the Executive Director of the CAB. CAB is unable to give informed consent until it serves as the full representative.*****

***** Note: If an alternative family member subsequently indicates a willingness to serve as correspondent, the issue would be revisited.

Failure to submit all required documentation delays the review, and will result in the return of the information packet to the originating requestor for resubmission. Piecemeal submission also delays the review process.

WHEN IS INFORMED CONSENT REQUIRED?

A physician/ hospital may request informed consent for any procedure regardless of whether it is required per 633.99 definition. Informed consent must be secured consistent with 633.99 even if the physician/hospital does not consider it necessary.

Local CAB representatives are available to answer questions and clarify the CAB review process. A message for the representative should be left at the CAB Central Office in Staten Island at (718) 477-8800.

Contact your DDSO Willowbrook liaison for local district procedures.

Lori Lehmkuhl, OPWDD, is also available by telephone at (518) 473-6026; or by email at Lori.Lehmkuhl@opwdd.ny.gov.

Questions on Informed Consent for OPWDD Counsel should be directed to Eileen Zibell by telephone at (518) 474-7700; or by email at Eileen.Zibell@opwdd.ny.gov

NYS Office For People With Developmental Disabilities
Putting People First

The Vision Statement for

NYS Office for People With Developmental Disabilities

People with developmental disabilities enjoy meaningful relationships with friends, family and others in their lives, experience personal health and growth and live in the home of their choice and fully participate in their communities.

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The Mission Statement for

NYS Office For People With Developmental Disabilities

We help people with developmental disabilities live richer lives.

## What happens in an emergency situation?

- 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 to 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 to give notice of the situation;
  - ✓ If CAB cannot be reached or cannot provide consent given the circumstances, the treatment should be provided on an "emergency" basis.
- Some hospitals/physicians will simply provide emergency 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 who is in the hospital and requires urgent care, contact should be made to the CAB Staten Island Office directly by telephone at 718-477-8800.
- In addition, 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.