American Association of Tissue Banks

STANDARDS FOR TISSUE BANKING - 12th edition, 2008
Approved Updates to Consent-related Standards, as amended
March 26, 2011

SECTION A
GENERAL INFORMATION

A2.000 DEFINITIONS OF TERMS

ADEQUATE INFORMATION — Information sufficient for the *Donor*, the *Authorizing Person* or the *Living Donor* to make a voluntary decision regarding the gift of tissues for transplantation, therapy, research and/or education. The parameters of what constitutes *Adequate Information* must include "*Core Elements*" contained in Standard D2.400 or D3.400, and such additional information as the *Donor, Authorizing Person,* or *Living Donor* requests or which the *Donation Coordinator* reasonably believes the *Donor, Authorizing Person* or *Living Donor* should know. When the *Donor* is authorizing the gift of tissue, publicly available information concerning the scope and use of the gift shall be deemed *Adequate Information*.

AUTHORIZING PERSON — Upon the death of the *Donor*, the person, other than the *Donor*, authorized by law to make an anatomical gift.

AUTHORIZATION — Permission given after *Adequate Information* concerning the donation, recovery and use of tissues is conveyed.

CLIENT DEPOSITOR (R)—A person, or persons, who store(s) reproductive cells or tissues for future use in artificial insemination or assisted reproductive technology procedures for themself(ves) or a sexually intimate partner; not considered a reproductive tissue donor.

COLLECTION—The acquisition of semen or retrieval of oocytes from a donor or *Client Depositor* by surgical or non-surgical procedures.

DOCUMENT OF AUTHORIZATION — Legal record of the gift of tissue, permitting and defining the scope of the postmortem recovery and use of tissues for transplantation, therapy, research and/or education *Signed* or otherwise recorded by the *Authorizing Person*, pursuant to law.

DOCUMENT OF GIFT — The *Donor's* legal record of the gift of tissue permitting and defining the scope of the postmortem recovery and use of tissues for transplantation, therapy, research and/or education. It must be *Signed* or otherwise recorded by the *Donor* or person authorized under law to make a gift during the *Donor's* lifetime.

DOCUMENT OF GIFT/AUTHORIZATION — Term used when the standard refers to both a *Document of Gift* and a *Document of Authorization* as defined above.

DONATION COORDINATOR — A *Responsible Person* who seeks *Authorization* from an *Authorizing Person*, or who makes *Notification* concerning donation, recovery and use of the gift, or in the case of a *Living Donor* or *Client Depositor*, the *Responsible Person* who seeks *Informed*

Consent. For *Authorization* purposes, this person may also be referred to as a "designated requestor."

DONOR— A living or deceased individual whose body is the source of the *Tissue*.

DONOR REGISTRY— A database established in accordance with law, consisting of legally valid *Documents of Gift*.

INFORMED CONSENT — Permission given by a *Living Donor* (LD) or *Client Depositor* who is presented with a description of the scope, use and any risks or benefits to her or him of the proposed donation, and who has been given the opportunity to ask questions and receive accurate answers. An LD who gives her or his *Informed Consent* to donation shall *Sign* an *Informed Consent Record*.

LIVING DONOR (LD)— An individual who consents to the *Recovery* or *Collection* of his or her *Tissue*, where *Recovery* or *Collection* is to take place while she or he is alive. For all *Living Donors,* (LD) standards apply, then tissue-specific standards apply. A *Living Donor* is a type of *Donor* and, unless otherwise specified, standards that apply to *Donors* in general apply to *Living Donors*.

NOTIFICATION — Provision and documentation of notice concerning an anatomical gift that was made by the *Donor* during the *Donor's* lifetime.

RECORD - Information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.

RECOVERY—Obtaining tissue from a donor that is intended for use in human transplantation, therapy, research or education.

RESPONSIBLE PERSON—A person who is authorized to perform designated functions for which he or she is trained and qualified.

SERVICES TO DONOR FAMILIES—A defined policy or program describing tissue donation follow-up that is offered to the *Authorizing Person*. These may include written communications regarding: potential uses of tissue; recovery outcome information; bereavement support; provision of a copy of the *Document of Authorization*; and/or guidance describing how to contact the tissue bank if any questions arise regarding the donation. Frequency of follow-up and program maintenance is at the discretion of the Director.

SHALL— Used to indicate a mandatory standard, same as MUST.

SHOULD—Used to indicate a recommendation; advisory, indicating a commonly accepted activity for which there may be effective alternatives.

SIGN (SIGNED, SIGNATURE) — A *Record* is signed when it has been authenticated or adopted by the signer by means in writing, or an electronic signature, symbol, sound, process or recording pursuant to applicable law.

WITNESS—An individual who signifies in writing, or in electronically recorded format, that he or she has observed the execution or verbal authorization of the *Document of Gift/Authorization* or *Informed Consent*. The *Witness'* signification must be contemporaneous with execution and the *Witness* must be identified by name, address and/or such other contact information as is relevant and feasible. A *Witness Should* not be an employee or agent of the tissue bank or requesting entity.

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SECTION D
ACQUISITION OF TISSUE: AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERYAND COLLECTION

Words that are defined in A2.000 Definitions of Terms, appear in *italics* and are capitalized (e.g., *Audit*). Some terms are used frequently; therefore, these words may be italicized only when they first appear in the text of these *Standards*.

D1.000 GENERAL POLICIES FOR TISSUE RECOVERY OR COLLECTION ORGANIZATIONS

All referral arrangements with organ procurement facilities and agencies, *Donor Referral Sources* and other tissue banks or facilities should be documented.

(A) The tissue bank shall establish written or verbal procedures for interacting with operating room staff, the patient's physician, or other sources/facilities for autologous tissue donation prior to *Recovery*.

(R) Procedures for accepting *Client Depositor* reproductive cells and tissues and for recruiting, accepting or excluding potential reproductive tissue *Donors* shall be established by the Director and Medical Director.

D1.100 Monetary Compensation or Other Valuable Consideration to Donors

Monetary compensation or other valuable consideration, including goods or services, shall not be offered to a *Donor, Authorizing Person*, the *Donor's* estate, or any other third party, except in the following instances:

1) the tissue bank may reimburse responsible third parties for costs directly associated with a donation.

2) the tissue bank may reimburse *Living Donors* for costs associated with an acceptable donation, including compensation for restoration of lost earnings when directly attributable to donation, if and as authorized by law.

(R) The *Reproductive Tissue Bank* may provide monetary compensation to donors of reproductive tissue if the compensation is compliant with current ASRM Guidelines for Gamete and Embryo Donation.

Donors or their families should not be responsible for any expenses related to the *Recovery* of allogeneic tissue.

D2.000 AUTHORIZATION

D2.100 Requirements

Authorization to acquire tissues and make them available for transplantation, therapy, research or education shall be obtained from a *Donor* or *Authorizing Person* in accordance with applicable anatomical gift acts and other laws or regulations. This *Authorization* shall be expressed in a *Document of Gift/Authorization*, the original or a copy of which shall be maintained in the *Donor's* record at the tissue bank responsible for recovery, as well as in the *Donor's* record at the tissue bank whose Medical Director is responsible for donor suitability determination. In the case of an electronic or voice recorded *Document of Gift/Authorization*, the original recording should be maintained in reproducible form.

NOTE: For international members, terminology used by the government/competent authority having jurisdiction applies regarding lawful authorization for donation of tissues for transplantation, therapy, research, or education.

D2.200 Conditions

Adequate Information concerning the donation and *Recovery* of tissue shall be presented in a language in which the *Authorizing Person* is conversant and in terms that are easily understandable by the *Authorizing Person*. The *Donation Coordinator* should be trained to appropriately answer the questions the *Authorizing Person* may have. Neither coercion nor inaccurate information shall be used in any manner to obtain *Authorization.*

D2.300 Signatures and Documentation

D2.310 Document of Gift

In cases where a *Donor* has executed a *Document of Gift* it may be acted upon (permits *Recovery*) provided it meets applicable laws and regulations. Acceptable documentation may include a state driver's license, living will, advanced directive,

state ID card, donor card, or photocopy thereof, and documentation that the donor registered in a *Donor Registry*.

D2.320 Document of Authorization

When a *Document of Authorization* is used it must contain the following *Signatures* and related information:

1) the *Authorizing Person's Signature* and:
   a) name;
   b) address;
   c) phone number; and
   d) relationship to the *Donor*;
2) the *Donation Coordinator's Signature* and:
   a) the date; and
   b) identity of their organization;
3) the *Signature* of each *Witness* if witnessing is required by law or regulation;
4) documentation that the *Core Elements* were used; and
5) a statement granting *Authorization* for tissue *Recovery*.

D2.330 Methods of Obtaining Authorization

Legal *Authorization* can be obtained using different methods. When *Authorization* is obtained:

1) **in person**, the *Authorizing Person* must read and *Sign* the *Document of Authorization*.

2) **by telephone**, the person obtaining the *Authorization* shall read to the *Authorizing Person* the *Document of Authorization* or, alternatively, shall present each of the *Core Elements* described in Standard D2.400.

   This telephone conversation shall be recorded. There shall be documentation that the *Authorization* was obtained by telephone.

   A sampling plan must be adopted that verifies that recordings match the content in the written *Document of Authorization*. This verification must be performed by someone other than the *Donation Coordinator* or *Witness*. In the rare event that the telephone conversation cannot be recorded (e.g., equipment failure), and no facsimile or electronic means is feasible for

documenting *Authorization*, the conversation *Should* be witnessed by a third person.

3) **using a facsimile transmission**, a copy of the *Document of Authorization* is provided to the *Authorizing Person*. The *Authorizing Person* shall return the signed *Document of Authorization* by facsimile transmission. A *Donation Coordinator* shall be available to respond to questions posed by the *Authorizing Person.*

   A sampling plan must be adopted that verifies signatures received by facsimile. This verification must be performed by someone other than the *Donation Coordinator* or *Witness*.

4) **using an electronic transmission**, a copy of the *Document of Authorization* is provided to the *Authorizing Person*. The *Authorizing Person* shall electronically respond (e.g., by e-mail) that he/she has read the *Document of Authorization*, is authorized to grant *Authorization*, and is granting such *Authorization*. A *Donation Coordinator* shall be available to respond to questions posed by the *Authorizing Person.*

   A *Document of Authorization* received by electronic transmission should be verified pursuant to the relevant law on electronic signatures, such as the Uniform Electronic Transactions Act of the relevant state. An electronically transmitted, read-only or otherwise protected *Document of Authorization* may be used.

D2.400 Core Elements for Authorization

The *Document of Authorization* shall contain *Adequate Information*. No *Document of Authorization* from an *Authorizing Person* shall be acted upon if it does not contain the following *Core Elements*. These *Core Elements* also apply to Standard D2.500.

Core Elements:

1) the name of the *Donor*;

2) the name, address, and telephone number of the *Authorizing Person*, and his/her relationship to the *Donor;*

3) an explanation that the tissue is a gift, and that neither the *Donor's* estate nor the *Authorizing Person* will receive monetary compensation or valuable consideration for it;

4) a description of the general types of tissue to be recovered;

5) a description of the permitted use(s) of the recovered tissues (i.e. transplant, therapy, research, or education);

6) an explanation that recovery of tissue requires the following actions, and the *Document of Gift/Authorization* thus specifically authorizes:

   a) access to, and required disclosure of, the *Donor's* medical and other relevant records;

   b) testing and reporting for transmissible diseases;

   c) the removal of specimens which may include, but are not limited to, the spleen, lymph nodes, and blood samples, for the purpose of determining suitability and/or compatibility of donor and recipient;

   d) the release to the tissue bank of any and all records and reports of a Medical Examiner, Coroner or Pathologist; and

   e) such other requirements as may be applicable for the specific donation or tissue bank, such as transport of body, archiving of samples, etc.

7) contact information for the organization represented by the *Donation Coordinator*; and

8) any additional information required by laws or regulations.

The following information should be provided to an *Authorizing Person*:

1) a general description of the recovery e.g., timing, relocation of donor if applicable, contact information, etc.;

2) an explanation that costs directly related to the evaluation, recovery, preservation, and placement of the tissues will not be charged to the family;

3) an explanation regarding the impact the donation process may have on burial arrangements and on appearance of the body; and

4) an explanation that the *Document of Authorization* is available.

Any explanation required by law, such as an explanation that multiple organizations (nonprofit and/or for profit) may be involved in facilitating the gift(s) and/or reference to the possibility that tissue may be transplanted abroad, must be included.

When an Organ Procurement Organization (OPO), or other entity (e.g., hospital), has initiated the process of obtaining *Authorization* for a potential organ and tissue donation, the *Tissue Bank* for which the *Authorization* is being obtained shall request that the OPO or other entity follow the procedure and utilize a *Document of Authorization* that satisfies the requirements of Standard D2.000.

For a *Donor* one month (28 days) of age or less, adequate consent pursuant to law shall be obtained for collection of blood from the birth mother needed for testing.

D2.500 Notification of Gift

In cases where the gift is authorized by a *Donor's* own *Document of Gift* (i.e. first person consent), including a *Document of Gift* recorded in a *Donor Registry* (i.e. donor designation), and where law mandates notification, such notification shall be made pursuant to law.

In all other cases, prior to transport of the body or *Recovery*, the *Donation Coordinator* **should** attempt to notify the person who would have been an *Authorizing Person* had no gift been made during the life of the *Donor* or the person who is authorized to make arrangements for final disposition. The information to be provided in the Notification **should** contain, at a minimum, *Core Elements* of *Authorization* but at no time shall the *Donation Coordinator* indicate that the recipient of the information is empowered to revoke or amend the gift made by the *Donor*.

The *Donation Coordinator* **should** inquire during the *Notification* whether the notified person is aware of any revocation or refusal made by the *Donor*.

Notification, if made, shall be documented.

Where good faith efforts to notify an appropriate person of the gift fail to result in actual notification within a time frame compatible with the successful recovery of the tissue, the attempt to notify shall be documented, and recovery may proceed.

D2.600 Services to Donor Families

Services to Donor Families or referral to a support system must be offered to the *Authorizing Person.* Subsequent communications shall be documented, maintained, and readily available. See AATB Guidance Document No. 4.

D3.000 INFORMED CONSENT FOR LIVING DONORS AND CLIENT DEPOSITORS

D3.100 Requirements

Informed consent to acquire tissues and make them available for transplantation, therapy, research or education shall be obtained from a *Living Donor* or *Client Depositor* in

accordance with applicable laws or regulations. This *Informed Consent* shall be documented in an *Informed Consent Record*, the original or a copy of which shall be maintained in the *Living Donor's* or *Client Depositor's* record at the tissue bank responsible for recovery or collection, as well as in the *Living Donor's* record at the tissue bank whose Medical Director is responsible for donor suitability determination. In the case of an electronic or voice recorded *Informed Consent Record*, the original recording should be maintained in reproducible form.

NOTE: For international members, terminology used by the government/competent authority having jurisdiction applies regarding lawful informed consent for donation of tissues for transplantation, therapy, research, or education.

D3.200 Conditions

Adequate Information concerning the *Recovery* or *Collection* of tissue shall be presented in a language in which the *Living Donor* or *Client Depositor* is conversant and in terms that are easily understandable by *Living Donor* or *Client Depositor*. The *Donation Coordinator* should be trained to appropriately answer the questions the *Living Donor* or *Client Depositor* may have. Neither coercion nor inaccurate information shall be used in any manner to obtain *Informed Consent*.

The potential donor shall not be under the influence of anesthesia or any drug that could influence his/her ability to give *Informed Consent*.

(A) Informed consent to store tissue must be obtained either prior to the *Recovery*, or when *Recovery* has already occurred, as soon as practical after the *Recovery* and before use of the tissue.

D3.300 Signatures and Documentation

The *Informed Consent Record* must comply with applicable laws and regulations. It must contain, at a minimum,

1) the *Living Donor's* or *Client Depostor's Signature* and:
    a) name;
    b) address; and
    c) phone number;
2) the *Donation Coordinator's Signature* and:
    a) the date; and
    b) identity of their organization;
3) the *Signature* of each *Witness* if witnessing is required by law or regulation;
4) documentation that the *Core Elements for Informed Consent* were used;

5) a statement that the *Living Donor* or *Client Depositor* understands what has been read or explained and is granting *Informed Consent* for tissue *Recovery* or *Collection*; and

6) a statement that the *Living Donor* or *Client Depositor* has been informed that his/ her name and address, as well as required records, shall be kept on file by the *Tissue Bank* or *Reproductive Tissue Bank*.

D3.310 Methods of Obtaining Informed Consent

Informed Consent can be obtained using different methods, if and as authorized by law or regulation. The methods below appear in preferential order. When *Informed Consent* is obtained:

1) **in person**, the *Living Donor* or *Client Depositor* must read and *Sign* the *Informed Consent Record*.

2) **by telephone**, the person obtaining the *Informed Consent* shall read to the *Living Donor* or *Client Depositor* the *Informed Consent Record* or, alternatively, shall present each of the *Core Elements* described at Standard D3.400.

   This telephone conversation shall be recorded and it shall be documented that the *Informed Consent* was obtained by telephone. A sampling plan must be adopted that verifies that recordings match the content in the written *Informed Consent Record*. This verification must be performed by someone other than the *Donation Coordinator* or *Witness*. In the rare event that the telephone conversation cannot be recorded (e.g., equipment failure), and no facsimile or electronic means are feasible for documenting *Informed Consent*, the *Informed Consent* may be made telephonically and *Should* be witnessed by a third person.

3) **using a facsimile transmission**, a copy of the *Informed Consent Record* is provided to the *Living Donor* or *Client Depositor.* The *Living Donor* or *Client Depositor* shall return the signed *Informed Consent Record* by facsimile transmission. A *Donation Coordinator* shall be available to respond to questions posed by the *Living Donor* or *Client Depositor.*

   A sampling plan must be adopted that verifies signatures received by facsimile. This verification must be performed by someone other than the *Donation Coordinator* or *Witness*.

4) **using an electronic transmission**, a copy of the *Informed Consent Record* is provided to the *Living Donor* or *Client Depositor.* The *Living Donor* or *Client Depositor* shall electronically respond (e.g., by e-mail) that he/she has read the *Informed Consent Record,* and is granting such *Informed Consent.* A *Donation*

Coordinator shall be available to respond to questions posed by the *Living Donor* or *Client Depositor*.

An *Informed Consent Record* received by electronic transmission should be verified pursuant to the relevant law on electronic signatures, such as the Uniform Electronic Transactions Act, of the relevant state. An electronically transmitted, read-only or otherwise protected *Informed Consent Record* may be used.

D3.400 Core Elements for Informed Consent

No *Informed Consent* from a *Living Donor* or a *Client Depositor* shall be acted upon if it does not contain the following *Core Elements*.

Core Elements:

1) the name of the *Living Donor* or *Client Depositor*; or

2) the identity of the person authorized by law to consent on behalf of the *Living Donor or Client Depositor* and his/her relationship to the subject including name, address, and telephone number;

3) if applicable, an explanation that the tissue is a gift, and that the *Living Don*or will not receive monetary compensation or valuable consideration for it;

4) a description of the general types of tissue to be *Recovered or Collected*, and any information pertinent to the specific *Recovery* or *Collection* contemplated;

5) a description of the permitted use(s) of the tissues (i.e. transplant, therapy, research, or education);

6) a description of the general purposes for which the tissue may be used;

7) a legally adequate release of the *Living Donor's* or *Client Depositor's* relevant medical records;

8) permission to test for disease, if applicable;

9) a statement that confirmed positive test results will be reported or disclosed if required by law or regulation (e.g., to the *Living Donor* or *Client Depositor*, to the attending physician, to appropriate health officials);

10) contact information for the organization represented by the *Donation Coordinator;*

11) information concerning possible risks and benefits to the *Living Donor* or *Client Depositor,* if applicable; and

12) any additional information required by laws or regulations.

(R) In the case of a *Client Depositor* the *Informed Consent Record* shall also include details about costs of tissue cryopreservation, storage, distribution and disposition options.

In the case of an *Anonymous Donor*, the *Informed Consent Record* shall also include details about monetary compensation. See Standard D1.100.

D5.000 RECOVERY AND COLLECTION POLICIES AND PROCEDURES

D5.100 Verification Procedures

D5.110 Confirmation

Prior to *Recovery or Collection*, staff shall confirm that in the case of a deceased donor, *Authorization* for donation has been obtained and documented in a *Document of Gift/Authorization*, and in the case of a *Living Donor, Informed Consent* for donation has been obtained and documented.

D5.120 Donor Identity

Prior to initiation of tissue *Recovery* or *Collection* procedures, at least one staff member shall verify the potential donor's identification with the donor's name as stated on the *Informed Consent Record* or *Document of Gift/Authorization*. Donor identity *Verification* shall be documented in the donor record prior to tissue *Recovery* or *Collection*. Records shall indicate the staff member(s) involved and include the source of the *Verification* information (e.g., hospital wristband, medical examiner number, driver's license, government issued identification with photograph).

Additional changes to other standards due to comments received & review:

SECTION C
RECORDS MANAGEMENT

C1.000 RECORDS MANAGEMENT

C1.100 General

Each tissue bank shall develop a donor record management system that will allow the detailed documentation of the tissue banking process(es) for which the bank is responsible. Documentation must be made concurrent with each significant step and must include, but not be limited to:

1) *Informed Consent Record,* or *Document of Gift/Authorization*;

2) *Donor Suitability Assessment* and donor identification;
3) Tissue *Recovery* or *Collection*, transport, and *Processing*;
4) *Quarantine* and infectious disease testing;
5) In-process testing;
6) Record review;
7) Tissue labeling, storage, release, and *Distribution*;
8) *Quality Control*; and
9) Services to Donor Families.

Records shall be created beginning with donor screening documentation. Such records shall indicate the responsible party(ies) and must delineate the dates, times, and locations of subsequent procedures as well as the individuals performing them in order to facilitate *Traceability*. The records shall be considered confidential and shall be kept in a location with controlled access; precautions for their safety and security should be evident.

(A) Records shall include, at a minimum, donor identification, and the date and time of *Recovery*.

C1.300 Retention

Informed Consent Records, Documents of Gift/Authorization, and records pertaining to donor suitability, *Recovery*, *Collection, Processing*, storage, date of *Distribution*, QA, and identity of person/entity to whom distributed, shall be retained at least 10 years beyond the date of *Distribution*, date of transplantation (if known), date of any other *Disposition*, or date of expiration of the tissue (whichever is latest) or longer if required by law or regulation. Records shall be maintained in a manner to preserve their completeness and accuracy over time. Donor suitability records of *Dura Mater* donors shall be retained indefinitely. Tissue banks that have their tissues processed by another agency must assure that *Processing* and QC records are retained for at least ten years.

(R) The *Reproductive Tissue Bank* should maintain current donor and *Client Depositor* addresses until tissues are used or destroyed.

C1.400 Traceability

A tissue bank's records management system shall identify tissue by use of a unique identifier. Each subsequent entity involved in the process of *Recovery* or *Collection* through tissue dispensing shall be required to correlate its donor identifier with the donor identifier of the entity from which it acquired the tissue. Records shall also indicate the dates and the identities of the staff involved in each significant step of the operation from the time of Recovery or *Collection* through final *Disposition* of the tissue.

Laboratory and QC specimens related to a donor of tissue shall also be traceable to the donor. Records shall indicate which specimens were used for testing and shall also permit

tracing from the donor to the specimen and from the specimen to the donor. Whenever an accredited tissue bank consigns tissue to a non-accredited entity, the accredited bank shall:

1) require the non-accredited entity to comply with the requirements of this section; and

2) impose the requirements of this section on all subsequent Consignees, up to and including the *Tissue Dispensing Service*.

AATB Consent/Authorization Task Force - Christina Strong, Esq., Task Force Chairperson

Compiled by SAB 3-26-2011.