

American Association of Tissue Banks
STANDARDS FOR TISSUE BANKING - 12th edition, 2008
Approved Updates to Consent-related Standards, with amendments
March 26, 2011

For purposes of clarity, text that is proposed to be added is underlined, italicized, and appears as blue font (e.g., *Example*), and text that is proposed to be deleted utilizes the strikethrough (e.g., ~~*Example*~~).

SECTION A
GENERAL INFORMATION

A2.000 DEFINITIONS OF TERMS

(SAB note: proposed new terms, as well as current relevant terms, appear below)

***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.*

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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 who is the source of tissue for transplantation in accordance with established medical criteria and procedures. ~~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—*A procedure whereby information concerning the donation process is presented to the donor or donor’s next of kin with an opportunity for them to ask questions, after which specific approval is documented. 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. ~~donor whose heart is beating at the time of tissue donation.~~ 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.*

NEXT OF KIN—*The person(s) most closely related to a deceased individual as designated by applicable law such as the Uniform Anatomical Gift Act.*

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.*

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SERVICES TO DONOR FAMILIES—A defined policy or program describing tissue donation follow-up that is offered to the ~~Consenting~~ *Authorizing Person* (~~or Party~~). These may include written communications regarding: potential uses of tissue; recovery outcome information; bereavement support; provision of a copy of the *Document of Consent/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—~~The~~ *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.*

SECTION D
**ACQUISITION OF TISSUE: *AUTHORIZATION, INFORMED* CONSENT, DONOR
SCREENING, AND TISSUE RECOVERY AND 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.

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- (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 ~~inducement~~ compensation or other valuable consideration, including goods or services, ~~of value~~ shall not be offered to a *Donor*, ~~Deceased Donor's Next of Kin~~ Authorizing Person, the Donor's estate, or any other third party, except ~~that~~ in the following instances:

- 1) the tissue bank may reimburse responsible third parties for costs directly associated with a donation. ~~and~~
- 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 ~~is allowed~~ 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 INFORMED CONSENT AUTHORIZATION

D2.100 Authorization Requirements

~~Permission to acquire tissues and make them available for transplantation or research shall be obtained through the granting of *Informed Consent* by a *Consenting Person* in accordance with applicable anatomical gift acts and federal, state and/or local laws and/or regulations. A *Consenting Person* is: (a) the potential donor; (b) a person legally empowered to grant consent in accordance with federal, state, and/or local laws and/or regulations; or (c) the deceased donor's *Next of Kin* in order of legal precedence. This permission shall be expressed in a written document (the "*Informed Consent Document*"), the original or a copy of which shall be maintained in the donor's record at the recovery facility as well as in the donor's record at the facility whose Medical Director is responsible for donor suitability determination.~~

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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 ~~Consent~~ Conditions

Adequate Information concerning the donation and Recovery of tissue shall be presented in a language in which the ~~Consenting~~ Authorizing Person is conversant and in terms that are easily understandable by the ~~Consenting~~ 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 ~~Consent shall be obtained under circumstances that provide the Consenting Person an opportunity to ask questions and receive adequate information to give Informed Consent in accordance with federal, state, and/or local laws and/or regulations. The person seeking consent should be trained to answer appropriately the questions the Consenting Person may have. Coercion shall not be exerted in any manner to obtain permission for donation.~~

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, ~~The Informed Consent Document~~ it must contain the following Signatures and related information:

- 1) the Authorizing Person's Signature and:
 - a) name;

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- b) address;
- c) phone number; and
- d) relationship to the Donor;

~~of the Consenting Person, and if the consent is obtained in person, their signature. It must also contain the date, signatures of the person obtaining the consent, and at least one witness, or such number of witnesses as may be required by applicable federal, state, and/or local laws and/or regulations, and information that identifies the organization represented by the person obtaining consent.~~

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) ~~In circumstances where it is not feasible to obtain the *Informed Consent* in person, *Informed Consent* may be obtained by telephone. Under this method *by telephone*, the person obtaining the *Informed Consent Authorization* shall read to the *Consenting Authorizing Person* the *Informed Consent Document of Authorization* or, alternatively, shall discuss each of the elements described in Section D2.400 with the Consenting Person *present each of the Core Elements described in Standard D2.400*. The *Consenting Person* shall respond that he/she understands what has been read or explained, is authorized to grant *Informed Consent*, and is granting such consent.~~

This telephone conversation shall be recorded. ~~The *Informed Consent Document* shall be completed and signed by the person obtaining the consent and a witness, if prescribed by federal, state, and/or local laws and/or regulations, and it *There* shall be documented *documentation* that the consent *Authorization* was obtained by telephone.~~

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A sampling plan must be adopted that verifies that recordings match the content in the written documents of consent Document of Authorization. This verification must be performed by someone other than the person obtaining consent Donation Coordinator or Witness, if applicable. 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, In circumstances where the Consenting Person is not present to provide an original signature, Informed Consent may be documented by facsimile transmission. Under this method, the person obtaining the Informed Consent shall send by facsimile transmission a copy of the Informed Consent Document of Authorization is provided to the Authorizing Person, which the Consenting Person shall sign and whose signature shall be witnessed as prescribed above. The Consenting Authorizing Person shall return the signed Informed Consent Document of Authorization by facsimile transmission to the person obtaining the Informed Consent. A The person obtaining consent Donation Coordinator shall be available to respond to questions posed by the Consenting Person 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, In circumstances where it is not feasible to document the Informed Consent by facsimile transmission, Informed Consent may be documented by electronic transmission. Under this method, the person obtaining the Informed Consent shall transmit electronically (e.g., by e-mail) the Informed Consent Document. a copy of the Document of Authorization is provided to the Authorizing Person. The Consenting Authorizing Person shall electronically respond (e.g., by e-mail) that he/she has read the Document of Authorization Informed Consent Document, is authorized to grant consent Authorization, and is granting such consent Authorization. A The person obtaining consent Donation Coordinator shall be available to respond to questions posed by the Consenting Person 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.

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- 1) ~~A self-signed donor document or official donor registry documentation that grants consent for donation (e.g., valid state driver's license, living will, advanced directive, state ID card, witnessed donor card, or photocopy thereof) may be used.~~
- (R) ~~Permission to acquire reproductive cells or tissues must be obtained from the donor or *Client Depositor*.~~

D2.400 Informed Consent *Core Elements for Authorization*

The ~~*Informed Consent Document*~~ *Document of Authorization* shall contain information *Adequate Information* that would be of material importance to a person making the decision to donate. Such information shall be accurate, shall not be misleading, and shall not omit discussion of any element that would be material to a decision to donate. This information should include at least the following items, and may include other information, if applicable, as outlined in Appendix III: *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 ~~identity~~ *of the Authorizing Person*, and his/her *relationship to the Donor* of the ~~Consenting Person~~, including name, address, and telephone number;
- 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;*
- 3) ~~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*

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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.

- ~~4) a statement granting permission to have access to the donor's medical records;~~
- ~~5) a statement that blood samples from the donor will be tested for certain transmissible diseases;~~
- ~~6) a description of the general purposes for which recovered tissue may be used, including a statement that such uses may include transplantation, research and medical education; and~~
- 7) contact information for the organization represented by the Donation Coordinator; and*
- ~~7) 8) any additional information required by federal, state, and/or local laws and/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 ~~consent~~ Authorization for a potential organ and tissue donation, the Tissue Bank for which the ~~tissue~~ Authorization is being obtained shall request that the OPO or other entity follow the procedure and utilize ~~an Informed Consent form~~ a Document of Authorization that satisfies the requirements of Section D2.000.

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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*

Services to Donor Families or referral to a support system must be offered to the ~~Consenting Person~~ *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

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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 Depositor's Signature and:

- a) the Living Donor's or Client Depositor's name;
- b) address;
- c) and 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.

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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

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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 ~~identity~~ 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 Donor 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.

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

~~(LD) — The potential donor shall not be under the influence of anesthesia or any drug that could influence his/her ability to give *Informed Consent*. The *Informed Consent* for surgical bone donors shall also include a statement that a blood sample from the donor will be tested for certain transmissible diseases and will document to whom confirmed positive test results will be reported, (e.g., to the patient, patient/donor's physician, and to the appropriate health officials if required by applicable federal, state, and/or local laws or regulations).~~

~~The *Informed Consent* shall include a statement that the donor 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*. The *Reproductive Tissue Bank* should maintain current donor or *Client Depositor* addresses until cells or tissues are used or destroyed.~~

~~(R) — The *Reproductive Tissue Bank* shall obtain written consent for the *Collection*, storage, *Distribution* and disposal of *Embryos*.~~

~~In the case of *Client Depositors*, the *Reproductive Tissue Bank* shall obtain written *Informed Consent* from the *Client Depositor* for participation in the tissue storage program, after the Director or designee has explained to the *Client Depositor* the procedures for *Collection*, storage, *retrieval* and dispensing of tissue, as well as costs associated with tissue *Cryopreservation*, storage and *Distribution*.~~

~~In the case of *Anonymous* and *Directed Donors*, the *Reproductive Tissue Bank* shall obtain written *Informed Consent* from the donor for participation in the donor program, after the Director or designee has explained to the donor the procedures for *Collection*, storage, and use of the reproductive tissue involved, screening rationale and techniques, payment, and details of privacy and responsibilities.~~

~~(A) — Patient donor (or legal alternative) consent to donate tissue must be obtained either prior to the *Recovery*, or when *Recovery* is unscheduled as soon as practical after the *Recovery* and before use of the tissue.~~

~~(SB) — The potential donor shall not be under the influence of anesthesia or any drug that could influence his/her ability to give *Informed Consent*. The *Informed Consent* for surgical bone donors shall also include a statement that a blood sample from the donor will be tested for certain transmissible diseases and will document to whom confirmed positive test results will be reported, (e.g., to the patient, patient's physician, and to the appropriate health officials if required by applicable federal, state, and/or local laws and/or regulations).~~

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D5.000 RECOVERY AND COLLECTION POLICIES AND PROCEDURES

D5.100 Verification Procedures

D5.110 ~~Informed Consent~~ 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 ~~Recovery~~ staff member shall verify the potential donor's identification with the donor's name as stated on the *Informed Consent Record Document or Document of Gift/Authorization*. Donor identity *Verification* shall be documented in the ~~Recovery~~ donor record prior to tissue *Recovery or Collection*. Records shall indicate the ~~Recovery~~ 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) ~~Cell and/or Tissue~~ *Recovery or Collection*, transport, and *Processing*;
- 4) *Quarantine* and infectious disease testing;
- 5) In-process testing;
- 6) Record review;
- 7) ~~Cell and/or Tissue~~ labeling, storage, release, and *Distribution*; ~~and~~
- 8) *Quality Control*; and

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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 *Collection* Recovery.

C1.300 Retention

The following records, *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 applicable federal, state, and/or local laws or regulations. 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:

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- 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*.

Appendix III

~~American Association of Tissue Banks
Association of Organ Procurement Organizations
Eye Bank Association of America~~

~~Model Elements of Informed Consent for Organ and Tissue Donation~~

~~Adopted November 30, 2000~~

~~Human organ and tissue transplantation has become an important and growing part of modern medical practice. Advances in medical science have made it possible for millions of Americans to receive these life-saving and life-enhancing gifts. None of this would be possible, however, were it not for the tens of thousands of donors and donor families who give their organs and tissues to help their fellow men and women.~~

~~The decision to donate must, therefore, be an informed consent, and it must be conducted under circumstances that are sensitive to the consenting person's situation. Information concerning the donation should be presented in language and in terms that are easily understood by the consenting person. The consent should be obtained under circumstances that provide an opportunity to ask questions and receive informative responses. An offer should be made regarding the availability of a copy of the signed consent form, and information should be provided regarding ways to reach the recovery organization following donation. Consent should be obtained in accordance with federal, state and/or local laws and/or regulations. The person seeking the consent should be trained to appropriately answer any questions that the consenting person may have. In addition, coercion should not be exerted in any manner, nor monetary inducement offered to obtain consent for donation. The identification of who may be the appropriate person to consent to donation, and whether the consent of any person in addition to the donor needs be obtained, should be evaluated in accordance with the applicable laws and organizational policy and is not addressed in this statement.~~

~~The following list of "Basic Elements of Informed Consent" is intended to highlight the information that may be considered critical to informed decision making by a family member or other legally authorized person, who is being approached for consent to organ and/or tissue~~

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~~donation. This listing, whether communicated verbally or included on consent forms, is not intended to preempt any applicable federal, state, or local laws or regulations that may require more or less information to be disclosed for informed consent to be legally effective.~~

Basic Elements of Informed Consent

~~In seeking informed consent, the following information should be provided to the person(s) being approached for consent:~~

- ~~1) A confirmation/validation of the donor's identity and his or her clinical terminal condition.~~
- ~~2) A general description of the purposes (benefits) of donation.~~
- ~~3) Identification of specific organs and/or tissues (including cells) that are being requested for donation (with subsequent information provided on specific gifts recovered).~~
- ~~4) An explanation that the retrieved organs/tissues may be used for transplantation, therapy, medical research, or educational purposes.~~
- ~~5) A general description of the recovery process (including timing, relocation of donor if applicable, contact information, etc.).~~
- ~~6) An explanation that laboratory tests and a medical/social history will be completed to determine the medical suitability of the donor, including an explanation that blood samples from the donor will be tested for certain transmissible diseases.~~
- ~~7) An explanation that the spleen, lymph nodes, and blood may be removed, and cultures may be performed, for the purpose of determining donor suitability and/or used to determine compatibility of donor and recipient.~~
- ~~8) A statement granting access to the donor's medical records, and that the medical records may be released to other appropriate parties.~~
- ~~9) An explanation that costs directly related to the evaluation, recovery, preservation, and placement of the organs and tissues will not be charged to the family.~~
- ~~10) An explanation regarding the impact the donation process may have on burial arrangements and on appearance of the body.~~
- ~~11) Any additional information required by federal, state and/or local laws and/or regulations.~~

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Additional Elements of Informed Consent

In some situations, there may be additional information that should be known by the consenting person(s), or that might be helpful for family decision making. At a minimum, if the donor family inquires about any of these or additional matters, explanations should be provided.

The guiding principle for the use of these “Additional Elements of Informed Consent” is to advance simplicity and reasonableness in seeking *Informed Consent*, i.e., include these elements or additional comments if they are appropriate and might clarify any exigencies. For example, if there is the likelihood that the patient will become a Medical Examiner’s case, then it should be appropriate to so inform the family. If it is unlikely that donated tissue is going to be used for aesthetic surgery, then it would not be reasonable to address this issue in the family approach.

One or more of the following elements of information may also be appropriate for communication to the person(s) being approached for consent, depending upon the circumstances surrounding the donation and the potential gift(s):

1. — A description of any involvement by the Medical Examiner and/or Coroner, including an explanation that an autopsy may be performed.
2. — An explanation that transplantation may include reconstructive and aesthetic surgery.
3. — A reference to the possibility that the final gift may take a different form than originally recovered.
4. — An explanation that multiple organizations (nonprofit and/or for profit) may be involved in facilitating the gift(s).
5. — Reference to the possibility that tissue and/or organs may be transplanted abroad.

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

Compiled by SAB 3-26-2011.