Informed Consent
Vs.
Donor Authorization

Presented by
Beverly Bliss
Vice President Donor Operations, RTI Donor Services
Goals

• Describe the legal definition of consent vs. authorization
• Describe a processor experience with multiple consent forms and processes
• Describe procedural and policy changes driven by events
Informed Consent:

Legal condition whereby a person can be said to have given consent based upon an appreciation and understanding of the facts and implications of an action.

The individual needs to be in possession of all of his/her faculties, such as not being mentally retarded or mentally ill and without an impairment of judgment at the time of consenting. Impairments include illness, intoxication, drunkenness, using drugs, insufficient sleep and other health problems.
Authorization:

To officially empower someone to act

A document giving an official instruction or command

A document that states some contractual relationship or grants some rights

The power or right to give orders or make decisions...the act of conferring legality or sanction or formal warrant
Legislative/ Regulatory History


- 1988 JCAHCO—donor ID & notification standards

- 1993 FDA initiates regulation of Tissue Banks-(21CFR1270)

- 2000 National Donor Family Council—position statement endorsing organ & tissue donation and information to be included for consent

- 2000 AOPO, AATB, EBAA publish Model Elements of Informed Consent

- 2005 (21CFR 1271) cGTP’s—does not address consent
States begin to enact legislation that focus on three specific issues:

- profit vs. non-profit
- use of skin for cosmetic purposes
- international distribution of tissue

Do we really believe this is the full scope of the informed consent process?
The Process

- Death referral is ‘authorized’ under Conditions of Participation-hospitals
- Identify if donor authorization is present or if informed consent is required
- Comply with applicable state laws for witness, documentation and required elements (Opt in/out)
- Qualified person proceeds to obtain consent or inform family of donor authorization-COP defines
First Person Consent/Donor Registries

Intent vs Consent

85% of states have adopted some form of First Person Consent

70% of states have Registries-majority are registries of intent

These legislated programs may be non-conforming with other states and vary in content and process.
Informed Consent vs. Authorization

HELP!

Sorting through the multitude of donor consent forms from other recovery partners AND hospital partners
Risks with multiple versions/visions of informed consent documents

- Annoying hospital and recovery partners by asking for additional elements to be included in consent process
- Re-contacting families to ‘redo’ the consent form-this doesn’t make anyone happy!
- Accepting consent forms that put your organization at risk
The Processor

- Establish procedures for approving consent forms
- Establish audit program → initial → continuous
- Ensure all reviewers, including medical directors understand required elements of informed consent
<table>
<thead>
<tr>
<th>Model Elements of Informed Consent (per AATB, AOPO &amp; EBAA)</th>
<th>Discussed during Informed Consent process</th>
<th>Minimum requirement for RTI</th>
<th>Minimum requirement per AATB Standards</th>
<th>Minimum requirement for Non-RTI Consents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation of donor's identity</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Description of the purposes (benefits) of donation</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identification of the tissues/organs that are being requested for donation [1]</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Explanation that recovered tissues / organs may be used for transplant, medical research or education</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Description of recovery process (including timing, relocation of donor, if applicable, and contact info)</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explanation that blood will be recovered and tested for infectious diseases; that tissue cultures and biopsies will be recovered to help determine eligibility</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Statement granting access to donor's medical records and that records may be released to other parties</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Explanation that costs of recovery, preservation and placement of tissues will not be charged to family</td>
<td>X</td>
<td>*</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Explanation regarding the impact donation may have on burial arrangements and appearance of body</td>
<td>X</td>
<td>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any additional information required by federal, state and/or local laws and/or regulations [2]</td>
<td>X</td>
<td>*</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
### Standard Operating Procedure

**Title:** Process Of Obtaining Informed Consent

#### Additional Model Elements – include when appropriate

<table>
<thead>
<tr>
<th>Description of involvement by ME or Coroner, including explanation that autopsy may be performed</th>
<th>Discussed during Informed Consent process</th>
<th>Minimum requirement for RTI</th>
<th>Minimum requirement per AATB Standards</th>
<th>Minimum requirement for Non-RTI Consents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explanation that transplantation may include reconstructive or cosmetic surgery [3]</td>
<td>X</td>
<td>*</td>
<td></td>
<td>State by State</td>
</tr>
<tr>
<td>Statement that gift may take different form that originally recovered</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explanation that nonprofit and/or for profit organizations may be involved [3]</td>
<td>X</td>
<td>*</td>
<td></td>
<td>State by State</td>
</tr>
<tr>
<td>Explanation that tissue may be transplanted abroad [3]</td>
<td>X</td>
<td>*</td>
<td></td>
<td>State by State</td>
</tr>
</tbody>
</table>

#### Signature and other documentation requirements

<table>
<thead>
<tr>
<th>Address, phone number and relationship of the consenting person to the donor</th>
<th>Discussed during informed consent process</th>
<th>Minimum requirement for RTI</th>
<th>Minimum requirement per AATB Standards</th>
<th>Minimum requirement for Non-RTI Consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>In person and first person consents must include signature of consenting person, date consent was granted, and signature of person obtaining consent and witness</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Telephonic consents must include signature of person obtaining consent and witness, and documentation that consent was recorded</td>
<td>*</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[1] - In the case of first person consents, RTI would require a copy of the donor registry record or driver's license of the donor, whichever is acceptable according to state law.

[2] - Inclusion of items mandated by state law is required by RTI, e.g. the California law requiring specific language.

[3] - Laws vary regarding the three items identified as "State to State." Some non-RTI consents include these items by law (such as California), others may not. Recovery may proceed provided RTI follows up with the NOK on these three items.
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Events Outside of our Control
Driving Change

- Post BTS-DRS
- UAGA-2006 version
- State legislation-CA, WI, NY
QUESTIONS ? ? ?