



Our Bodies? Compliance Challenges and Solutions for Body and Specimen Donation for Research

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- The information provided here is for educational purposes only and not legal advice. Consult with your own attorneys for advice relevant to your particular situation.
- Ask questions any time.



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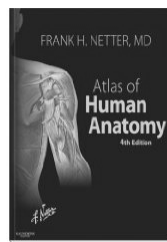
AGENDA

- Legal Primer
 - Anatomical Gift Laws
 - Medicare COPs
 - Human Research Regulations
 - HITECH (?)
- Informed Consent
 - Issues for human and cadaver donation for research
- Biospecimen banking for research
 - Policy and governance options



The Compliance Issue

- Researchers need human specimens to do research
- Specimens (and associated annotations) come from:
 - Deceased individuals
 - Anatomical gifts
 - Living individuals
 - "Excess" / "discarded"
 - Donated for research
- Laws, regulations, accreditation standards, and institutional policies govern all of these activities, as well as the use of data (annotations) for research



Legal Primer

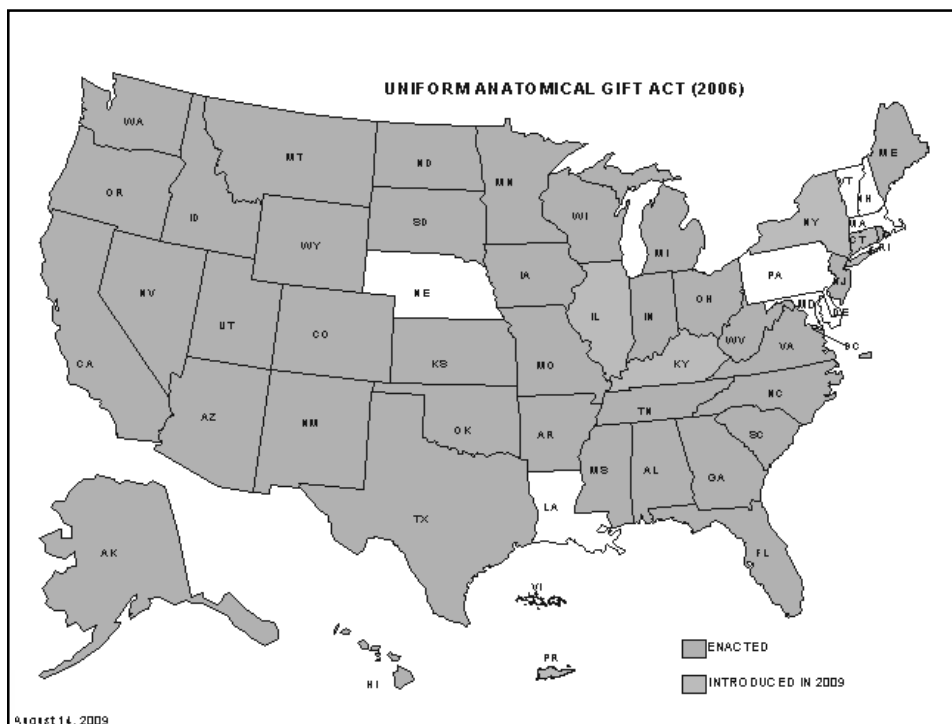


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Anatomical Gift Laws

- Uniform Anatomical Gift Act (2006 Revisions)***
 - Expands who can make anatomical gifts before death; gives healthcare advocates (POAs) new rights
 - Also facilitates easier revocation (e.g., by later inconsistent statements)
 - Authorizes, encourages use of donor registries
 - Strengthens respect for donor's wishes as against inconsistent decisions that may later be made by surrogates ... disempowers coroner/ME to donate
 - Expands who can make gifts after death (e.g., to include adults who exhibited special care and concern for the deceased)
 - Transplantation and therapy are clearly preferred over research and education where suitable
 - Addresses choice of law challenges
 - Enforcement: felony exposure for altering, concealing, etc. any document of gift, amendment, revocation, or refusal ... but immunity for good-faith compliance
 - More information: www.anatomicalgiftact.org

*** Check your state's laws – they may vary!!!



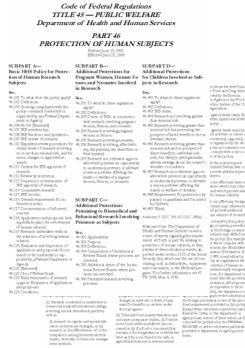
Medicare Conditions Of Participation (Hospitals)

- 42 CFR 482.27 (SOM Tags A-0585 to A-0586)
 - Laboratory must have written procedures for collection, preservation, transportation, receipt, and reporting of tissue specimens
 - Written policies approved by medical staff and pathologist must state which tissue specimens require macroscopic or microscopic examination (or both)
- 42 CFR 482.45 (SOM Tags A-0885 to A-893)
 - Hospital must have written policies and procedures to address its organ procurement responsibilities
 - Policies must incorporate appropriate OPO (and if necessary eye and tissue bank) agreement(s)
 - Specify criteria and timing for referral of individuals whose death is imminent or who have died in the hospital (must define “imminent death”)
 - OPO’s responsibility to determine medical suitability for organ donation (and, absent alternative arrangements made by hospital, tissue and eye donation)
 - Ensure the family is notified of options (intent is clearly to enhance donation)
 - Provide for education of staff
 - Etc.

Common Rule (45 CFR part 46)

- Prospective collection of identifiable biospecimens generally requires:
 - Prospective IRB approval of proposed research plan
 - Written informed consent from each prospective participant

- Exceptions
 - Research that does not involve “human subjects”
 - Deidentified biospecimens originally collected for another purpose
 - Biospecimens of decedents
 - Research involving collection of existing biospecimens or data that are not directly or indirectly linked to individuals



IRB Approval

- Risks to participants are minimized
- Risks are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result
- Equitable selection of participants
- Informed consent (or waiver), appropriately documented
- Data monitoring for participant safety (if appropriate)
- Participant privacy and confidentiality are adequately addressed
- Additional safeguards to protect the rights and welfare of vulnerable participants

Informed Consent

- Must be secured in advance of participation – absent waiver granted by IRB upon finding:
 - Minimal risk to participants
 - Waiver/alteration won't adversely affect rights of participants
 - Research would otherwise be impracticable
 - Whenever appropriate, participants will be provided with additional pertinent information after participation
- Special rules for research involving children:
 - If minimal risk, at least one parent generally must sign
 - Investigators should seek and obtain re-consent when child reaches majority (unless waived)

(More on) Informed Consent

Who is Authorized to Make a Gift or Consent to Participate?

- Donor/Participant (Subject)
 - Competent adults
 - Others who are not “children”
 - Emancipated minor
 - For UAGA – anyone of age to apply for a driver’s license
 - Common Rule – anyone who can consent to the procedures being performed in the research
- Surrogate
 - For decedents
 - Order of authority is specified in UAGA; patient advocates have first preference
 - Special rules provided in case of disputes
 - Drafters intended donor’s wishes to control, not surrogates post-mortem
 - For living individuals
 - Legally authorized representative (determined by reference to state law)

Who is Authorized to Receive an Anatomical Gift?

- The following as specified by the donor:
 - Hospital; accredited medical school, dental school, college, or university; organ procurement organization; or other appropriate person, for research or education
 - An individual designated by the person making the anatomical gift if the individual is the recipient of the part
 - If not suitable, then gift generally passes to OPO unless otherwise designated by the donor
 - An eye bank or tissue bank
- The following if purpose but not recipient is specified by the donor:
 - Eyes for transplantation or therapy -> eye bank
 - Tissue for transplantation or therapy -> tissue bank
 - Organ for the transplantation or therapy -> OPO
 - Any part for research or education -> OPO

Purpose(s) of Gift/Donation or Research



- Decedents
 - Generally:
 - Transplantation and therapy or research and education or both
 - Special Rules:
 - If multiple purposes are specified without priority, the gift must be used for transplantation or therapy (but if not suitable then research or education)
 - If no purpose is specified, the gift may be used only for transplantation or therapy via the appropriate bank or OPO [unless surrogates expand]
- Living individuals
 - As specified in the informed consent document
 - A specific clinical trial, or a correlative study
 - Any research on a specified condition (e.g., cancer, diabetes, Alzheimer's)
 - Deposit into a biorepository
 - If data annotations are included, HIPAA/HITECH rules apply

Consent Process

- Decedents
 - Living individual may make a gift (or refuse)
 - Surrogates cannot generally reverse or amend ... but if surrogates donate:
 - Any reasonably available member of a prior class can amend or revoke orally or in writing before incision is made/invasive procedures are started
- Living Individuals (Research Participants/Subjects)
 - Common Rule/FDA Regulations govern requirements for informed consent
 - HIPAA (as amended by HITECH and GINA) governs requirements for authorization – new regulations are in development for HITECH and GINA is budgeted for FY 2010
 - State laws vary



	Common Rule/FDA	HIPAA/HITECH
Purpose	Statement that the study involves research, explanation of the purposes	Description of purpose(s) of any use or disclosure of PHI
Procedures	Description of procedures (identifying any that are experimental) and expected duration of subject's participation	Description of information to be used or disclosed; who may release PHI for the research and who may receive it
Risks	Description of any reasonably foreseeable risks or discomforts resulting from the research; statement (if applicable) the research may involve unknown risks	Statement that once disclosed, information may no longer be protected by HIPAA
Benefits	Description of any potential benefits reasonably expected from the research	n/a
Alternatives	Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to subjects	n/a
Confidentiality	Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (FDA requires explicit reference to FDA)	n/a [But patients also receive a "Notice of Privacy Practices" from their health care providers at first encounter.]
Compensation	For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available in the event of injury	[HITECH bars sale of ePHI for research unless the price charged reflects the costs of and preparation and transmittal of the data for that purpose.]
Voluntary	Statement re: voluntary nature of participation	Description of requestor's ability or not to condition treatment, etc. on granting of authorization (treatment generally may be conditioned in clinical trials)
Termination	<ul style="list-style-type: none"> Anticipated circumstances where subject's participation may be terminated without subject's agreement Consequences of subject's decision to withdraw and description of procedures for orderly termination of participation 	<ul style="list-style-type: none"> Description of person's right to revoke authorization and any limits (as permitted by HIPAA) Expiration date or event (may be "end of the study" or "none" for research)
Additional Costs	Any additional costs to the subject that may result from participation	n/a
Miscellaneous	<ul style="list-style-type: none"> Statement re: additional information to be provided in case of significant new findings Approximate number of subjects involved Contact information for questions Signature/date of subject or subject's LAR 	<ul style="list-style-type: none"> Minimum necessary rules apply absent express authorization (generally LDS) Form must be written in plain language understandable to subject Signature/date of subject or subject's LAR (and LAR's relationship to subject)

https://cabig-kc.nci.nih.gov/DSIC/uploaded_files/c/c1/HIPAA%26BCR%26FDA-Auth%26Consent.doc

Consent Documentation: UAGA

DONOR CARD

I wish to donate my organs, eyes, and tissue. I give:

___ Any needed organs, eyes, and tissue.

___ ONLY the following organs, eyes, and tissue: _____

Date: _____ Donor's Signature: _____

Consent Documentation: UAGA (Continued)

DONOR CARD

I wish to donate my organs, eyes, and tissue. I wish to give (complete either Section A, B, or C):

<u>Subject of Gift</u>	<u>Purpose of Gift</u>					
	<i>Transplantation or Therapy</i>		<i>Research or Education</i>		<i>Both</i>	
<i>Section A:</i>						
<i>ALL of my organs, eyes, and tissue</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Section B:</i>						
<i>My Organs</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>My Eyes</i>						
<i>My Tissue</i>						
<i>Section C</i>						
<i>Special Instructions (If none of the above apply,) I wish to give only:</i>						

Date: _____ Donor's Signature: _____

Consent Documentation: UAGA (Continued)

DONOR CARD

I give, upon my death, the following gifts for the purpose of (*choose whichever applies*): only transplantation and therapy, only research and education, transplantation, therapy, research, or education.

For the purposes specified above, I give:

ALL needed organs, tissues, and eyes; or

(*If you checked the box immediately above, you should not check specific boxes below*).

Organs Tissues Eyes

If none of the above applies, I wish to give ONLY:

The following organs and tissues: _____

Date: _____ Donor's Signature: _____

Informed Consent Challenges

- Process
 - Avoidance of “human subjects research” designation
 - Legally: no consent required (but possibly still authorization)
 - Ethically: consent still may be required (e.g., dbGaP)
 - Appropriateness of waivers
- How much information is too much
 - Are lengthy descriptions and explanations appropriate
 - Description of biorepository governance policies
 - Does separation of “form” from “brochure” help
- Nature of risk discussion
 - No biospecimen research is risk-free
 - Likelihood of reidentification
 - Risk of stigmatization, discrimination, or similar harms associated with potential misuse of data
- Recontact considerations
 - Required for new research?
 - Can participants opt out?

In Essence

- Donors or participants must be given sufficient information to:
 - Understand the purpose of the research (‘contribution to a biobank’ may be sufficiently narrow)
 - Understand what will happen to them (and to contributed biospecimens and data) in connection with the research
 - Understand their options
 - Be able to knowledgeably evaluate the risks, potential benefits, and alternatives (and their risks-?) to participation
 - Risks may be physical or not (e.g., privacy/confidentiality, legal, reputational, etc.)
 - Benefits to themselves or more generally
 - Make a voluntary and uncoerced choice to participate or to decline without penalty
 - Common Rule and HIPAA also provide a right to withdraw
 - Both subject to some restriction



Tissue Banking for Research: Policy and Governance Considerations

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Governance and Policies Generally

- Transparency
- Extent of external influence
 - Interested/independent scientific advisory/review board
 - Interested/independent consumer/participant advisory board
- Provenance
 - Acceptable/unacceptable specimens and data
 - Informed consent/authorization requirements
- Future use/storage
 - Approval mechanisms (IRB, SAB, etc.)
 - Opportunity to re-consent (at defined intervals, at majority, for individual projects, etc.)
 - Right to withdraw consent

Custodianship

- Who is the custodian
 - If not a disinterested third party, how are conflicts of interest resolved
- What is their authority/accountability
 - Who does it derive from
 - Who are they accountable to
- What are their obligations
 - Choose winners/losers?
 - What is relationship to SAB/community?
 - Any appeals process?
 - Stewardship of funds to support biospecimen resource (cost recovery)
 - Arrangements for appropriate disposition if biospecimen resource shuts down

Management

- How centralized
 - Single institutional resource with centralized decisionmaking
 - Centralized physical resource with decentralized decisionmaking
 - Multiple resources with common policies
 - Multiple resources with no common policies
- Physical integrity of specimens
 - Conditions of collection
 - Conditions of storage
 - Conditions of transmission
- Integrity of data
 - Physical, technical, administrative safeguards
- Policy development, review, approval, implementation, enforcement
 - Ethics review of provenance policies
 - Pathology review of storage policies
 - Privacy/security official review and approval of data policies
 - Role of legal review

Intellectual Property/Data Sharing

- Inventorship
 - Custodian (what is contribution)
 - Researchers
 - Others
- Licensing
 - Retain rights for future use for government/non-profit research, educational activities?
- Reach-through rights
 - Benefitting whom?
- Other data sharing considerations
 - Applicability of NIH, local institutional policies?



Practical Tips for Compliance and Oversight

Practical Tips for Compliance

- Survey laws, regulations applicable to collection and subsequent use of biospecimens for research
 - Consider all potential sources
 - Specimens previously collected under standards that are not state-of-the-art
 - Excess clinical specimens
 - Donated specimens – anatomical gifts; research
 - “Standard” HRPP regulations and standards
 - Common Rule/FDA/AAHRPP
 - State Laws (including UAGA as adopted locally)
 - Special considerations
 - Stem cell research
- Develop and implement policies that address at least the items described above
- Educate, monitor, enforce

Useful Links

- **UAGA:** <http://www.anatomicalgiftact.org>
- **OHRP/General Information:** <http://www.hhs.gov/ohrp>
 - Regulations: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
 - Guidance: <http://www.hhs.gov/ohrp/policy/index.html>
- **HIPAA/HITECH:** <http://www.hhs.gov/ocr>
 - Generally: <http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html>
 - Research: <http://privacyruleandresearch.nih.gov>
- **OBRR:** <http://biospecimens.cancer.gov>
 - Best Practices:
http://biospecimens.cancer.gov/global/pdfs/NCI_Best_Practices_060507.pdf
 - Revisions in Progress and Comments: <https://cabig-kc.nci.nih.gov/DSIC/forums/viewtopic.php?f=20&t=57&sid=fa9154c768af8b5adcf27ee4a007bd30>
- **caBIG Data Sharing & Intellectual Capital Knowledge Center:**
<https://cabig-kc.nci.nih.gov/DSIC/KC>



Questions?

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