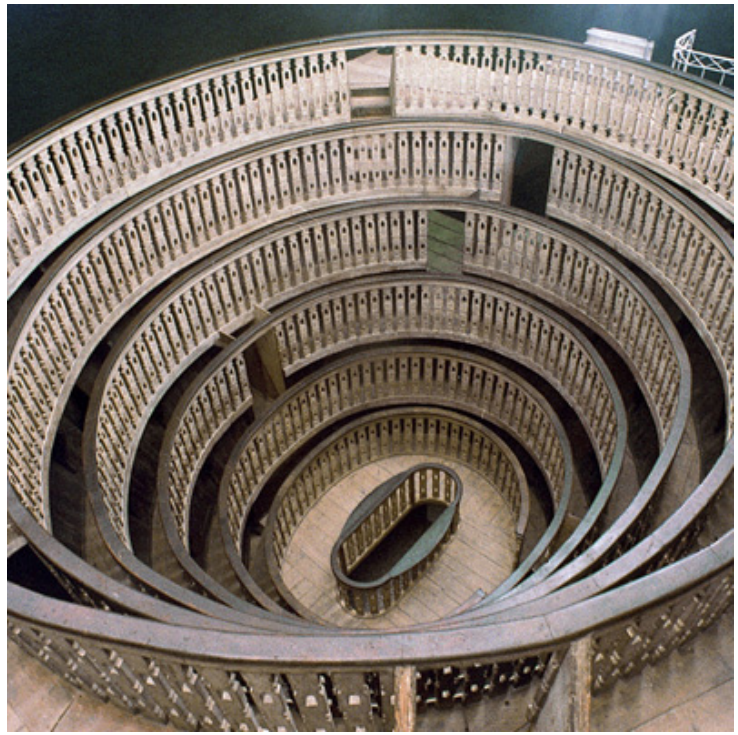
Modalità internazionale di utilizzo dei tessuti per ricerca



diego.ponzin@fbov.it

Fondazione Banca degli Occhi, Venezia

UNI EN ISO 9001:2000
CERTIQUALITY
SISTEMA DI GESTIONE QUALITÀ CERTIFICATO

CENTRO NAZIONALE TRAPIANTI

Agence française de sécurité sanitaire des produits de santé

2002-2008

EYE BANK ASSOCIATION of AMERICA

IV corso di formazione - Società Italiana Banche degli Occhi

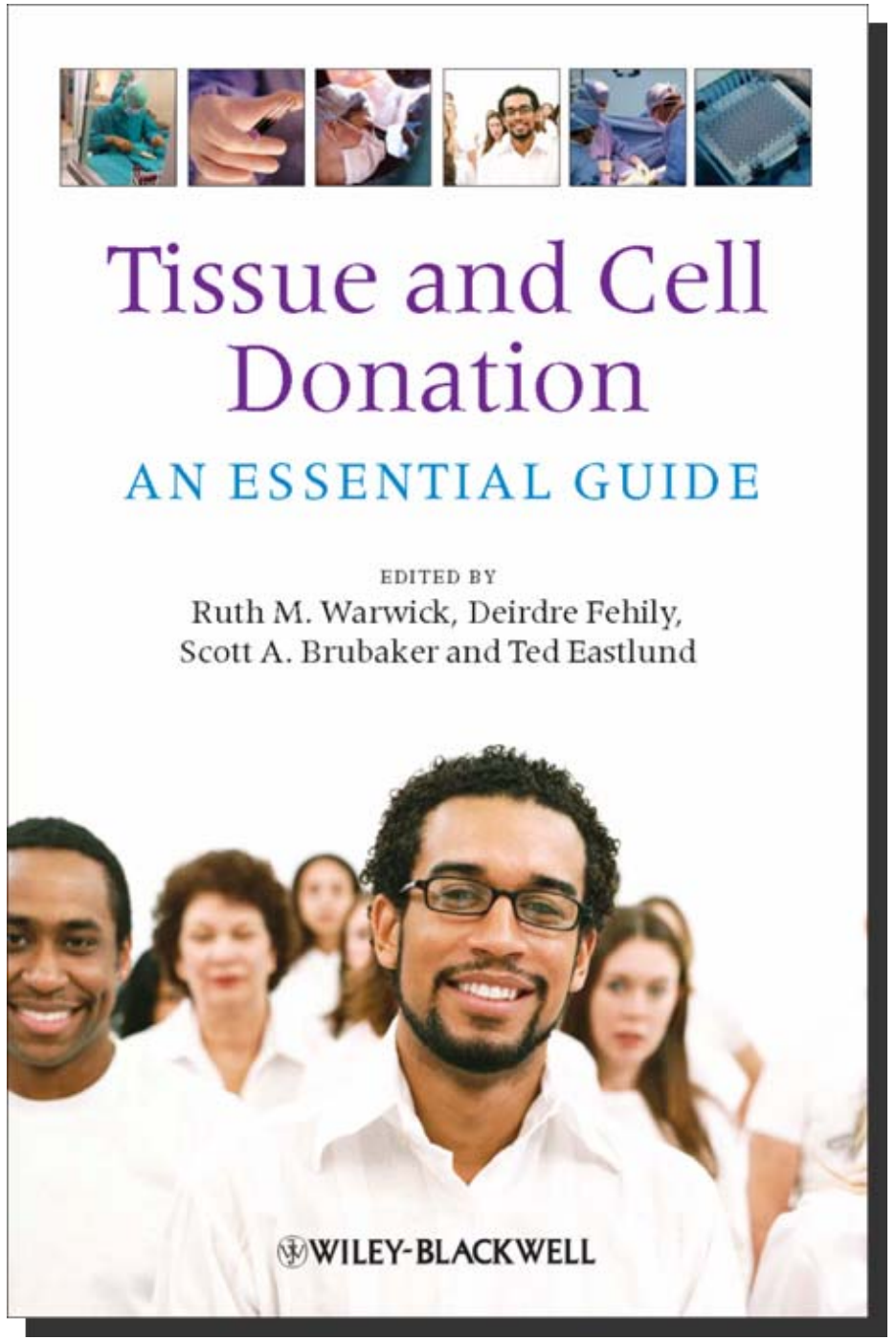
Torino, 10 ottobre 2009

Donation for research

- A relatively new donation option in many parts of the world, including the US
- May occur:

✓in conjunction with donation for transplant

✓or the patient's entire body may be donated



ISBN: 9781405163224, April 2009

www.wiley.com

Donarsi alla scienza

- Regione Veneto
- Università degli studi di Padova
- Proposta al Senato n 899, 10 luglio 2008

✓R Decreto 31 agosto 1933, n 1592, GU 283, suppl ord 7 dicembre 1933): Approvazione del testo unico delle leggi sull'istruzione superiore (art. 32, no parenti fino al 6° grado)

✓DPR 10 settembre 1990, n 285: Approvazione del regolamento di polizia mortuaria (capo VI, rilascio di cadaveri a scopo di studio)

✓Legge 30 Marzo 2001, n 130: Disposizioni in materia di cremazione e dispersione delle ceneri, GU 91, 19 aprile 2001

Donarsi alla scienza

- Atto di donazione redatto in vita
- I famigliari negano la volontà di provvedere a trasporto e seppellimento sulla base della volontà espressa dall'interessato

Codice Penale, Titolo IV, Capo II: Dei delitti contro la pieta' dei defunti, Art. 413, Uso illegittimo di cadavere:

✓Chiunque disseziona o altrimenti adopera un cadavere, o una parte di esso, a scopi scientifici o didattici, in casi non consentiti dalla legge, è punito con la reclusione fino a sei mesi o con la multa fino a lire un milione. La pena e' aumentata se il fatto e' commesso su un cadavere, o su una parte di esso, che il colpevole sappia essere stato da altrui mutilato, occultato o sottratto

Donation for research

- Education of medical and nursing students
- Development of medical devices and instrumentation
- Training in surgical procedures
- Development of new therapeutic intervention

  - ✓Hospitals
  - ✓Academies
  - ✓Public research organization
  - ✓Private, not-for-profit organizations
  - ✓Commercial sector

Warwick RM, Fehily D, Brubaker SA, Eastlund T. Tissue and cell donation – An essential guide. ISBN: 9781405163224, April 2009

Directive 2004/23/EC: standards of quality and safety for donation, procurement, testing, processing, preservation, storage and distribution of human T & C

I programmi di applicazione di tessuti e cellule dovrebbero basarsi su:

- filosofia della donazione volontaria e gratuita
- anonimato del donatore e del ricevente
- altruismo del donatore
- solidarietà tra donatore e ricevente

Gli Stati membri sono invitati ad adottare misure per incoraggiare un forte contributo del settore pubblico e del settore non profit alla prestazione di servizi per l'applicazione di cellule e tessuti e al relativo impegno in termini di ricerca e sviluppo

Directive 2006/17/EC: technical requirements for the donation, procurement and testing of human T & C

Tra i dati che l'istituto dei tessuti deve registrare (tranne in caso di donatori di cellule riproduttive destinate alla donazione al partner) rientrano:

- l'assenso o autorizzazione, in particolare lo scopo per cui possono essere impiegati i tessuti e le cellule (ovvero uso terapeutico o uso di ricerca, oppure uso sia terapeutico che di ricerca)
- qualsiasi istruzione specifica relativa all'eliminazione se i tessuti o le cellule non sono utilizzati per lo scopo a cui erano destinati

Donation for research: UK

Cadaveric tissue supply to the commercial sector for research: collaboration between NHS pathology and NBS Tissue Services in the UK, extending the options for donors

Womack C, Gray NM, Pearson JE, Fehily D. *Cell and Tissue Banking* 2001; 2: 51-55

Ethical issues relating to supply of human tissue to the commercial biomedical sector

Womack C. *Cell and Tissue Banking* 2002; 3: 203-209

The Nuffield Council on Bioethics

- Fondazione, dal 1991, finanziata da Nuffield Foundation, Medical Research Council, Wellcome Trust
- Esamina e relaziona su problemi etici sorti dai recenti avanzamenti nella ricerca medica e biologica
- The Nuffield report. Human tissue: ethical and legal issues, April 1995:

The Nuffield report, April 1995

- Tissue removed during an operation may be used for research
- Alternatively a researcher may obtain tissue from a tissue bank or some other source
- The researcher may be a commercial enterprise
- Consent (as part of general consent to surgery) is recommended for use of anonymized left-over tissue
- Removal of tissue from the dead for ethically acceptable purposes may be regarded as lawful as long as consent has been obtained
- Human tissue research may take place at pharmaceutical or biotechnology companies
- Tissue to be used for research purposes should only be obtained form medical intermediates
- There is an onus on the researcher to ensure that any proposed uses of human tissue are ethically acceptable
- Ethics committee approval is not required where anonymised surplus surgically removed tissue is concerned, anonymised archived material is utilized, DNA is being extracted

Medical Research Council guidelines, 2001

- No commercial company should have exclusive rights to a supply of tissues
- The patient waives any rights to profits that may derive from use of his or her tissue
- A local Research Ethics Committee should approve all MRC funded research on human tissue

Donation for research: UK

Human Tissue Act 2004

HTA Code of Practice on consent

Relevant part: Schedule 1, p.37: sets out the purposes requiring consent

Part 1 — Removal, storage and use of human organs and other tissue for scheduled purposes

…where the specimen is to be used for the purpose of education, training or research

Human Tissue Authority's website (Competent Authority for the European Union Tissue and Cells Directives) www.hta.gov.uk

Donation for research: USA - EBAA

- more of an individual State donation consent law matter
- State & Federal consent laws
- inform & ask the next of kin at the time of consent, that if the tissue is unable to be used surgically if we can provide the tissue for research or training purposes
- more often than not, families do give consent for tissue to be used for research/training purposes if unable to be used surgically
- Families are informed, via letter, several weeks after the donation how the tissue was utilized, or not

Uniform Anatomical Gift Act, 2006

EBAA MEDICAL STANDARDS

A1.000 Introduction and Purpose

These standards have been developed to assure consistently acceptable levels of quality, proficiency, and ethics in dealing with eye tissue for transplantation and define the minimum standards of practice in the recovery, preservation, storage, and distribution of eye tissue for transplantation and research, as determined by the ophthalmological medical community.

A1.100 Scope

These standards are intended to apply to any and all aspects of eye banking, to include:

- Recovery of eye and corneal tissue
- Processing of tissue
- Storage of tissue
- Evaluation of tissue
- Determination of donor eligibility
- Distribution of tissue for transplant, research and teaching

C3.200 Equipment, Maintenance and Cleaning

Each eye bank laboratory shall have a refrigerator with a device, visible without opening the refrigerator, for recording temperature variations. The temperature recording device should reflect the temperature of the stored tissue under normal storage conditions. Temperature variations must be recorded daily and remain within the range of 2 to 8° Celsius. The refrigerator's continuous temperature recorder must be calibrated against an NIST standard thermometer (or for eye banks outside the U.S.A., a standard thermometer as defined by their countries' regulatory agencies) at least once a year. The refrigerator shall be maintained for the use of tissue and tissue storage media and must contain clearly defined and labeled areas for all tissue stored, i.e., quarantined tissue, surgical tissue awaiting distribution, and research tissue. Eye banks must detail required refrigerator cleaning intervals and documentation in their Policies and Procedures manual.

H1.000 **Non-Surgical Donor Tissue**

If donor tissue is provided for purposes other than surgery, e.g., research, practice surgery, etc., and if that donor tissue is not screened for HIV or Hepatitis, a label stating that screening for HIV-antibody, Hepatitis B or Hepatitis C has not been carried out or stating "potentially hazardous biologic material" or some other designation acceptable under the guidelines of the CDC must be attached to the container used for the donor tissue storage and/or transport.

L1.000 **Documentation to Accompany Donor Tissue**

L1.100 Tissue Report Form

For special research studies, by recommendation of the Medical Advisory Boar and approved by the EBAA Board of Directors, certain specific data may be masked on the tissue report form and label. A copy of the tissue report form and/or donor screening form shall accompany the tissue. The tissue report shall contain the following:

2008 Eye Banking Statistics Reported by U.S. Banks: Distribution of Tissues 77 U.S. Eye Banks Reporting

Distribution	2008	2007	2006	2005	2004
Corneal Grafts Total	52,487	50,122	45,035	48,298	51,544
Penetrating Keratoplasty	32,524	34,806	38,064	45,821	51,544
Anterior (Lamellar) Keratoplasty	1,072	950	806	869	-
Endothelial Keratoplasty	17,468	14,159	6,027	1,429	-
Keratolimbal Allograft	173	207	138	179	-
Tectonic	1,250	-	-	-	-
Sclera	5,374	4,698	4,018	3,886	5,323
Long-Term Preserved Corneas	989	-	-	-	-
Research	13,730	13,824	11,845	14,332	15,780
Training	5,385	4,801	4,858	5,477	4,852

Donation for research: Australia

EBAANZ
Eye Bank Association of Australia & New Zealand

For an eye donation consent to be informed, it should contain the following:

- Permission for removal of eye tissue either as whole eyes, or as corneas only (as applicable).
- Information as to the tissues which can potentially be used for transplantation, or research (as applicable)
- The purposes for which these tissues will potentially be utilized
- Information concerning the donation process e.g. location, timing, viewing of the body
- The requirement for blood testing of the donor to test for infectious diseases or tissue typing purposes

- The possible requirement for further medical information to be obtained, and permission for this e.g. from GP, specialist
- Information concerning potential unsuitability of tissue for transplant, and uses for which permission is given in these instances (research, clinical training, return of tissue, disposal)
- Permission for use of tissue for research, clinical training or education should be obtained as a separate explicit consent
- Information on follow-up options and notification of outcome
- That there shall be no cost to the donor and/or their family for any expenses relating to donation
- Information on possible use for cosmetic procedures or applications involving commercial gain (only if this is applicable to the tissue(s) being consented)
- Ability and time for person to ask questions and receive clear answers

Donation for research: conclusion

- Donors or next of kin should be able to veto uses of donated tissues for research, cosmetic, or educational purposes that are contrary to their personal reasons for donating
- Where research is offered as the primary purpose of the donation, the research and all associated protocols should have been reviewed by an independent ethical committee
- Consent and review is particularly important if:
  - ✓data links might compromise donor confidentiality
  - ✓research might lead to financial gain by third parties

Warwick RM, Fehily D, Brubaker SA, Eastlund T. Tissue and cell donation – An essential guide. ISBN: 9781405163224, April 2009

Donation for research: conclusion

- For research consent, any promotion of the potential benefits to others would be seen as unacceptable coercion, as there are actually unknown

Warwick RM, Fehily D, Brubaker SA, Eastlund T. Tissue and cell donation – An essential guide. ISBN: 9781405163224, April 2009

Tissue banks and procurement agencies, and the professionals who work within them, are ***the guardians of the altruistic gifts*** *that donors and their families have entrusted to them for the benefit of others, to save and improve lives*

Warwick R, 2009

VENERDÌ 23 OTTOBRE

Auditorium Ore 11.00 -13.00
Innovazione in oncologia: terapie, tecnologie, farmaci, costi sanitari e finanziamento alla ricerca
Convegno istituzionale, moderato da **Mario Pappagallo**, Corriere Salute
Lecture: **Francesco Schittulli**, Presidente Lega Italiana per la Lotta contro i Tumori - **Francesco Boccardo**, Presidente AIOM (Associazione Italiana di Oncologia) (invitato)
Sponsor istituzionale: **FONDAZIONE ZOE - ZAMBON OPEN EDUCATION**

Aula A Ore 9.00 - 11.00 **2 punti ECM**
L'occhio e le applicazioni cliniche e tecnologiche innovative
Workshop di approfondimento, coordinato da **Alessandro Galan** Primario Oculista U.O. Complessa Ospedale Sant'Antonio ULSS 16 di Padova

Aula A Ore 11.00 - 13.00 **2 punti ECM**
Quattro sfide critiche nell'ambito di donazione e trapianto. Il caso di Fondazione Banca degli Occhi
Workshop di approfondimento a cura della **FONDAZIONE BANCA DEGLI OCCHI DEL VENETO**

Aula B Ore 9.00 - 13.00 **3 punti ECM**
Modelli di risk management per contrastare l'inefficienza sistemica
Workshop di approfondimento, coordinato da **Walter Pitscheider**, Primario della Divisione di Cardiologia dell'Azienda Sanitaria di Bolzano e Professore di Malattie dell'Apparato Cardiovascolare, Università di Verona
In collaborazione con **NOEMALIFE**

Aula E Ore 10.00 - 14.00 **2 punti ECM**
Health Technology Assessment (HTA): una sfida per il sistema sanitario italiano
Workshop di approfondimento, coordinato da **Carlo Favaretti**, Presidente **SIHTA** - Società Italiana HTA e Direttore generale Azienda Ospedaliero - Universitaria Santa Maria della Misericordia di Udine

Aula F Ore 9.00 - 12.30
Chi ha incastrato il Fascicolo Sanitario Elettronico?
Workshop di approfondimento a cura di **Claudio Saccavini**, Direttore tecnico di **ARSENÀL.IT** - Centro Veneto Ricerca e Innovazione per la Sanità Digitale
In collaborazione con **EXPRIVIA**

MODERATORE: *G Rupolo*, Coordinatore Regionale Trapianti

D Ponzin: Donazione, trapianto e medicina rigenerativa: possibilità, domande e soluzioni nell'esperienza di Fondazione

D Rodriguez: La sfida etica: la donazione di organi e tessuti come necessità, problema privato o risorsa pubblica? Implicazioni e prospettive di un "gesto di libertà"

A Nanni Costa: La sfida tecnica: il futuro tra disponibilità, nuove metodologie e prospettive cliniche nel trapianto di organi e tessuti

E Cozzi: La sfida della ricerca: organi artificiali, xenotrapianti, potenzialità delle cellule rigenerate e modificate. Quali direzioni per la ricerca?

*G Ruscitt*i: La sfida dei costi: come individuare le priorità? Saper scegliere, saper distribuire, saper finanziare