



UNIVERSITY
OF TRENTO - Italy

Faculty of Law
Department of Legal Sciences

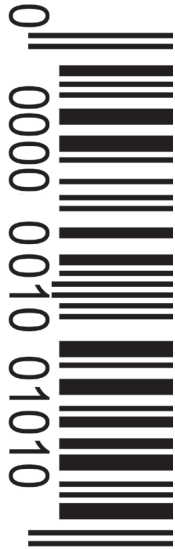
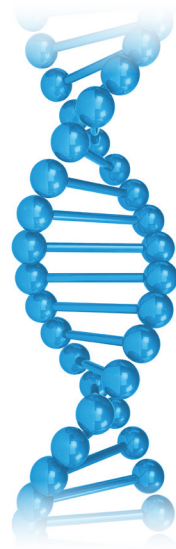
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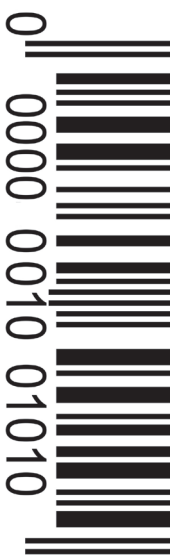
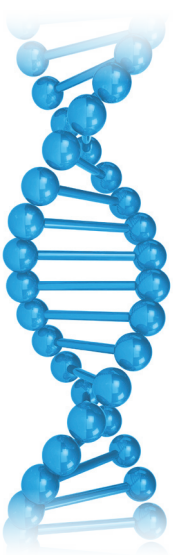
The Law and Technology Research Group
www.lawtech.jus.unitn.it

**INTERNATIONAL
CONFERENCE**

**COMPARATIVE
ISSUES IN THE
GOVERNANCE
OF RESEARCH
BIOBANKS:
PROPERTY,
PRIVACY,
INTELLECTUAL
PROPERTY,
AND THE ROLE
OF TECHNOLOGY**

**Trento, Faculty of Law
May 7-8, 2010**





Research biobanks today are proliferating in big research centers and secondary hospitals serving peripheral areas. Alongside this development, huge population biobanks - where biological materials of entire communities are gathered, catalogued and studied - are being established in a growing number of countries all over the world. Private companies offering biobanking services are emerging as flourishing new businesses. Just recently, the Report on a “National Cancer Plan 2010/2012”, issued by the Italian Ministry of Health in January 2010, stresses the role that a network of Italian biobanks will play in developing a national strategy for cancer research.

The biobanking boom of recent years has prompted a lively debate on a host of interrelated legal issues: 1) the Gordian knot of the ownership of biological materials; 2) the privacy concerns raised by the difficulty of accepting that biological samples must be completely anonymous without incurring the practical impossibility of exploiting their information potential, since biological and genetic data retain such potential only if they can be traced to the evolving clinical history of the original donor; 3) the delicate role and the changing content of the donor’s “informed consent”, as the main legal tool which may serve to link the privacy and property interests of the donor with the research interests and the set of principles that should inform the functioning of the biobank; 4) the IP issues and the patentability of biological samples and the protection of databases storing genetic information obtained from the samples. Responding to these problems will be crucial for pursuing the optimal allocation of the benefits that can be obtained by exploiting the scientific research carried out on the biological samples stored in biobanks.

The conference on “Comparative Issues in the Governance of Research Biobanks: Property, Privacy, Intellectual Property and the Role of Technology” is aimed at exploring, from a comparative viewpoint, the extent to which digital technology may assist in tackling the many regulatory issues raised by the practice of biobanking for research purposes, issues which may be considered and analyzed under the traditional paradigms of Property, Privacy, Informed Consent and Intellectual Property (Patents). These different theoretical legal facets of biobanking activity are strictly interconnected and must be analyzed taking such interconnection into consideration. A holistic consideration of the issues involved in research biobanking appears to be the only way in which an optimal regulatory governance of biobanking activity can be successfully pursued. This perspective highlights the importance of digital technology as the element capable of providing the infrastructure that may help to coordinate the different interests involved in biobanking activity, at the same time (1) enabling the infrastructure in itself to implement the regulatory standards and (2) providing an environment where the self determination of the donors can find its real expression without incurring transaction costs which may be impossible to sustain.

Friday May 7, 2010

8:30 Registration

8:50 Welcome greetings

Davide Bassi - Rector of the University of Trento

Gianni Santucci - Director of the Department of Legal Sciences

Giuseppe Bernardi - President "Fondazione prof. Alessio Pezcoller - Trento"

9:15-10:00

OPENING SESSION: INTRODUCING THE ISSUES

Giovanni Pascuzzi, University of Trento

A Law & Technology Approach to the Law of Biobanking

Umberto Izzo, University of Trento

The Role of Technology in Answering to the Regulatory Needs of Research Biobanking: General Remarks and Interests at Stake

Mattia Barbareschi, Trentino Biobank - APSS di Trento

The Reality of Biobanking Regulation from a Biobanker's Perspective: Scientific and Managerial Premises and Unresolved Issues

FIRST SESSION: PROPERTY, PRIVACY & INFORMED CONSENT

Chairman: Roberto Pardolesi, Luiss University, Rome

10:00-11:15

FIRST SUB SESSION

Gideon Parchomovsky, University of Pennsylvania

Properties of Biobanks

Stephen Munzer, UCLA School of Law

Privacy and Ownership: Research Biobanks Meet Synthetic Biology

Roger Brownsword, King's College - London

Regulating Biobanks: Another Triple Bottom Line

11:15-11:30 Coffee Break

11:30-12:45

SECOND SUB SESSION

Jane Kaye, University of Oxford

Protecting Privacy in the World of Global Biobanking

Eric Feldman, University of Pennsylvania

The Genetic Information Nondiscrimination Act: A Solution in Search of a Problem?

Francesco Pizzetti, President of the Italian Data Protection Authority

Personal Health Data and Research Biobanking:

The Italian Data Protection Authority View



12:50-14:10 Lunch

14:10-16:20

THIRD SUB SESSION

Mariachiara Tallacchini, Cattolica University of Piacenza

Human Tissues in the 'Public Space': Beyond the Property/Privacy Dichotomy

Amedeo Santosuosso, University of Pavia

Should Privacy Be Abolished in Biobanking?

Andrea Rossato, University of Trento

Digital Architectures and the Regulation of Research Biobanks

Paolo Guarda, University of Trento

Biobanks as Electronic Gatekeepers of Personal Health Data: Open Issues

Matteo Macilotti, University of Trento

Reshaping Informed Consent in the Biobank Context

Question time for the entire session and preliminary conclusions

16:20-16:35 Tea break

SECOND SESSION:

MEDICAL AND TECHNOLOGICAL PERSPECTIVES

16:35-17:55

FIRST SUB SESSION

Chairman: **Giorgio Stanta**, University of Trieste

Giuliano D'Agnolo, Vice-President, National Committee for Biosafety - Rome

with the collaboration of **Elena Bravo**, Istituto Superiore di Sanità

The Italian Prototype Networks of Research Biobanks

Georges Dagher, Director for clinical research infrastructures at the French national health and medical research institute (INSERM - Paris)

The Biobanking and Biomolecular Resources Research Infrastructure (BBMRI):

Coordination of European Tissues Banks

Manfred Dietel, Charité - Universitätsmedizin Berlin

Surgical Pathology Archives: Invaluable Historical Collections for Cancer Research

Giorgio Inghirami, University of Turin

Biospecimen Collection, Storage and Quality Assurance.

Do We Need an European Standard?

20:00 Dinner

Saturday May 8, 2010

8:00-9:45

SECOND SUB SESSION

Special Panel organized with the scientific collaboration of SIAPEC (Italian Society of Anatomical Pathology and Diagnostic Cytopathology) & Istituto Superiore di Oncologia

Chairman: **Gianluigi Taddei**, University of Firenze; **Paolo della Palma**, APSS - Trento

Oscar Nappi, Cardarelli Hospital - Napoli

Biobanks and the Italian Society of Surgical Pathology

Mattia Barbareschi, Trentino Biobank, APSS - Trento

Surgical Pathology: A Powerful Source of Well Annotated

Human Tissues for Cancer Research

Giorgio Stanta, University of Trieste

An Italian Network of Archival Tissues Biobanks

Mauro Truini, National Institute for Cancer Research - Genova

Governance of Biobanks for Cancer Research:

Proposal for a Material Transfer Agreement

Discussants:

Enzo Galligioni, APSS - Trento; **Guido Grandi**, Novartis Milano; **Marco Pierotti**,

Cancer Institute - Milano; **Alessandro Quattrone**, University of Trento.

9:45-10:00 Coffee Break

10:00-12:50

THIRD SESSION: BIOBANKS, INTELLECTUAL PROPERTY, AND DIGITAL TECHNOLOGY

Chairman: **Gideon Parchomovsky**; **Giovanni Pascuzzi**

Roberto Caso, University of Trento

Control over Biobanks' Information: A Law and Technology Approach

Donna Gitter, Baruch College - New York City

The Challenges of Achieving Open Source Sharing of Biobank Data

Thomas Margoni, University of Western Ontario / **Matteo Macilotti**, University of Trento

The Role of Material Transfer Agreements in Biobanking

Richard Gold, McGill University - Montreal

Beyond Open Source: Patents, Biobanks and Sharing

Mark Perry, University of Western Ontario

Accessing Biobanks and Benefit-Sharing

12:15 Plenary discussion

12:40 Conclusions

12:50 End of the conference

INFORMATION ABOUT THE CONFERENCE

WORKING LANGUAGES

English and Italian - Simultaneous translation from and to the working languages of the conference will be provided.

DEADLINE FOR REGISTERING ONLINE TO THE CONFERENCE

<http://events.unitn.it/en/biobanks>

April 27, 2010

VENUE

ROOM B - Faculty of Law
University of Trento
via Verdi 53, Trento - ITALY

ORGANIZATION, SPONSORSHIPS, CREDITS

The event is promoted by the LawTech Research Group of the Department of Legal Science of Trento, acting as Local Research Unit of the FIRB National Research Project "Genetic Tests and Biobanks: Bioethical Issues in Law and Society" (2008-2011), a multicentric research project carried on by the Universities of Trento, Bologna, Milano Bicocca, and Pisa and funded by the Italian Ministry of Education, University and Research.

Additional financial support for the conference is gratefully acknowledged from the following sponsors:

- Fondazione Pezcoller Trento
- Fondazione Cassa di Risparmio di Trento e Rovereto

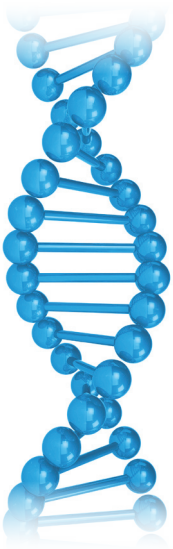
The following institutions have granted their **special patronage** to the conference:

- Azienda Provinciale per i Servizi Sanitari Trento
- ISS (Istituto Superiore di Sanità) Rome
- SIAPEC, Società Italiana di Anatomia Patologica e Citologia diagnostica
- LILT, Lega Italiana per la Lotta contro i Tumori
- Fondazione Trentina per la Ricerca sui Tumori

Attendance of the conference will be acknowledged as giving title to **professional credits** by the following professional organizations:

- Trento Bar Association
- Italian Notaries Association (accreditation procedure still pending)
- National Biologists Association (accreditation procedure still pending)





SCIENTIFIC AND ORGANIZING COMMITTEE

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