Biobanking e consenso informato: *perché, per chi e per cosa*

Paolo Rebulla

Centro di Medicina Trasfusionale, Terapia Cellulare e Criobiologia

Fondazione Ca' Granda Ospedale Maggiore Policlinico, Milano

Il consenso informato

o

l'informato consenso?

1. informazione
2. consenso

Nonostante tutti lo abbiamo pensato, la raccolta del consenso informato non è (solo) una formale e noiosa incombenza

Campioni anonimi = consenso 'soft'

Campioni con nome e cognome = consenso dettagliato

Uso locale e distruzione dei campioni al termine dello studio

Biobanking prospettico e uso internazionale

Caratteristiche del consenso informato

- Adeguatamente informato
- Dato volontariamente
- Dato da una persona con adeguata capacità di prendere la decisione

Perché

- Autonomia
- Giustizia
- Beneficenza
- Non maleficenza

Analisi concettuale

- Definizione di Capacità Decisionale
- Metodi per valutare la capacità decisionale
- Variabilità degli elementi del consenso informato

Behavioral Sciences and the Law
Behav. Sci. Law **24**: 553–568 (2006)
Published online 16 May 2006 in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/bsl.691

Enhancing the Informed Consent Process: A Conceptual Overview†

Lisa T. Eyler, Ph.D.,[1,2]*
and Dilip V. Jeste, M.D.[2,3]

Concern about limitations in the ability to give valid informed consent among certain groups of individuals has led to increased interest in defining, measuring, and enhancing consent-related decision-making. In this overview, we summarize issues related to the definition of decision-making capacity, discuss methods that have been used to assess decision-making abilities and other aspects of informed consent, and briefly describe studies that aim to understand variation in different elements of informed consent. We then review strategies that have been used with the intent of improving aspects of the informed consent process. Finally, we provide an outline of areas that are in need of future studies in order to reach the ultimate goal of preserving as much autonomy as possible in at-risk populations, while still achieving valuable research and treatment goals. Published in 2006 by

Behavioral Sciences and the Law
Behav. Sci. Law **24**: 535–546 (2006)
Published online in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/bsl.700

The Therapeutic Misconception and Our Models of Competency and Informed Consent

Charles W. Lidz, Ph.D.*

The doctrine of informed consent rests on empirical claims. This is true particularly of what commentators have characterized as the "strong" model of informed consent. This model assumes that if adequate information is given to a competent individual, understanding will result and, permitted to make a voluntary decision, the individual will make a rational decision. However, the "therapeutic misconception" posits that individuals may confuse the goals of research with those of treatment and may make decisions that do not rest on adequate understanding. This article reviews research suggesting that this

L'equivoco terapeutico

- La dottrina del consenso informato poggia su presupposti empirici
  - 'strong' model
  - se spiego bene, il paziente 'capisce'
- 'Therapeutic misconception': il paziente ritiene che l'obiettivo della ricerca coincida con l'obiettivo della terapia...

… other issues and problems …

Behavioral Sciences and the Law
Behav. Sci. Law 21: 121–133 (2003)
Published online 5 August 2002 in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/bsl.493

The Emerging Debate Over the Shape of Informed Consent: Can the Doctrine Bear the Weight?

John Petrila, J.D., LL.M.*

Informed consent has traditionally focused on treatment-related issues. However, since the mid-1990s, courts have debated whether informed consent should be stretched to accommodate other concerns. For example, some courts have considered whether economic limitations on treatment availability must be made known to a patient as part of the informed consent process. Other courts have considered whether characteristics of the treatment provider (e.g., experience with a particular procedure) should be disclosed as part of informed consent. Consideration of these issues turns in large part on whether the information in question would be considered "material" to a decision to accept or reject treatment. This article discusses these developments,

Elementi

- Tradizionale focus su ricerca e terapia
- Limitazioni economiche dell'applicabilità?
- Dichiarazione dell'esperienza del 'provider'?

Informed Consent for Pediatric Leukemia Research

Clinician Perspectives

Chris Simon, Ph.D.
Michelle Eder, M.A.
Pauline Ratz, B.S.
Stephen Zyzanski, Ph.D.
Rebecca Pentz, Ph.D.
Eric D. Kodish, M.D.

Rainbow Center for Pediatric Ethics, Department of Pediatrics, Rainbow Babies and Children's Hospital of University Hospitals of Cleveland, Cleveland, Ohio.

BACKGROUND. Good, fully informed consent is critical to the ethical conduct of clinical cancer research. The authors examined clinician perspectives on informed consent for pediatric research by surveying clinicians at five major medical centers that routinely enroll patients in Children's Cancer Group studies.

METHODS. Building on a pilot study, a questionnaire was designed to elicit clinicians' general opinions, approaches, and suggestions related to informed consent in pediatric leukemia trials. Questionnaires were mailed to 132 clinicians. Eighty-nine questionnaires were returned, along with 13 nonparticipant forms notifying us of the clinician's inability to participate because of a lack of experience in pediatric informed consent. The response rate was 75%.

RESULTS. Providing information so that families can decide about study entry was ranked as the most important goal of the informed consent process, whereas parents' state of shock was rated the most significant obstacle to good informed consent. Clinicians cited high levels of parental comprehension of key aspects of clinical research studies and reported information overload and increased anxiety as effects of the informed consent process on parents. Several key items were associated with clinicians' gender, race, and professional experience. Finally, one open-ended question yielded 126 suggestions for how to improve the informed consent process that were grouped into 10 meaningful categories.

Per cosa?

- Biobanking
- Ricerca

In this month's *The Lancet Oncology*, Hansson and colleagues,[1] contend that individuals do not need to give specific consent for future use of their biological samples for biobank research to be ethical. They do, however, reject the idea of blanket consent, in which individuals would consent to any type of future research with their samples. Instead, they propose a middle-ground of broad and future consent, which avoids researchers having complete freedom to do whatever they want with biobank samples, yet increases the number of samples likely to be available for future research compared with an approach that requires researchers to recontact individuals to obtain consent for every new study. The model of broad and future

KJ Maschke, The Lancet Oncology, 2006

Broadening consent—and diluting ethics?

B Hofmann

ABSTRACT

Biobank research is potentially fruitful. It is argued that broad consent is acceptable for future research on biological material because a) the benefit is high, b) it pays respect to people's autonomy, c) it is consistent with current practices and d) because the risk is low. Furthermore, broad consent should be allowed if information is handled safely, people can withdraw and expanded research should be approved by an ethics review board. However, these arguments are flawed and the criteria for broad consent are either too restrictive to allow any research or fail to address important challenges with biobank research. Broad consent for biobank research can hide substantial ethical challenges and threaten trust in research. This does not mean that biobank research should be abandoned or that people cannot authorise future research on donated biological material.

EMBO reports

viewpoint

Banking together

A unified model of informed consent for biobanking

Elena Salvaterra, Lucilla Lecchi, Silvia Giovanelli, Barbara Butti, Maria Teresa Bardella, Pier Alberto Bertazzi, Silvano Bosari, Guido Coggi, Domenico A. Coviello, Faustina Lalatta, Maurizio Moggio, Mario Nosotti, Alberto Zanella & Paolo Rebulla

During the past 10 years, human biological material—body fluids, cells, tissues, intracellular substances or DNA—and the related data have become an important resource for academic medical research, and for the industrial development of diagnostics and therapeutics (Godard Europe (COE; Strasbourg, France) described as the "increasing cross border flow of biological materials of human origin and data" (COE, 2006), and the interests of third parties, such as the pharmaceutical and biotechnology industries (Elger & Caplan, 2006; Anderlik, 2003).

The research tasks included: a comparative review of international, regional and national requirements for biobanking (Table 1)—laws, guidelines and ethical statements—to identify definitions of informed consent (Table 2); an analysis of articles about the ethical and legal aspects of biobanking research, which

Table 1 | Comparative review of international laws, guidelines and regulations on biobank-based research and consent requirements

Organization or country	Laws (L), guidelines (G) and regulations (R)	Informed consent requirements
World Health Organization	(G) Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells and Fluids in Research (2003) (G) Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services (1997)	Specific informed consent Partially restricted consent Broad consent
Council for International Organizations of Medical Sciences	(G) International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002)	Specific informed consent
United Nations Educational, Scientific and Cultural Organization	(G) International Declaration on Human Genetic Data (2003)	Partially restricted consent
Human Genome Organization	(G) Statement on DNA Sampling: Access and Control (1998)	Broad consent
Council of Europe	(L) Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (1997) (L) Treaty Series No. 195, Human Rights and Biomedicine. Protocol on Biomedical Research (2005) (G) Recommendation (2006) 4 on Research on Biological Materials of Human Origin (2006)	Specific informed consent
National Bioethics Advisory Commission	(G) Research Involving Human Biological Materials: Ethical Issues and Policy Guidance (1999)	Multi-layered consent
Australia	(G) National Statement on Ethical Conduct in Human Research (2007)	Specific informed consent Partially restricted consent Broad consent
Estonia	(L) Human Genes Research Act (2001)	Broad consent
France	(G) Ethical Issues Raised by Collections of Biological Materials and Associated Data: 'Biobanks', 'Biolibraries'—National Consultative Bioethics Committee for Health and Life Sciences (2003)	Specific informed consent
Germany	(G) Biobanks for Research—National Ethics Council Opinion (2004)	Broad consent
Italy	(G) Biobanks and Research on Human Biological Material—National Bioethics Committee Opinion (2006) (G) Guideline for Clinical Protocols of Genetic Research—Italian Society of Human Genetics (2006)	Partially restricted consent

Japan	(G) Ethical Guidelines for Analytical Research on the Human Genome/ Genes (2001)	Broad consent
Switzerland	(G) Biobanks: Obtainment, Preservation and Utilization of Human Biological Material (2006)	Broad consent Specific informed consent
Spain	(R) Royal Decree 411/1996, by which Activities Regarding the Use of Human Tissues are Regulated (1996)	Informed expressed consent
United Kingdom	(L) Human Tissue Act (2004) (G) Human Tissue and Biological Samples for Use in Research—Medical Research Council (2001)	Broad consent
The Netherlands	(L) Civil code, article 467 (1994) (G) Code for Proper Secondary Use of Human Tissue in The Netherlands (2002)	Informed expressed consent
Iceland	(L) Act on Biobanks No. 110 (2000)	Broad consent
Denmark	(L) Law on Biobanks No. 312 (2003)	Informed expressed consent
Sweden	(L) Law No. 297 (2005)	Specific informed consent
Norway	(L) Act on Biobanks (2003)	Informed expressed consent

Table 2 | Definition of informed consent models for biobank-based research according to the characterization used in international ethical and legal documents

Model of informed consent	Definition
Broad consent	Allows the use of biological specimens and related data in immediate research and in future investigations of any kind at any time
Partially restricted consent	Allows the use of biological specimens and related data in specific immediate research and in future investigations directly or indirectly associated with them
Multi-layered consent	Requires several options to be explained to the research subject in a detailed form
Specific informed consent	Allows the use of biological specimens and related data only in immediate research; forbids any future study that is not foreseen at the time of the original consent

Information letter

Dear Mr./Ms. [write name and surname]

If you agree, your samples collected during [diag
study] will be kept at the Italian Biobank, a public
the collection, storage, characterisation, use and
the university hospital "Fondazione IRCSS Ospe
Regina Elena".

Your samples will be used for the specific purpos
purposes of the specified study] and for all kinds
to those purposes [describe in general the field a

As these studies will be performed using sample
course of your treatment, for biopsy evaluation, e
risk associated with sample collection.

Your samples, and the data and information obta
research, will be treated confidentially and [speci
etc.].

The results obtained on the basis of the research
of scientific publications or teaching material, as
products from which you will receive no financial

You are free to withdraw from the studies at any
withdraw, you can ask for your samples and data
anonymous.

Consent form

In the light of the information that I have received, and having had the opportunity to ask questions that have been answered, I agree to participate in these research studies and consent to the following:

- The samples collected during [specify] may be kept at the Italian Biobank of the Fondazione Ospedale Maggiore Policlinico, Mangiagalli e Regina Elena ☐ YES ☐ NO
- The samples and associated data may be used for the specific purposes of this study [specify: area, type and purposes of the specified study] ☐ YES ☐ NO
- The samples and associated data may be used for all kinds of researches that, directly or indirectly, relate to the specific purposes of this study [describe in general field and type of associated secondary uses] ☐ YES ☐ NO
- The samples, data and study results may be used by researchers for scientific publications and for educational purposes ☐ YES ☐ NO
- The samples, data and study results may be used by researchers for the development of commercial products, without any financial benefit to myself ☐ YES ☐ NO

I declare:

- I have been informed of my right to withdraw my consent to the storage and/or use of samples and associated data at any time and without giving any reason ☐ YES ☐ NO
- I have been informed that I will be given information from the research team concerning the progress and general results of the research studies upon my explicit request. I have also been informed that they will not communicate any individual results to me. ☐ YES ☐ NO

Date _____ Time _____

The present consent form was collected by:

Name and surname of patient/donor _____

Name and surname of physician/researcher _____

Signature _____

Signature _____

Social Science & Medicine 70 (2010) 217–220

Contents lists available at ScienceDirect

Social Science & Medicine

journal homepage: www.elsevier.com/locate/socscimed

Short report

"Broad" consent, exceptions to consent and the question of using biological samples for research purposes different from the initial collection purpose

Carlo Petrini*

Bioethics Unit – Office of the President, Istituto Superiore di Sanità, Via Giano della Bella 34, 00162 Roma, Italy

ARTICLE INFO

Article history:
Available online 21 October 2009

Keywords:
Informed consent
Biobanks
Ethics
Research
Broad consent

ABSTRACT

An important ethical issue regarding biological samples stored in biobanks is unforeseen future sample use, when no or limited subject consent is obtained. Biobanks of biological samples have significant future research potential, but may cause conflicts of interest regarding the consent obtained. Indeed, ethics, deontology, and jurisprudence generally advise that consent must be specific and circumstantiated. However, it is not possible to foresee all of the future circumstances in which the samples might be useful, nor is it possible to re-contact all subjects in order to gain consent for a new use. The main arguments for the use of "broad" consent are presented with a brief discussion of the conditions where it may be legitimate not to obtain consent. Particular attention is given to the expressed positions of national and international bioethics bodies.

CONSENSO INFORMATO per la Raccolta, conservazione e utilizzo di materiali biologici umani per ricerca

Istituto/Ospedale/Fondazione _____
Unità Operativa scrivere il nome e il numero dell'UO se della Fondazione
Padiglione_____Piano_____ se della Fondazione
Dipartimento_____
Indirizzo: Via _____N._____ cap _____ Città_____
Telefoni: Segreteria_____, Reparto_____
Fax_____e-mail_____
Responsabile Unità Operativa Prof./Dr._____
Referente: Prof./Dr._____ Telefono_____e-mail_____

Gentile Signore/a,
durante scrivere la denominazione dell'atto clinico/il progetto di ricerca/studio/altro per il quale ha già prestato il Suo consenso, è utile conservare alcuni Suoi materiali biologici per compiere eventuali studi di ricerca/diagnostica/altro futuri che attualmente non è possibile delineare in modo preciso.
Questo documento ha lo scopo di affiancare il medico/personale sanitario nel fornirle un'informazione corretta e completa sulla raccolta, conservazione e utilizzo di tale materiale biologico e/o dei dati associati, affinché Lei possa esprimere una scelta libera e informata.
Questa informazione al consenso per la raccolta, conservazione e utilizzo di materiale biologico viene proposta a:

COGNOME_____NOME_____SESSO: M F
NATO/A IL_____A_____
dal Dr. COGNOME_____NOME_____
QUALIFICA_____

1. Motivazioni per cui viene proposto la raccolta, la conservazione e l'utilizzo del Suo materiale biologico:

Durante l'accertamento diagnostico/intervento chirurgico/il prelievo/la raccolta di cellule/altro per il quale ha già prestato il Suo consenso:

☐ avanzerà materiale biologico che è utile conservare in vista di studi futuri

☐ potrà essere prelevato materiale biologico in aggiunta a quello utilizzato per accertamento diagnostico/ studio/intervento/ricerca/altro che è utile conservare in vista di studi futuri. Il prelievo avverrà scrivere le modalità del prelievo e la quantità raccolta, le possibili conseguenze e i possibili rischi sono: scrivere le possibili conseguenze e i rischi

Tale materiale biologico potrà essere utilizzato per compiere indicare la natura degli studi, l'area di afferenza e le finalità secondo un rapporto di coerenza con la natura dell'atto clinico/progetto di ricerca/altro nel contesto del quale è raccolto il materiale biologico

Ha compreso le motivazioni per cui le si propone la procedura? ☐ SI ☐ Ho chiesto ulteriori chiarimenti

2. Informazioni sulla raccolta e conservazione dei Suoi materiali biologici

Dopo essere stato raccolto il Suo materiale biologico potrà essere conservato scrivere come e dove verrà conservato es. in azoto liquido, in congelatore a -80 °C, altro presso:

☐ questa UO/laboratorio/reparto/altro

☐ la Biobanca Italiana, una banca pubblica di materiali biologici che opera senza scopo di lucro e che ha sede presso la Fondazione IRCCS Ospedale Maggiore Policlinico, Mangiagalli e Regina Elena di Milano.

Per garantire il rispetto della riservatezza, nel rispetto delle normative vigenti, il Suo materiale biologico e i dati associati verranno utilizzati dai ricercatori e dal personale incaricato in forma riservata. Al materiale biologico verrà attribuito un codice. Il legame tra il codice e i Suoi dati anagrafici e sensibili verrà mantenuto dalla Biobanca Italiana, che pertanto potrà utilizzare tali dati.

La condivisione di dati tra ricercatori verrà effettuata in forma anonima scrivere la modalità di anonimizzazione proposta: codice, altro.

Nell'eventualità in cui dovesse decidere di ritirare il suo consenso agli studi che potrebbero essere compiuti in futuro, il Suo materiale biologico e i dati associati, se non già utilizzati, verranno distrutti. La decisione di ritirare il consenso dovrà essere da Lei comunicata in forma scritta al Direttore dell'Unità Operativa proponente la ricerca/studio/altro, che avrà la responsabilità di informare la Biobanca Italiana

Ha compreso le informazioni sulla procedura proposta? ☐ SI ☐ Ho chiesto ulteriori chiarimenti

3. Utilizzo delle informazioni acquisite dal compimento degli studi

Le informazioni acquisite dagli studi compiuti con il Suo materiale biologico e i dati associati potranno, sulla base del Suo consenso:

☐ essere condivise in forma anonima con altri ricercatori al fine di scrivere la finalità

☐ essere utilizzati, in forma anonima, in pubblicazioni scientifiche

☐ contribuire allo sviluppo di scrivere le potenzialità es. preparazione di farmaci, terapie, strumenti, altro. Gli eventuali proventi economici derivati dalla messa a punto di scrivere es. farmaci strumenti, altro possono essere utilizzati per il perseguimento di benefici collettivi. Essi non comportano compensi diretti per chi mette a disposizione il proprio materiale biologico. Comunque, l'utilizzo del materiale prelevato rispetterà i fini e le condizioni disposti dalle norme giuridiche italiane, con le ulteriori limitazioni da lei di seguito precisate con l'espressione del suo consenso.

Se lo desidera, potrà richiedere informazioni sui risultati confermati degli esami analitici compiuti durante lo svolgimento di tali studi e su eventuali nuovi risultati e/o possibilità diagnostiche/terapeutiche derivanti dal compimento di tali indagini.

Ha compreso i benefici attesi dalla procedura proposta? ☐ SI ☐ Ho chiesto ulteriori chiarimenti

4 Rischi derivabili dalla raccolta e/o dalla conservazione del Suo materiale biologico per gli studi proposti

La raccolta/il prelievo in aggiunta e/o la conservazione e/o l'utilizzo del Suo materiale biologico e dei dati associati:

- comporterà i seguenti rischi per la Sua salute [descrivere]
- non comporterà alcun rischio per la Sua salute

Ha compreso i rischi derivabili dalla procedura proposta? SI Ho chiesto ulteriori chiarimenti

5. Smaltimento del materiale biologico conservato

Il materiale biologico conservato presso la Biobanca Italiana può essere non più disponibile perché:

5.1 completamente utilizzato,

5.2 il contenitore (provetta o sacca) nel quale è contenuto risulta irrimediabilmente danneggiato,

5.3 il Responsabile dell'UO che ha richiesto la conservazione presso la Biobanca Italiana ha dato disposizioni alla Biobanca Italiana di eliminare il materiale biologico, o ha disposto la conservazione presso un altro Ente.

Ha compreso in quali casi il materiale biologico può non essere più disponibile? SI Ho chiesto ulteriori chiarimenti

DICHIARAZIONE DI CHI HA RACCOLTO IL CONSENSO

Io sottoscritto/a dichiaro di aver informato il paziente sulla raccolta, la conservazione e l'utilizzo che potrebbe essere fatto in futuro del suo materiale biologico e dei dati ad esso associati in modo chiaro, con linguaggio semplice, assicurandomi della sua comprensione, di aver risposto ad ogni domanda e di prendere atto della sua libera decisione di seguito espressa.

Data ...../...../..... Firma _____

Cognome Nome _____ Qualifica _____

FIRMA INFORMATIVA

Io sottoscritto/a dichiaro di aver ricevuto le informazioni che mi hanno permesso di comprendere la raccolta, la conservazione e l'utilizzo che potrebbe essere fatto in futuro del mio materiale biologico e dei dati ad essi associati, anche alla luce degli ulteriori chiarimenti da me richiesti.

Data ...../...../..... Firma del paziente. _____

Cognome Nome _____

ESPRESSIONE DEL CONSENSO

Le viene qui richiesto di dichiarare o di rifiutare il suo consenso alla raccolta/prelievo/aggiunta/altro conservazione e utilizzo dei Suoi materiali biologici e dei dati associati per il compimento di eventuali studi di ricerca futuri.

In ogni caso Lei potrà comunque, in qualsiasi momento successivo, ritirare il consenso precedentemente espresso e richiedere la distruzione irreversibile del Suo materiale biologico e dei dati associati.

ACCONSENTO che:

- Sia prelevata una parte di materiale biologico in aggiunta a quello necessario per il compimento dell'atto clinico/progetto di ricerca
  SI NO
- Il materiale biologico raccolto/prelevato in aggiunta durante scrivere intervento/prelievo/altro come scritto nell'informativa e i dati associati siano conservati presso l'U.O./l'Istituto e presso la Biobanca Italiana della Fondazione Ospedale Maggiore Policlinico, Mangiagalli e Regina Elena
  SI NO
- Il materiale biologico e i dati ad essi associati siano utilizzati per eventuali studi di ricerca futuri di carattere scrivere quanto descritto nell'informativa riguardanti scrivere quanto descritto nell'informativa e finalizzati a scrivere quanto descritto nell'informativa
  SI NO
- I dati anagrafici e sensibili siano gestiti dall'UO e dalla Biobanca Italiana, nel rispetto della legge sulla privacy e che venga mantenuto il legame con il codice attribuito al materiale biologico
  SI NO
- Il materiale biologico e i dati associati siano condivisi in forma anonima con altri ricercatori per precisare la motivazione
  SI NO
- Il materiale biologico e i dati associati siano utilizzati in forma anonima per pubblicazioni scientifiche
  SI NO
- I risultati acquisiti mediante il compimento degli studi con uso del mio materiale biologico e dei dati ad essi associati siano utilizzati in forma anonima per lo sviluppo di precisare le finalità
  SI NO
- I materiali biologici siano smaltiti nei termini precisati nell'informativa
  SI NO

DICHIARO di:

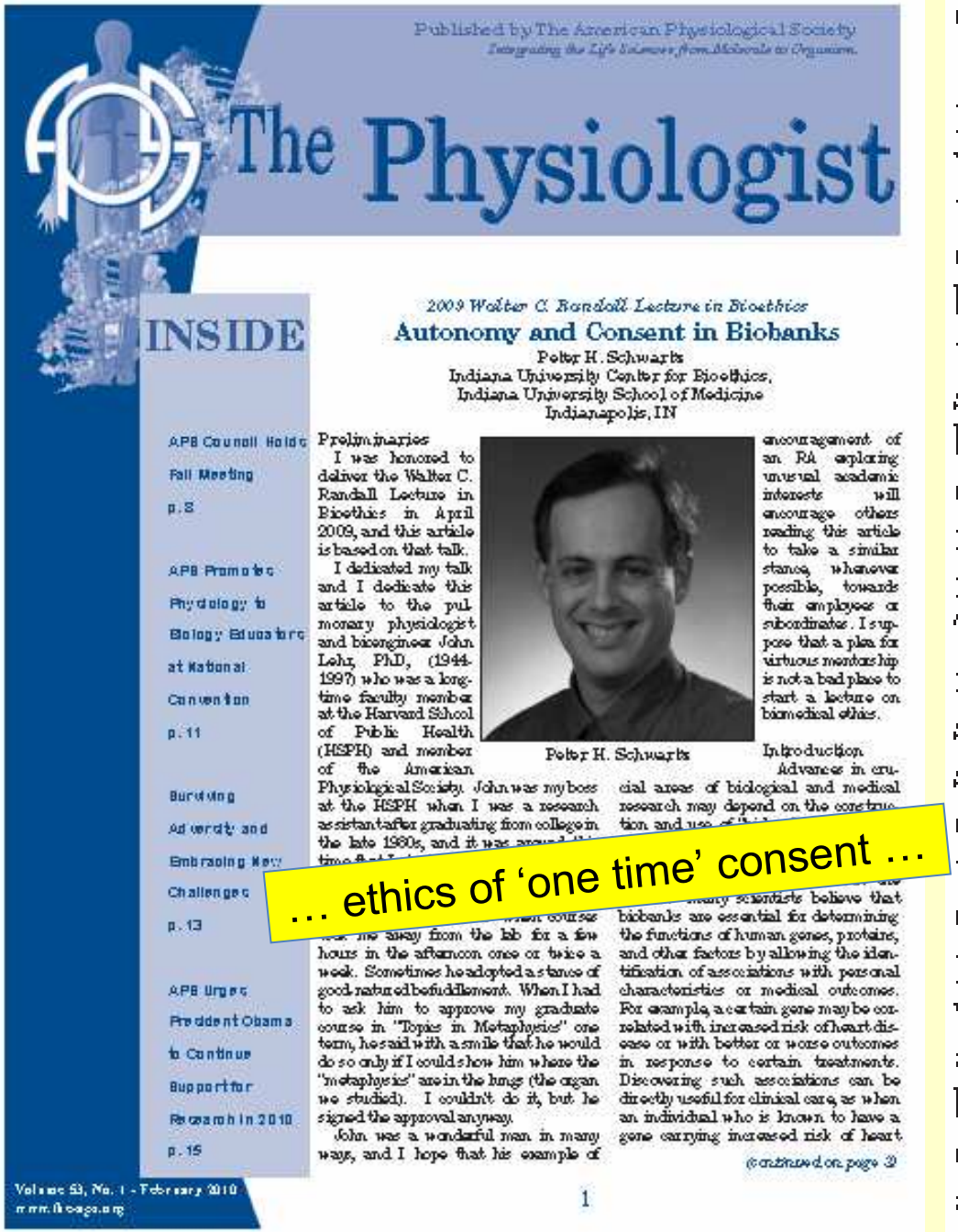
- essere stato/a informato/a della possibilità di revocare il consenso alla raccolta e/o, alla conservazione e/o all'utilizzo del mio materiale biologico e dei dati associati in qualunque momento e per qualunque motivazione e della possibilità di richiedere la distruzione irreversibile dei medesimi

  ☐ SI ☐ NO

Data ...../...../..... Firma del paziente _____

Cognome Nome _____

ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO – via Francesco Sforza n. 35 – 20122 MILANO
UO 517 Biobanca Italiana Tel. 02/55034050 Fax. 02/55034050 e-mail: micb@policlinico.mi.it



Published by The American Physiological Society
Integrating the Life Sciences from Molecule to Organism

The Physiologist

INSIDE

2009 Walter C. Randall Lecture in Bioethics

Autonomy and Consent in Biobanks

Peter H. Schwartz
Indiana University Center for Bioethics,
Indiana University School of Medicine
Indianapolis, IN

Preliminaries

I was honored to deliver the Walter C. Randall Lecture in Bioethics in April 2009, and this article is based on that talk.

I dedicated my talk and I dedicate this article to the pulmonary physiologist and bioengineer John Lehr, PhD, (1944-1997) who was a long-time faculty member at the Harvard School of Public Health (HSPH) and member of the American Physiological Society. John was my boss at the HSPH when I was a research assistant after graduating from college in the late 1960s, and it was around [illegible] time. [illegible] course [illegible] me away from the lab for a few hours in the afternoon once or twice a week. Sometimes he adopted a stance of good-natured befuddlement. When I had to ask him to approve my graduate course in "Topics in Metaphysics" one term, he said with a smile that he would do so only if I could show him where the "metaphysics" are in the lungs (the organ we studied). I couldn't do it, but he signed the approval anyway.

John was a wonderful man in many ways, and I hope that his example of encouragement of an RA exploring unusual academic interests will encourage others reading this article to take a similar stance, whenever possible, towards their employees or subordinates. I suppose that a plea for virtuous mentorship is not a bad place to start a lecture on biomedical ethics.

Peter H. Schwartz

Introduction

Advances in crucial areas of biological and medical research may depend on the construction and use of [illegible] many scientists believe that biobanks are essential for determining the functions of human genes, proteins, and other factors by allowing the identification of associations with personal characteristics or medical outcomes. For example, a certain gene may be correlated with increased risk of heart disease or with better or worse outcomes in response to certain treatments. Discovering such associations can be directly useful for clinical care, as when an individual who is known to have a gene carrying increased risk of heart

continued on page 2

… ethics of 'one time' consent …

Conclusion

Some would see this as a cynical process of rationalization: as long as it was easy for researchers to comply with the specificity requirement, it was enshrined as part of ethics, but once it became difficult in at least some situations, ethicists began to argue that it should be dropped. And while one must be vigilant for self-serving arguments, one also must respect the process of reflection and reconsideration that makes up so much of ethical thought. Those who would defend the specificity requirement and reject one-time consent should respond by explaining the presumed link to autonomy or other basic ethical requirements more clearly. If they do so, then defenders of one-time consent must respond in kind. Such a process of give and take represents conversation and reasonable disagreement at its best. And the result, I believe, will be an improved understanding of the ethics of one-time consent in biobanks and informed consent more generally.

Conclusioni

- Necessaria armonizzazione di norme, regolamenti e linee guida
- Necessaria armonizzazione dei modelli utilizzati per la raccolta del consenso informato
- Specificità del biobanking prospettico rispetto agli studi definiti al momento della raccolta dei campioni
- Problematiche legate ai diversi riferimenti etici