

Selected Paper Presentation

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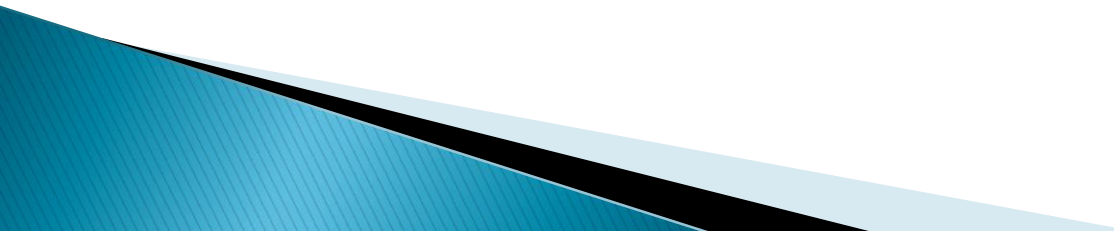
SCIENCE AND SOCIETY

From patients to partners: participant–centric initiatives in biomedical research

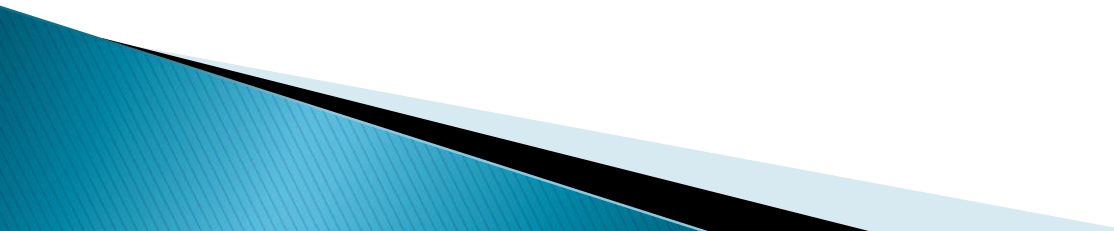
Nature Review Genetics 13, 371–376 (May 2012)

Jane Kaye, Liam Curren, Nick Anderson, Kelly Edwards,
Stephanie M. Fullerton, Nadja Kanellopoulou, David Lund,
Daniel G. MacArthur, Deborah Mascalzoni, James Shepherd,
Patrick L. Taylor, Sharon F. Terry and Stefan F. Winter

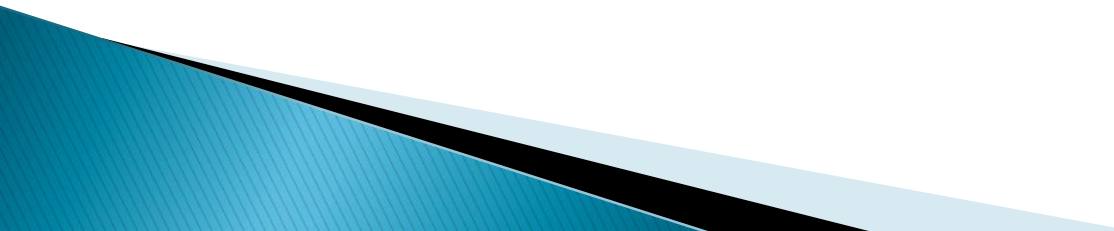
Background

- ▶ Advanced in computing technology and bioinformatics mean that medical research is increasingly characterized by large international consortia of researchers that reliant on **large data sets and biobanks**.
 - ▶ Recent advances in digital technologies have led to increasing **concern about the use of personal data**, in particular about amount of control that individuals have over their information and who may have access to it.
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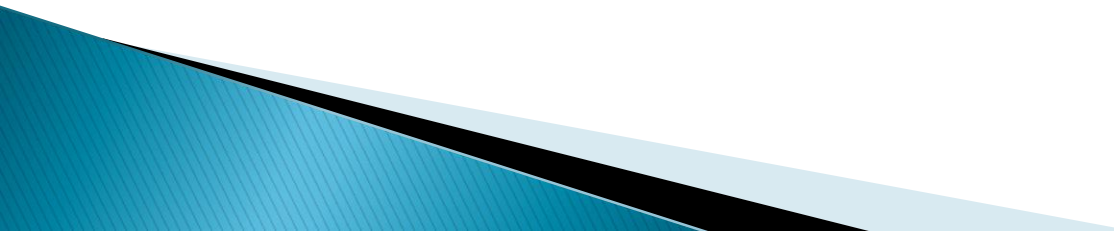
Emerging Issues

- ▶ Protecting individual interests
 - ▶ New trends in research demanding new consents models
 - ▶ Giving research participants a greater choice
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Protecting individual interests

- ▶ The central concern of medical research ethics is to **protect the interests of research participants** while allowing beneficial research to proceed.
 - ▶ Those who agree to take part in any form of biomedical research are required to **give their consent** to the use of any donated samples and associated data in the given study before the research commences.
 - ▶ How to achieve enough?
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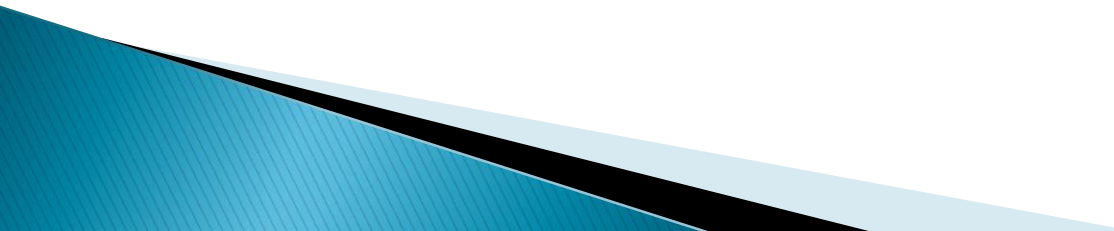
New trends in research demanding new consents models

- ▶ Consent is of fundamental importance, but there are no uniform standards of it.
 - ▶ The legal, ethical, and regulatory requirement may differ between jurisdictions at different levels.
 - ▶ As research evolve over time, it is increasingly difficult to guarantee individuals anonymous.
 - ▶ Ongoing participation is required to provide more detailed information or samples.
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Giving research participants a greater choice

- ▶ From an ethical perspective, it is necessary to enable participants that have given consent under one set of circumstances to **reassess this in the light of new research possibilities** on the same data sets that contain their information or samples.
- ▶ The major challenge is to **develop ways to engage and to communicate with diverse groups over long periods of time**, as personal data are used and reused for new studies.

What is a PCI?

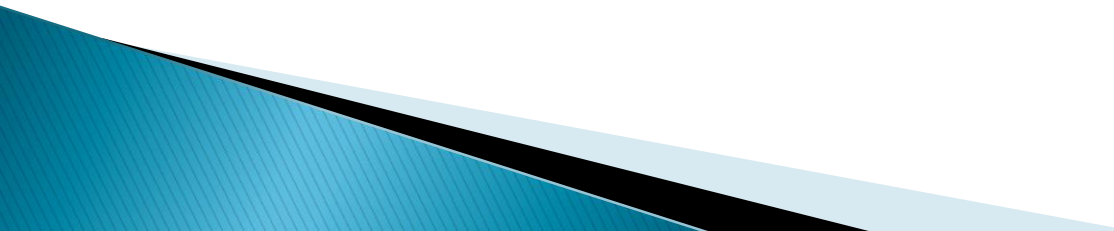
- ▶ **P**articipant-**C**entric **I**nitiative
 - ▶ Generally defined as ‘tools, programs and projects that empower participants to engage in the research process’ using IT interface
 - ▶ The key feature of all PCI interfaces is that **patients and research participants are located at the center of decision making as equal partners in the research process.**
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Function	Characteristics	Examples
Matchmaking	<ul style="list-style-type: none"> • Brings together participants and researchers by either promoting communication or facilitating recruitment 	<ul style="list-style-type: none"> • PrivateAccess (USA)
Direct-to-consumer services	<ul style="list-style-type: none"> • Provides participants with services as well as social-networking capabilities • Provides opportunities for involvement in research 	<ul style="list-style-type: none"> • 23andWe (USA)
Dynamic negotiation	<ul style="list-style-type: none"> • Enables an ongoing discourse and negotiation between researchers and participants • Enables participants to manage their preferences for personal data sharing while facilitating more accountable research governance 	<ul style="list-style-type: none"> • CuraRata and String of Pearls Initiative (Netherlands) • CHRIS — Cooperative Health Research in South Tyrol (Italy) • EnCoRe and the Oxford Radcliffe Biobank (UK)
Citizen science	<ul style="list-style-type: none"> • Allows participants to provide and to control the samples and data and, in so doing, to have an active involvement in facilitating research • Allows participants to drive the research agenda and to carry out their own research projects 	<ul style="list-style-type: none"> • PatientsLikeMe (USA) • TuAnalyze (USA) • Genomes Unzipped (UK) • Genomera (USA)

Features of PCIs

- ▶ Placing participants in control
 - Place the individual at the center
- ▶ **Using social media technology**
 - Phone, blog, FB, all IT interfaces
- ▶ Promoting active participation
 - Reciprocity and commitment on both side
- ▶ Facilitating communication
 - Inform participants and keep in regular contact
- ▶ Appealing to public goods
 - Other advantages for public, such as accelerating research, improving clinical outcome, and increasing public knowledge about genomics.

Benefits of adopting a PCI approach

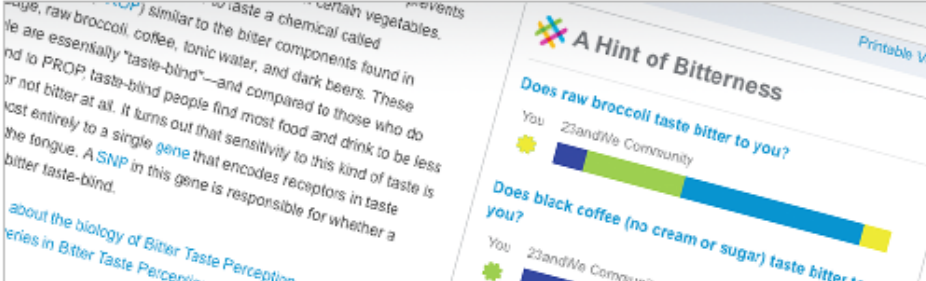
- ▶ Streamlining the consent process
 - ▶ **Removing the need for anonymized data**
 - ▶ Facilitating participant recruitment
 - ▶ Facilitating participant retention
 - ▶ Promoting the delivery of better quality and more cost-effective health care
 - ▶ Sustain public confidence in research
 - ▶ Improving the quality of research
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Name of PCI (country; URL)	Key aims and features	Activity
23andWe (USA; https://www.23andme.com/research)	This is the research arm of 23andMe. Customers can leverage their data by contributing it to studies of genetics to “produce revolutionary findings that will benefit us all” but that can also be used to “discover new genetic associations that could shed more light on your data”	It gives customers the opportunity to contribute their genetic test results to research studies of their choosing and to be involved in specific online research projects
CHRIS — Cooperative Health Research in South Tyrol (Italy; http://www.chrisstudy.it)	Aims to use the research findings to improve the health of all people living in the Tyrol region in Italy. It ensures continuous, interactive consent and communication with participants by traditional methods as well as novel online tools	Through online tools, participants can: manage their consent in relation to subprojects; restrict the use of information in different studies; determine the extent to which they receive follow-up contact and updates; and opt out of the initiative. The options are explained to participants through a range of media
CuraRata (Netherlands; http://www.curarata.nl/uk/3/patients/home.html) and String of Pearls Initiative (Netherlands; http://www.string-of-pearls.org)	A unique data-sharing partnership between eight teaching hospitals in the Netherlands. CuraRata aims to use novel IT systems to use pooled clinical information and biomaterials and to link clinical and research data. The aim is to develop high-quality health-care provision that is innovative and affordable by encouraging participant involvement. It is essentially a personalized medical approach, and the process is dependent on active patient participation	Through the Home Care interface “the patient is able to obtain access to healthcare via his or her own electronic patient file from home or from work. Home Care also offers the opportunity of monitoring the patient’s disease, use of medication and quality of life, of undertaking laboratory research from home and of planning or changing appointments with healthcare providers”

http://www.nature.com/nrg/journal/v13/n5/fig_tab/nrg3218_T2.html

- ▶ 23andMe Research
- 23andMe Research Findings
- Physicians
- Scientists

23andWe Research



The screenshot shows a survey titled "A Hint of Bitterness" with two questions: "Does raw broccoli taste bitter to you?" and "Does black coffee (no cream or sugar) taste bitter to you?". Each question has a progress bar comparing the user's response to the 23andWe Community. Below the survey, there is a call to action: "We're interested in advancing genetic research. Get involved and learn about yourself while contributing to science." and a "view slideshow" button.



23andMe isn't just about you. Our research arm, 23andWe, gives customers the opportunity to leverage their data by contributing it to studies of genetics. With enough data, we believe 23andWe can produce revolutionary findings that will benefit us all.

Get involved in a new way of doing research.

- Direct research by participating in studies of conditions and traits you care about.
- Join an effort to translate basic research into improved health care for everyone.
- Support 23andMe's efforts to discover new genetic associations that could shed more light on your data.

Participate in research while exploring your own genetics.

- Take surveys that collect important data for scientific research

CHRIS: Bevölkerungsstudie zur Gesundheit in Südtirol

WAS IST EINE BEVÖLKERUNGSSTUDIE?

Bevölkerungsstudien erfassen und untersuchen klinische Daten von tausenden Personen, um Ursachen von Krankheiten sowie deren Auftreten und Verbreitung in der Gesellschaft auf die Spur zu kommen. Solche Studien sind ein unverzichtbares Instrument der biomedizinischen Forschung, weil sie es ermöglichen, den Gesundheitszustand von Menschen über einen längeren Zeitraum zu beobachten. Alle vier bis fünf Jahre werden über Gesundheitszustand oder Krankheitsverläufe in der Bevölkerung Informationen gesammelt. Dadurch sollen Erkenntnisse über Ursprung und Schwere von verbreiteten Krankheiten gewonnen und erklärt werden, weshalb manche Personen gegen bestimmte Krankheitsbilder besser geschützt scheinen als andere.

Bevölkerungsstudien wie die CHRIS-Studie verfolgen das Ziel Risikofaktoren von Krankheiten zu erkennen, indem sie das Verhältnis zwischen genetischen und Umweltfaktoren in Betracht ziehen.

Umweltfaktoren beeinflussen unser Leben und unseren Gesundheitszustand und können das Auftreten bestimmter Krankheiten fördern. Faktoren wie Umweltverschmutzung oder das Klima können nicht direkt vom Einzelnen verändert oder beeinflusst werden; der persönliche Lebensstil dagegen, also Ernährung, Bewegung, der Genuss von Alkohol oder das Rauchen können sehr wohl vom Einzelnen beeinflusst werden. Umweltfaktoren gelten dann als Risikofaktoren, wenn sie das Auftreten oder die Verschlechterung von Krankheiten zur Folge haben. Im Gegensatz dazu werden sie zu Schutzfaktoren, wenn sie bestimmten Krankheitsbildern entgegenwirken oder den Gesundheitszustand gar verbessern.

Die **genetischen Faktoren beziehen** sich auf Informationen, die in der DNA enthalten sind, und mit Hilfe einer Blutprobe gewonnen werden können.

Die DNA ist mit einer Enzyklopädie zu vergleichen, die alle notwendigen Anweisungen enthält, damit sich unser Organismus entwickeln kann und funktioniert. Die einzelnen Einträge in dieser Enzyklopädie sind die Gene, welche die Informationen enthalten, die unsere körperlichen Eigenheiten oder einzelne Körperfunktionen festlegen. Manche Gene enthalten anomale Informationen, die für das Auftreten bestimmter Krankheiten verantwortlich sind. Andere komplexe Krankheiten entstehen durch das Zusammenspiel von genetischen und Umweltfaktoren.

Zentrum für Biomedizin

« Zurück zu Zentrum für Biomedizin

CHRIS Studie

- » [Allgemeine Informationen](#)
- » Teilnahme
- » Rechte der Teilnehmer
- » Kommunikation und Information
- » Webzugang für Teilnehmer

Kontakt

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CuraRata is an innovative healthcare process in which screening and care for complex illnesses, such as chronic diseases and cancer, are individualized and take place within a research environment. With one single goal: prevention and cure. In addition, this integration of prevention, scientific research and individual care should reduce the number of patients, decrease costs related to specialized care and promote the re-integration of the ill into the job market. Also CuraRata will generate more income by involvement and valorization on the part of the private sector.

News

••• [Ab Klink opens CuraRata](#)
| Publication date: 25 June 2009

••• [No Title](#)

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SEARCH OK



Downloads

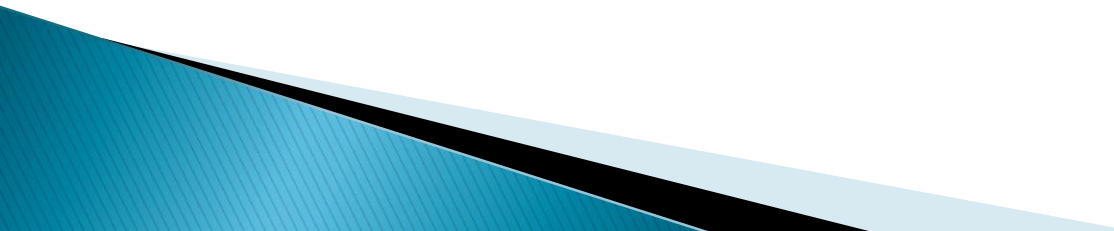
••• [Download the brochure in PDF.](#)



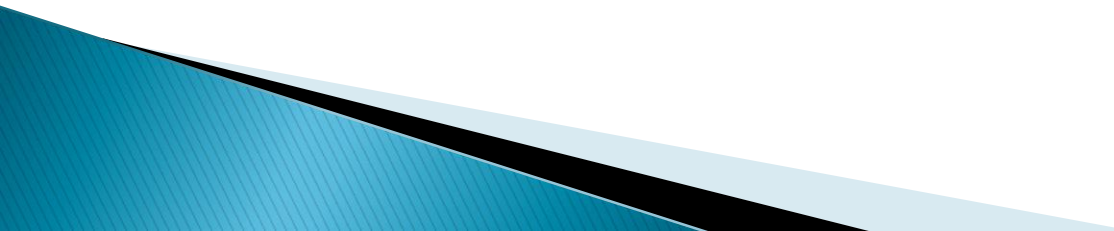
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Challenge of adopting PCIs

- ▶ Require a shift in current attitudes and approaches towards patients and participants.
 - ▶ As the bulk of consent efforts are still paper-based, there are difficulties in making the transition to effective electronic consent models.
 - ▶ Boarder implementation in research will be hampered by the lack of a common reference ontology that can accurately capture a continuum of patient consent state.
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Challenge of adopting PCIs

- ▶ The implementation of PCIs also requires a change for research participants, as PCIs alter the nature of involvement in research.
 - ▶ Although the greater use of PCIs may lead to greater empowerment of participants and better control over personal information and samples, certain lines of research may not be possible if many participants opt out.
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Conclusion

- ▶ The motive and advantages of PCIs are wonderful, but there are still lots of problems and challenges to be overcome.

Thank you for listening!