**eHealth Workshop**
**25-26 April 2013**
**Middlesex University**
**London, UK**
**http://goo.gl/tgDaf**

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# UPSIDE DOWN
# How the health 2.0-era significantly changes our view of informed consent

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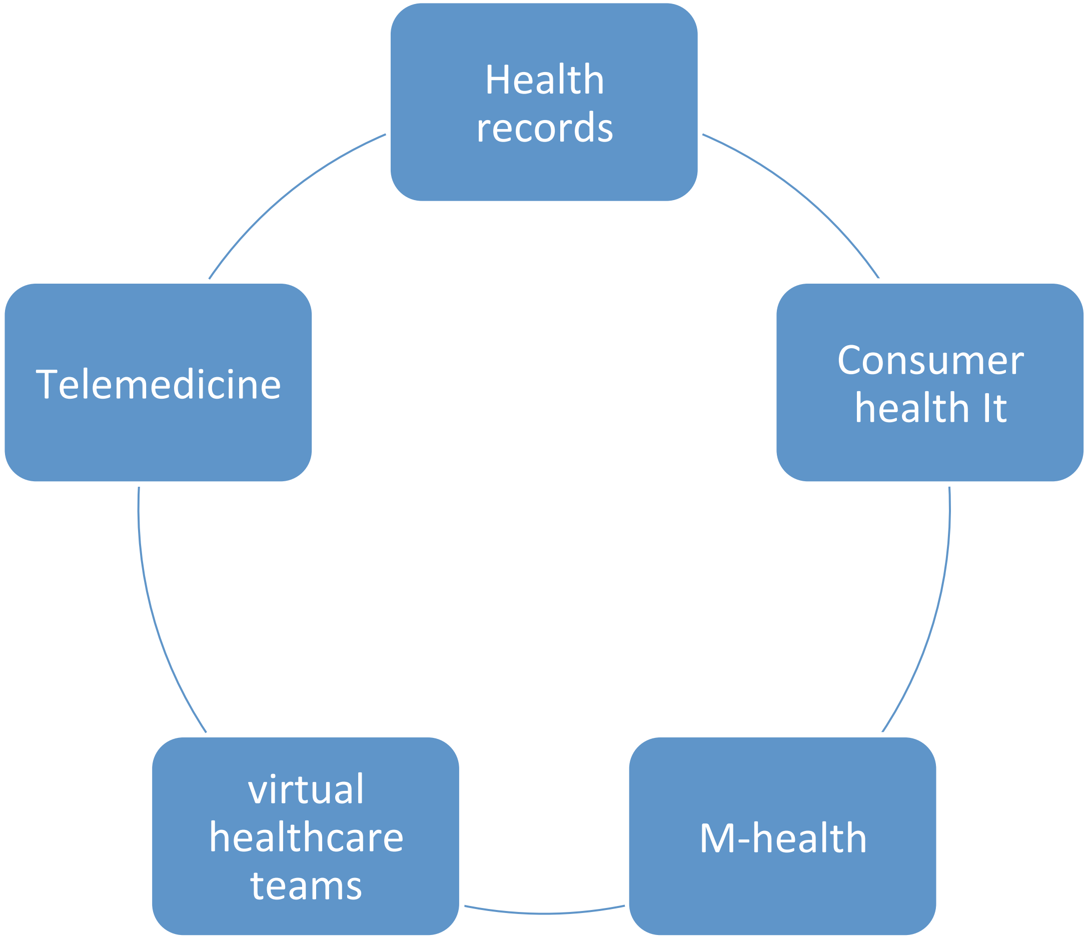
# E-health



Health records

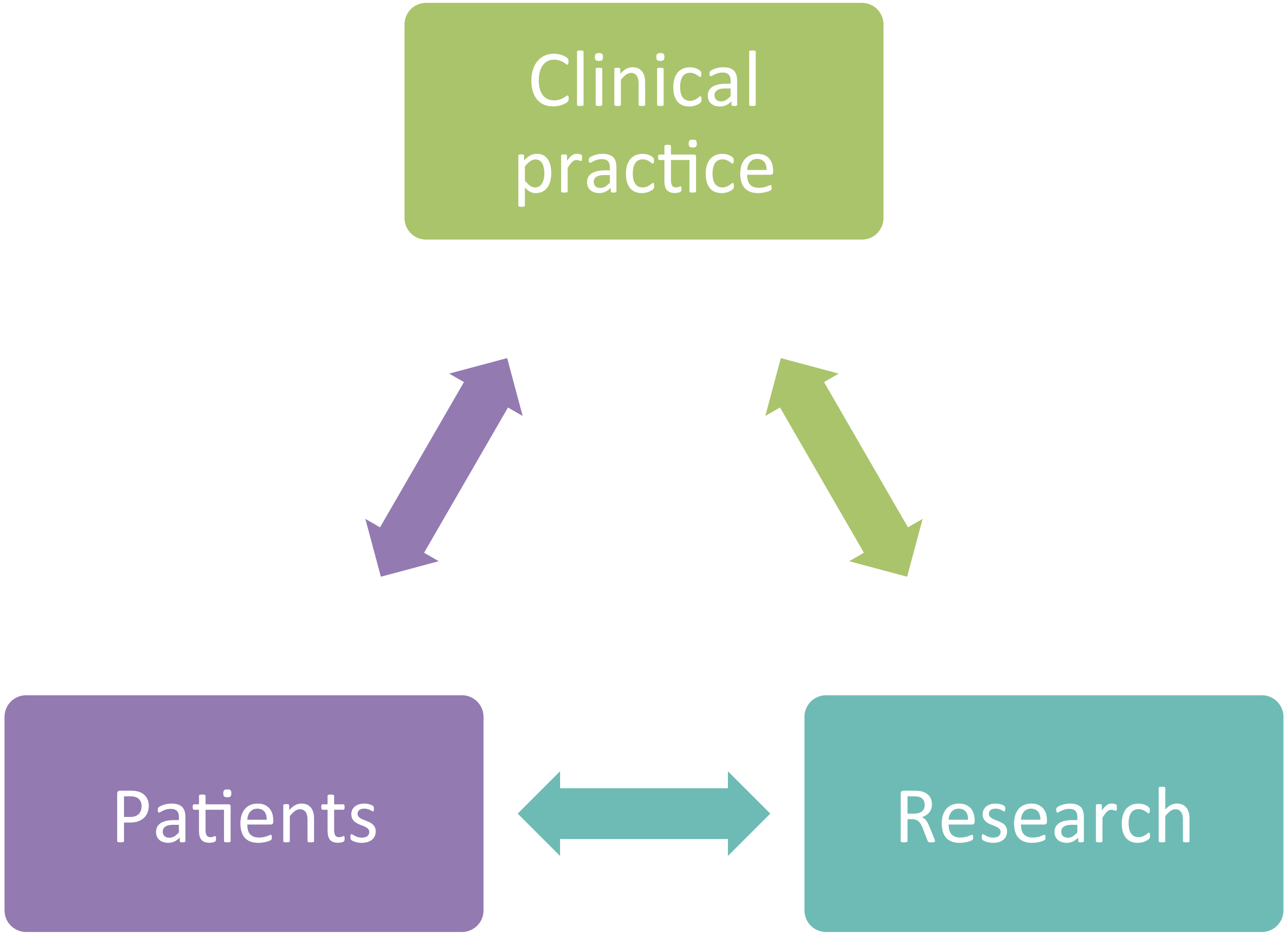
Consumer health It

M-health

virtual healthcare teams

Telemedicine

# health data



Clinical practice

Patients

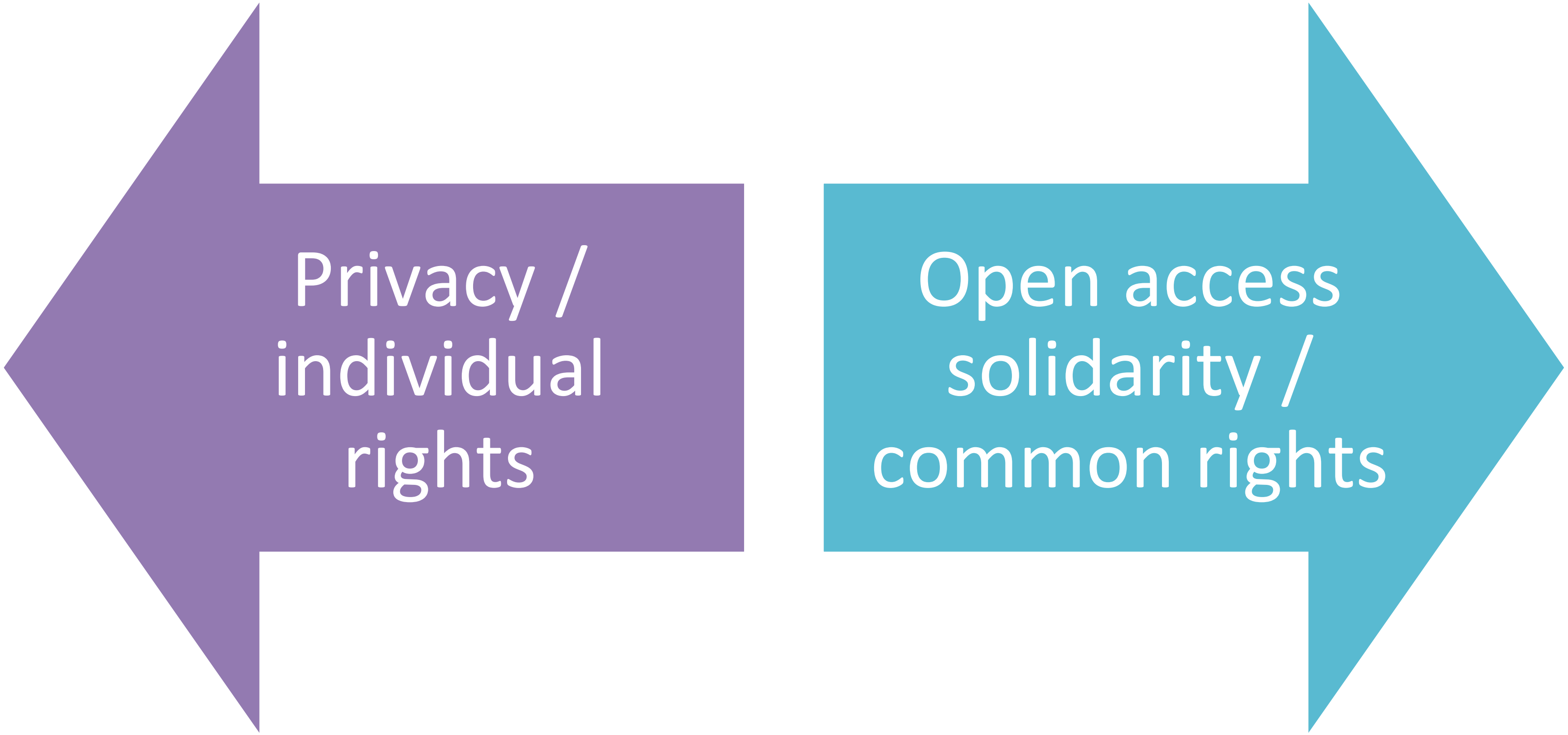
Research

# Whose health information?

February 4, 2010

CNN Health

# Control over data



Privacy / individual rights

Open access solidarity / common rights

# The two ends of the spectrum: fear and hope

"We were appalled when we found out. Why do they need to store my baby's DNA indefinitely? Something on there could affect her ability to get a job later on, or get health insurance."

*Karen Brown, Nurse, new mother, Florida*

It is the moral imperative of every person on the planet to freely share their health information.

*Paraphrase of Jamie Heywood, Co-founder, Patients Like Me*

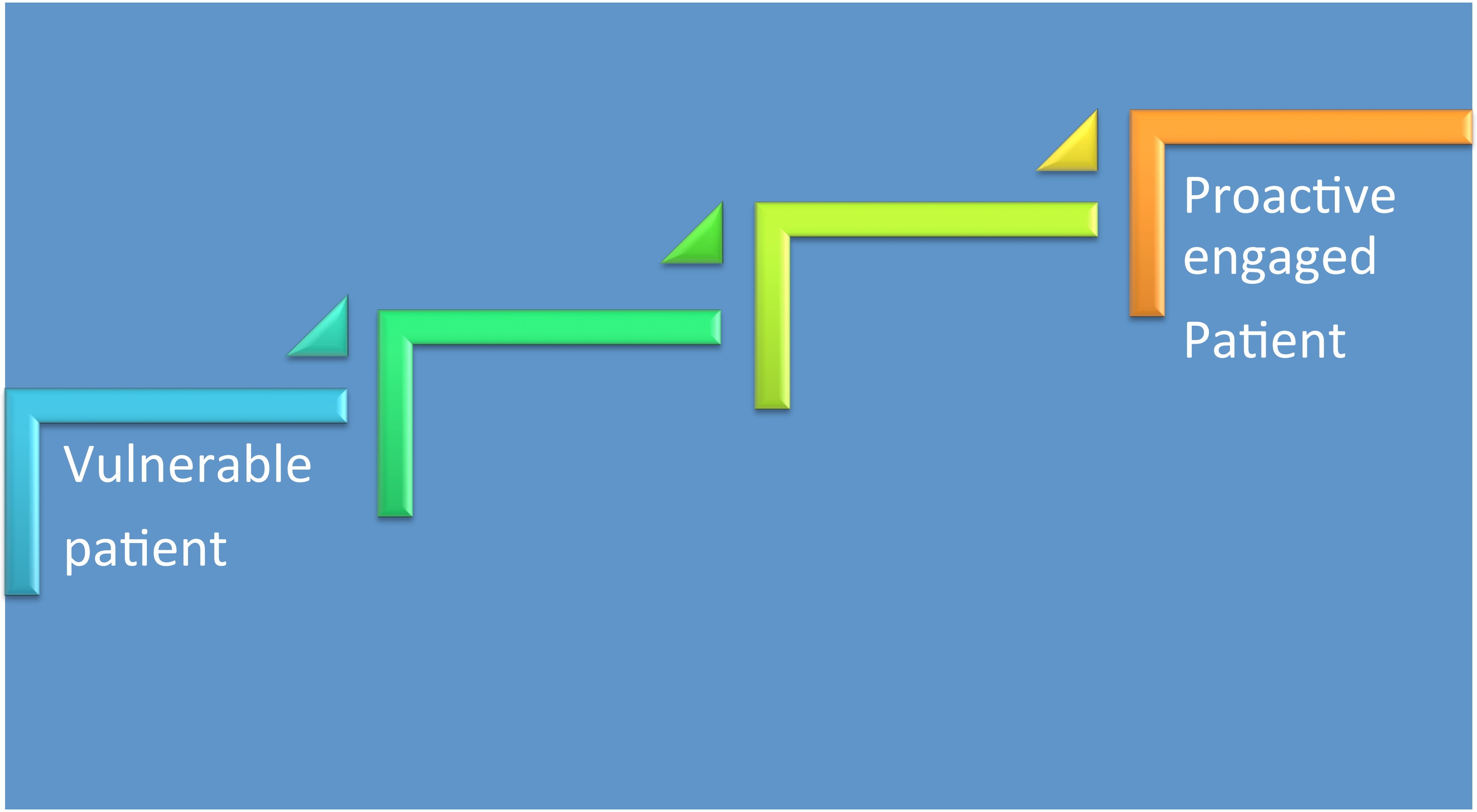
# Taking Informed Consent seriously

- Consent is the prerequisite for protecting patients in the clinical setting and in research (not there to protect phisicians/researchers)
- Consent to participate is the fundamental component in bio-ethics and should, in all circumstances, be ***valid***, ***voluntary*** and ***informed***
- Consent is a process of information and decision-making not the signature of a piece of paper
- Should provide enough information in order to guarantee a risk-benefit assessment
- Patient have the right to withdraw anytime

# Issues wit current IC practices

- Informed consent is too long and often too complicated for patients
- No method to ensure that patients understood the information
- No follow ups on information over time
- Right to withdraw not taken seriously

# wide range of positions

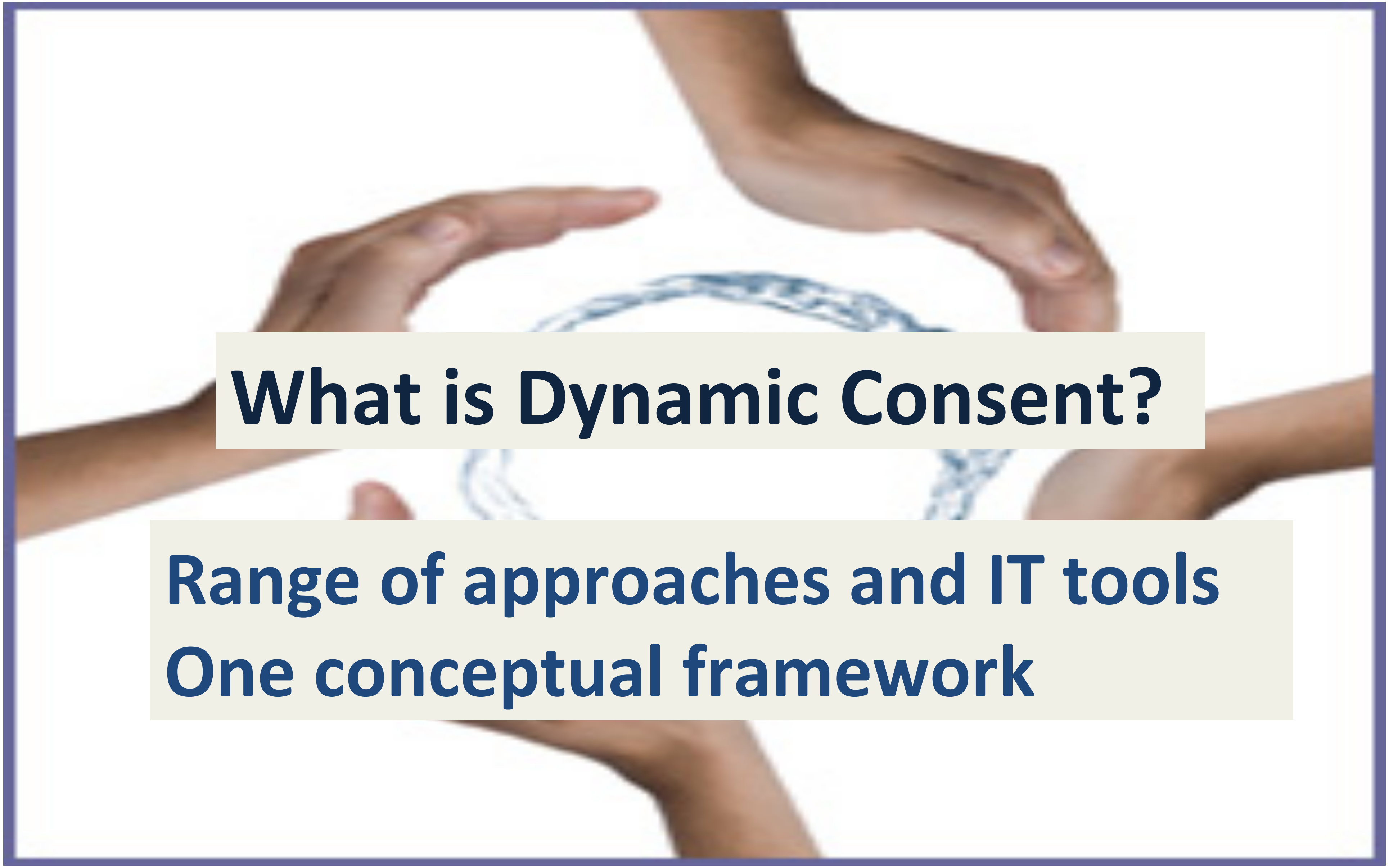


Vulnerable

patient

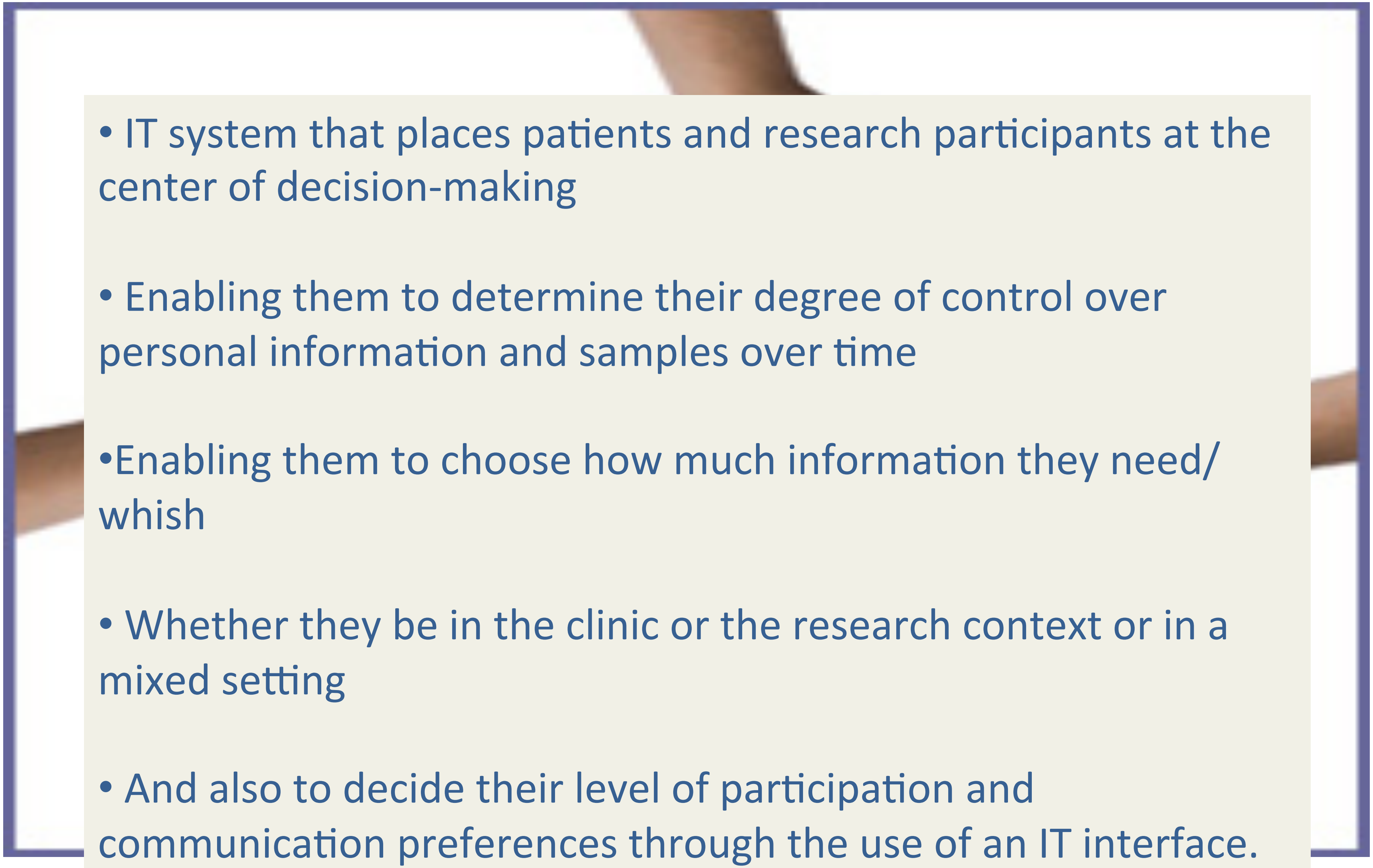
Proactive
engaged

Patient



# What is Dynamic Consent?

Range of approaches and IT tools
One conceptual framework



- IT system that places patients and research participants at the center of decision-making

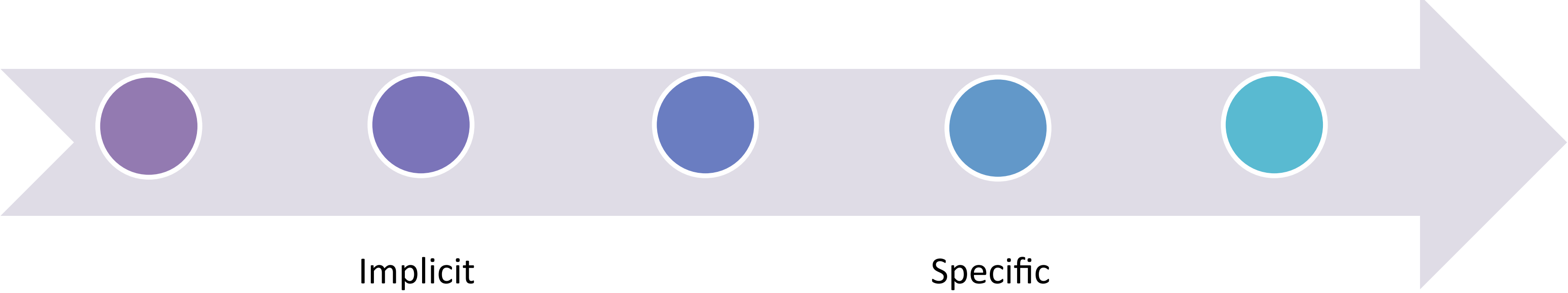
- Enabling them to determine their degree of control over personal information and samples over time

- Enabling them to choose how much information they need/ whish

- Whether they be in the clinic or the research context or in a mixed setting

- And also to decide their level of participation and communication preferences through the use of an IT interface.

# Informed consent spectrum



No consent

Implicit consent

Broad consent

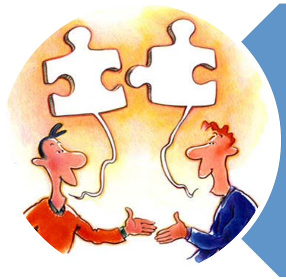
Specific consent

Knowledge based dynamic consent process

# Aids to overcome barriers

Caring about contextual communication (TIME/needs)

Use different media/ tools to reach different users more efficiently



Feedback Channell:

Get the real needs in order to address them

# information on demand

| SHORT | MEDIUM | FULL |
|---|---|---|
| • I trust what you do | • I want to know more | • I want to know all |

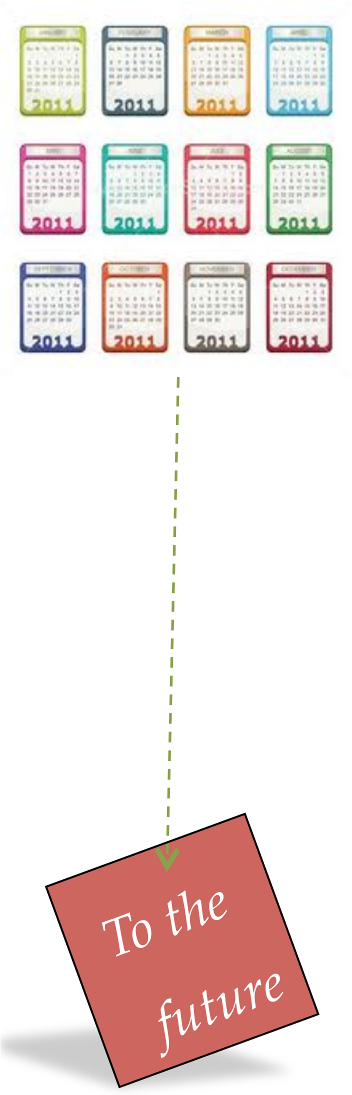
# CHRIS

Südtiroler Gesundheitsstudie
Studio sulla salute in Alto Adige

# Cooperative health study in South-tyrol

- Collection of extensive data an bio-samples on population level
- Epidemiological genetic study in an Alpine valley in South Tyrol
- 10.000 individuals involved
- Hospitals involved
- 25 years with follow up every 5 years

# Participant‘s workflow in dynamic consent in CHRIS



*Months before*

*4/2 weeks before*

*Day before*

- General info to the public through media
- Invitation letter and Brochure at home

  via e-mail if possible
- SMS reminder (drugs, info, time)

*7'*

- Information movie
- Web based dynamic Informed consent
- Questions

*Coming Days*

*Coming Months*

- Updates on the personal WEB page
- Questionnaire
- Follow up
- Newsletter…..

CHRIS

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# Dynamic consent

- RE-consent/ follow up/ changes
- Information
- Re-contact
- Withdrawal

Allow over time contact (not 1 time)

Interactive (vs. passive)

Multiple methods

(Web, Cellphones, e-mail, Paper)

Individually targeted

- Preference sensisitive (diverse options)
- Enact preferences (taylored)

**ethical values into practice:**
**respect/accountability/transparency**

# What are the benefits of it?

# Ensuring consent and Revocation

# In conclusion

**New tools enable us to do more for IC:**

Better information

Tailored

Over time/on demand

Interactive

But also …..

**Help to build a new participatory culture supported by all the means we can use**

- Move toward a patient centred approach
- Understanding and valuing of the active role that patients play in health management
- Empowering control and individual choice
- Development of policies and practice to accompany it