The Importance of Trustworthy Governance – Is Dynamic Consent one Solution?

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Outline of Talk

1. What is Governance?
2. What are some of the problems with our current research governance systems?
3. What is Dynamic Consent?
4. How does Dynamic Consent provide one solution to some of these challenges?

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1. What is Governance?

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Governance is……

‘the complex mechanisms, processes, relationships and institutions through which citizens and groups articulate their interests, exercise their rights and obligations and mediate their differences.’

United Nations Development Program (Discussion Paper 2, 1997) 9.


Institutions

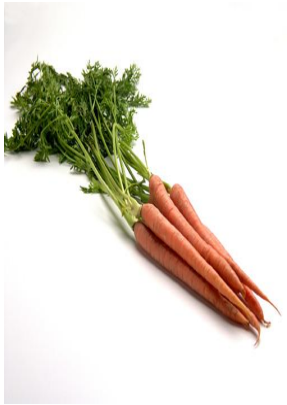

People

Law and Policy

Procedures

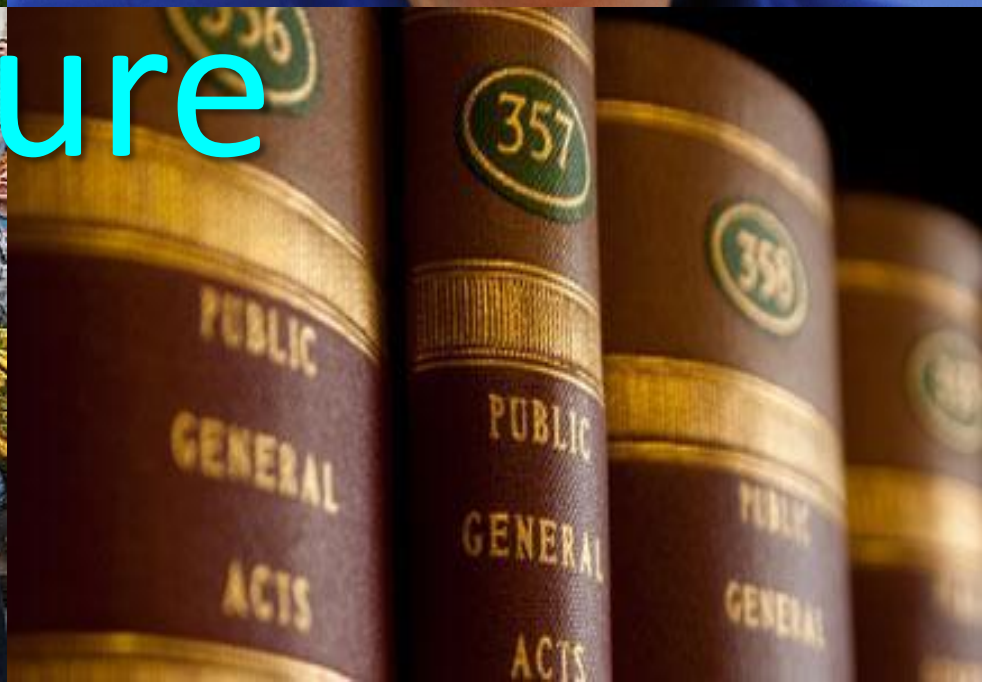
Compliance Mechanisms

Adapted from Ayers and Braithwaite 1992



Governance

Structure



Why do we need Governance?

- **CERTAINTY AND EFFICENCY**
  - People know what the rules are and what happens, when
- **UNIFORMITY AND EQUALITY**
  - Everyone and the same issues are treated the same
- **PROMOTES GOOD THINGS**
  - Enables problems to be anticipated
  - Ensures that when things go wrong there are procedures and people to deal with it
- **ENSURES ETHICAL AND LAWFUL RESEARCH**
  - Accountable, transparent decision-making
- **PROTECTS INTEGRITY OF THE RESEARCH COMMUNITY**
- **PROMOTES PUBLIC CONFIDENCE AND TRUST**

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What is Trustworthy Governance?

- **Ongoing Relationships**
  - Built up over time, based on respect
- **Reciprocal Relationships**
  - Focus on benefits for everyone
  - Awareness of what other parties concerns are
  - People know what it means for them
- **Transparency**
  - People know what is going to happen
  - Good communication
- **Accountability**
  - Accountable, transparent decision-making
  - Audit and scrutiny by independent bodies
  - People know who is responsible

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2. What are some of the problems with our current research governance systems?

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1. changing law

Legal requirements vary between countries

Change over time

Culture Change

The GDPR sets a high standard for consent, but the biggest change is what this means in practice for consent mechanisms. You will need clear and more granular opt-in methods, good records of consent, and simple easy-to-access ways for people to withdraw consent. The changes reflect a more dynamic idea of consent: consent as an organic, ongoing and actively managed choice, and not simply a one-off compliance box to tick and file away.

UK Information Commissioners Office 2016

2. scandals

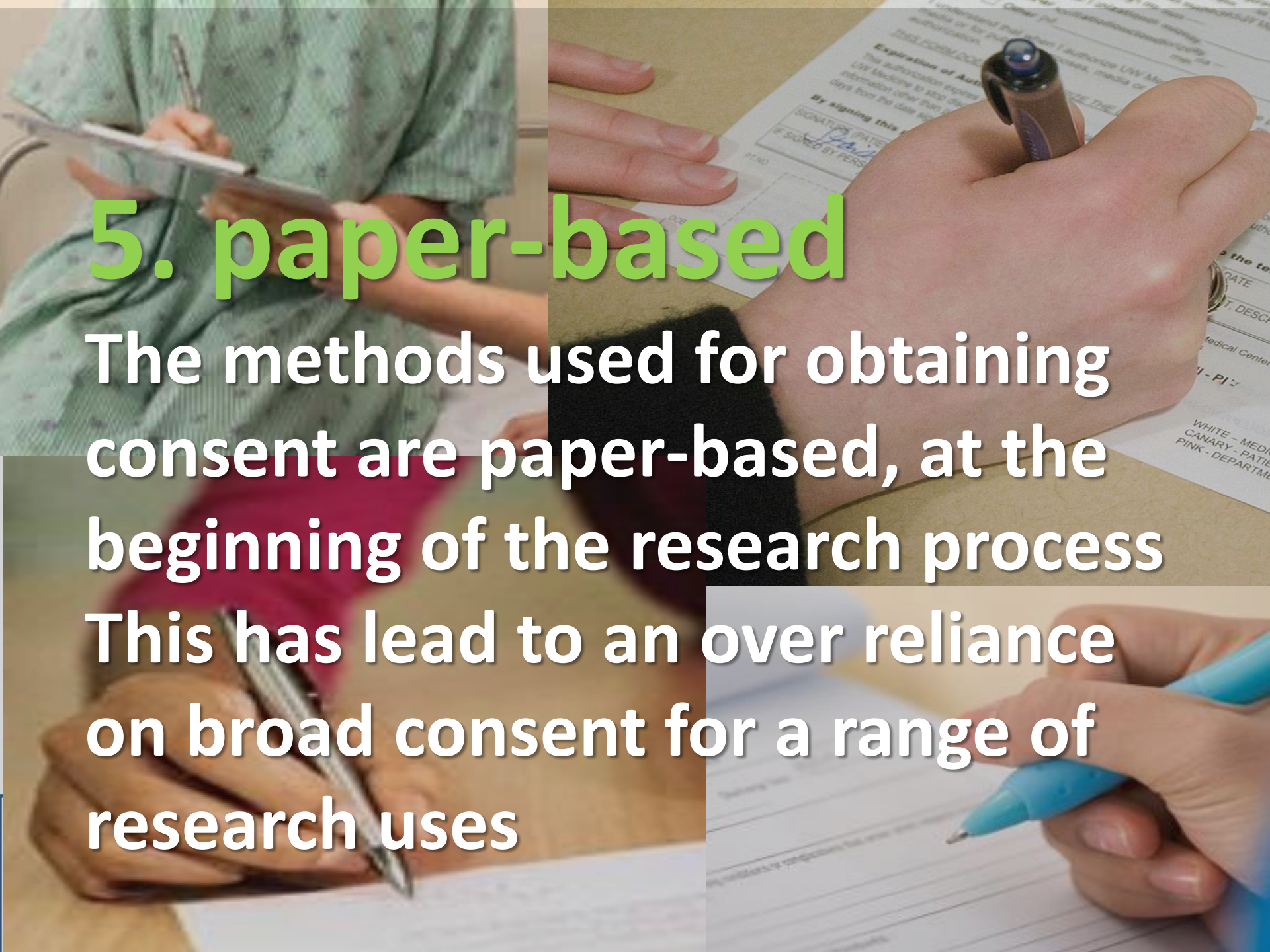
High profile cases have shown that if the secondary use of data does not meet societal expectations it can lead to public backlash

3. different domains

The regulatory requirements for consent vary between the clinic and research domains

4. samples and data

Different legal regimes apply to samples and data which leads to complexity and double regulatory burden



5. paper-based

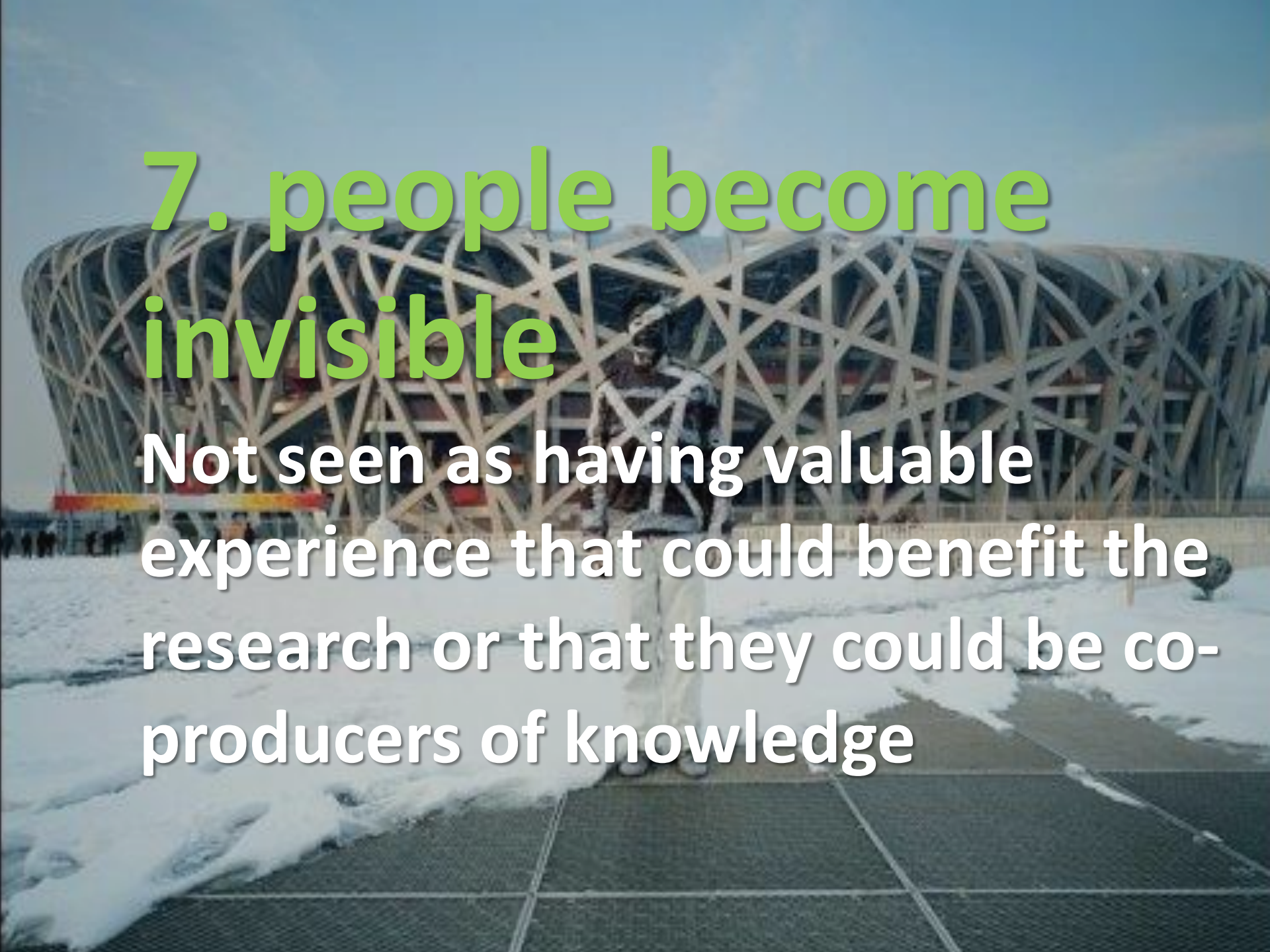
The methods used for obtaining consent are paper-based, at the beginning of the research process

This has lead to an over reliance on broad consent for a range of research uses

6.delegated decisions

Research ethics committees make decisions on behalf of participants

People do not know how their data is used when it is used in a number of research projects



7. people become invisible

Not seen as having valuable experience that could benefit the research or that they could be co-producers of knowledge

2. What is Dynamic Consent?

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Dynamic Consent is:

A personalised, digital interface to enable greater participant engagement in clinical and research activities over time.

It is dynamic because:

Individuals can:

- give different kinds of consent;
- change their consent preferences;
- receive information on the progress of research;
- enrol in new studies; and
- engage in self-reported research

Kaye et.al EJHG (2015) 23, 141–146; doi:10.1038/ejhg.2014.71

NHS
National Institute for Health Research

Sign up today

More Information

What is Rudy?

Rudy is a study in Rare diseases

Which rare diseases are we interested in?

At present we are prioritizing rare diseases affecting the bone, joints and/or

My Consent

Events

I agree to provide information about previous events and consequences using my secure personal profile on the RUDY website and for this information to be made available to the RUDY research team

I agree to provide information about current and future events and consequences using my secure personal profile on the RUDY website and for this information to be made available to the RUDY research team

Records

I agree that my medical records held at previous NHS hospitals, GP surgeries and local authorities can be made available to researchers as these are relevant for this study.

I agree that my medical records held at current NHS hospitals, GP surgeries and local authorities can be made available to researchers as these are relevant for this study.

Samples

I agree that any surplus tissue that is removed as part of my medical care can be used by the researchers as part of this study.

I agree that blood and urine samples can be taken for use in this research and understand that there will not be any direct participant commercial benefit from this.

I agree that the research team can contact me to arrange appointments to visit my nearest research facility for blood, urine and height tests every two years until the study is completed.

I agree that the research team can contact me to arrange appointments to visit my nearest research facility for bone density tests every two years and that these results will be made available to me as well as my current GP and hospital doctor, if I have one.

I agree to have punch skin biopsies , and for the skin samples collected to be used in the study.

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I agree to have punch skin biopsies , and for the skin samples collected to be used in the study.

I agree that my donated samples can be used in genetic research aimed at understanding genetic basis for rare diseases and that any results that are clinically important as judged by the Rudy Data Oversight Governance Committee will be sent to the clinical team caring for me.

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Data

I agree that the data that is collected about me during the study may be looked at by the University of Oxford and Oxford University Hospitals NHS Trust, and by researchers approved by the Rudy Data Access Governance Committee, both nationally and internationally that contribute to the aims and objectives of Rudy.

I would like to be sent reminders to complete questionnaires and provide follow up information every 6 months

By

Letter	Telephone	**Text Message**	Email

I would like to be sent updates on the progress of the study

By

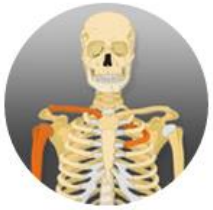
Website	Email	Letter

At a rate of:

Whenever available	Monthly	Quarterly	**Annually**

To do

Whats New



Timeline & Fracture map now online!

We have recently updated Rudy with new features. You can now add your fracture history to your timeline. To get started click here.

Questionnaires

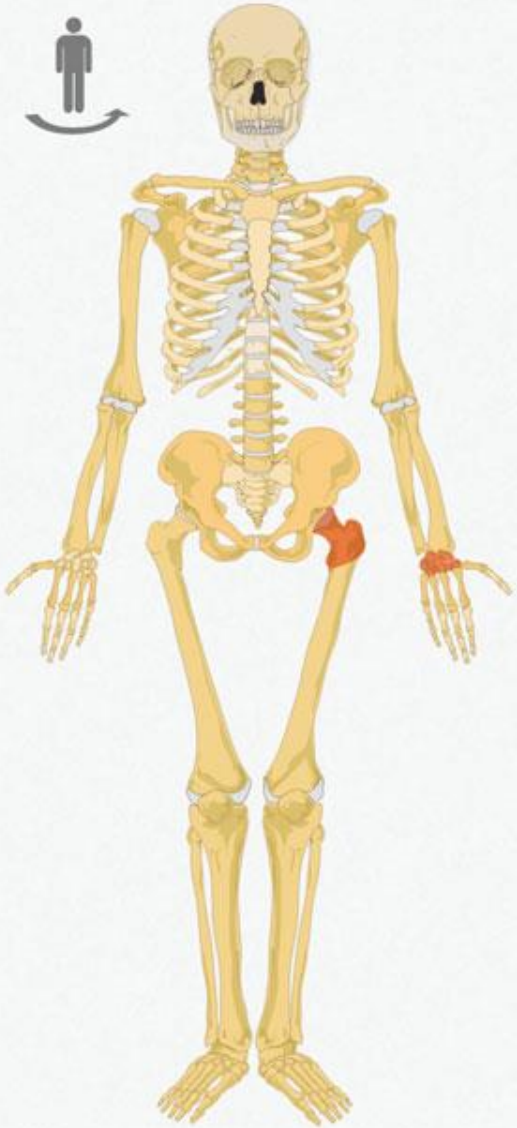
Every 6 months you will be invited to fill out a selection of questionnaires. These help us to track your health through time, and may offer valuable insights to researchers seeking to understand your condition.

- **HADS** — Hospital anxiety and depression scale — Submitted
- **FACIT** — Fatigue scale for chronic illness — Submitted
- **Pain** — Wong / Baker Faces — Submitted
- **Rheumatic Illness** — PedsQL — Started
- **Pain 2** — PainDetect — Submitted
- **Quality of Life 2** — SF36 Health Survey — Submitted

Recent Activity

saved fracture: Tripped	2 minutes ago
saved fracture: Fell	2 weeks ago
submitted hads questionnaire	3 weeks ago
saved hads questionnaire	3 weeks ago
submitted wong questionnaire	3 weeks ago
saved wong questionnaire	3 weeks ago
submitted facit questionnaire	3 weeks ago
submitted sf36 questionnaire	3 weeks ago
saved facit questionnaire	3 weeks ago
saved sf36 questionnaire	3 weeks ago

Fracture Event:

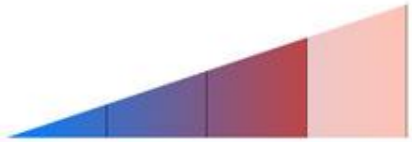


Fracture Details

Date of Fracture

14/02/2008

Level of Trauma



Trauma Level 3: e.g. intermediate

Fractured Bones

Search

Left Hip

Fracture Count: 1 2 3 More than 3

Left Wrist (Carpals)

Fracture Count: 1 2 3 More than 3

Cancel

Next

My Profile

Personal Details: Edit

Name: **Test 4**
Age: **24**
Gender: **Female**
Email:
4@test.com

Address:
4 Street
Ox
ox4 1aa

07834626103

Diagnosis: Edit

Brittle Bone / Osteogenesis Imperfecta - Type V

My Settings:

My Consent

General Practitioner: Edit

Dr Smith

19 Beaumont Street
Oxford

Consultants: Edit

Dr Spock

Speciality: Space Tim

Other Studies: Edit

StudyName: UKIVAS
REC ID:
Lead Research Centre:
Contact Name:

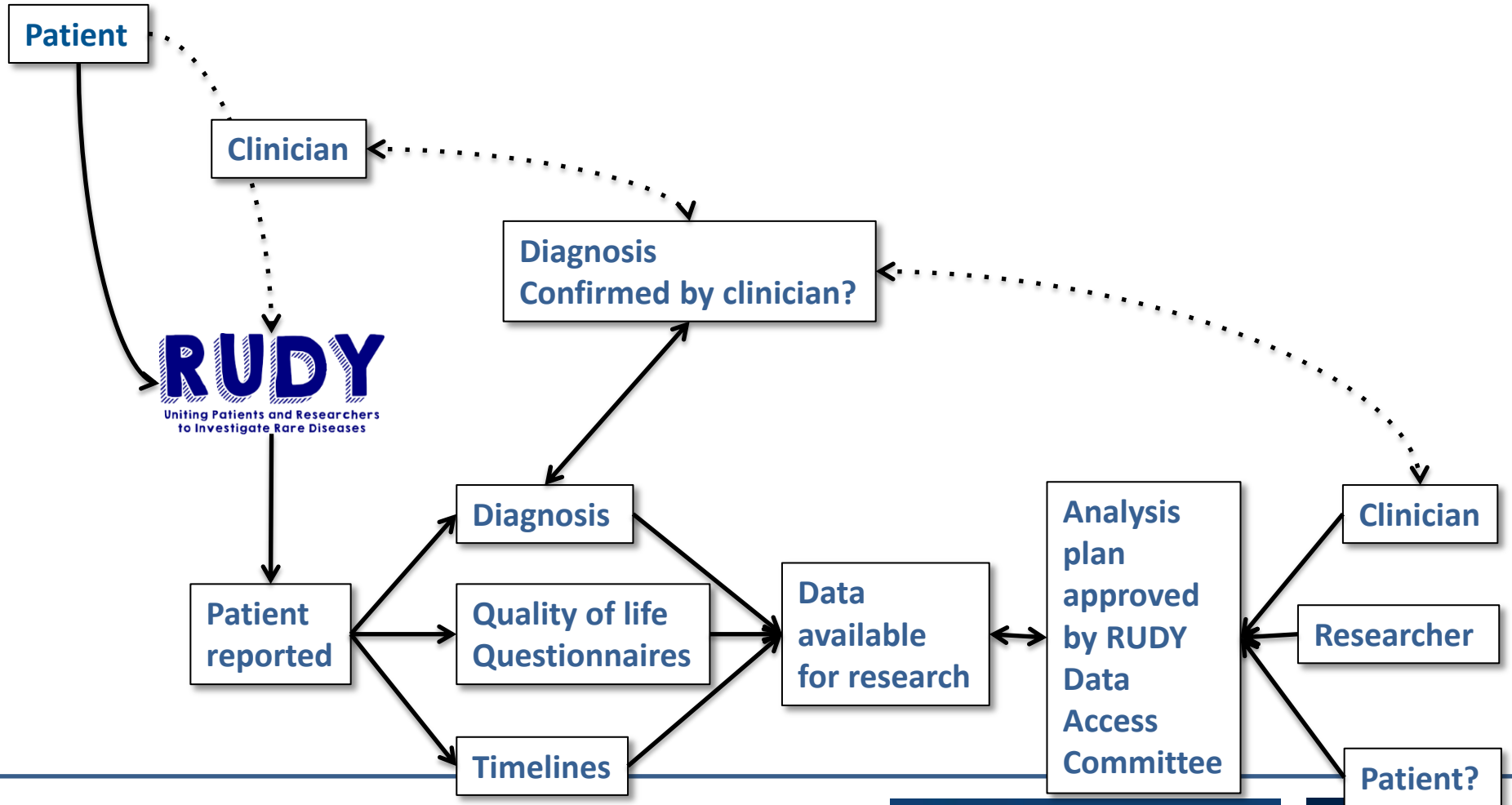
My Contribution to Research

The following are papers that have been published using your data.

Quality of Life

Using the RUDY study platform to capture quality of life of adults with rare diseases of the bone: *Preliminary findings*

RUDY Translational Pathway



Münchner Digital Health Summit
Munich, 30th November 2018
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3. What are the benefits of Dynamic Consent?

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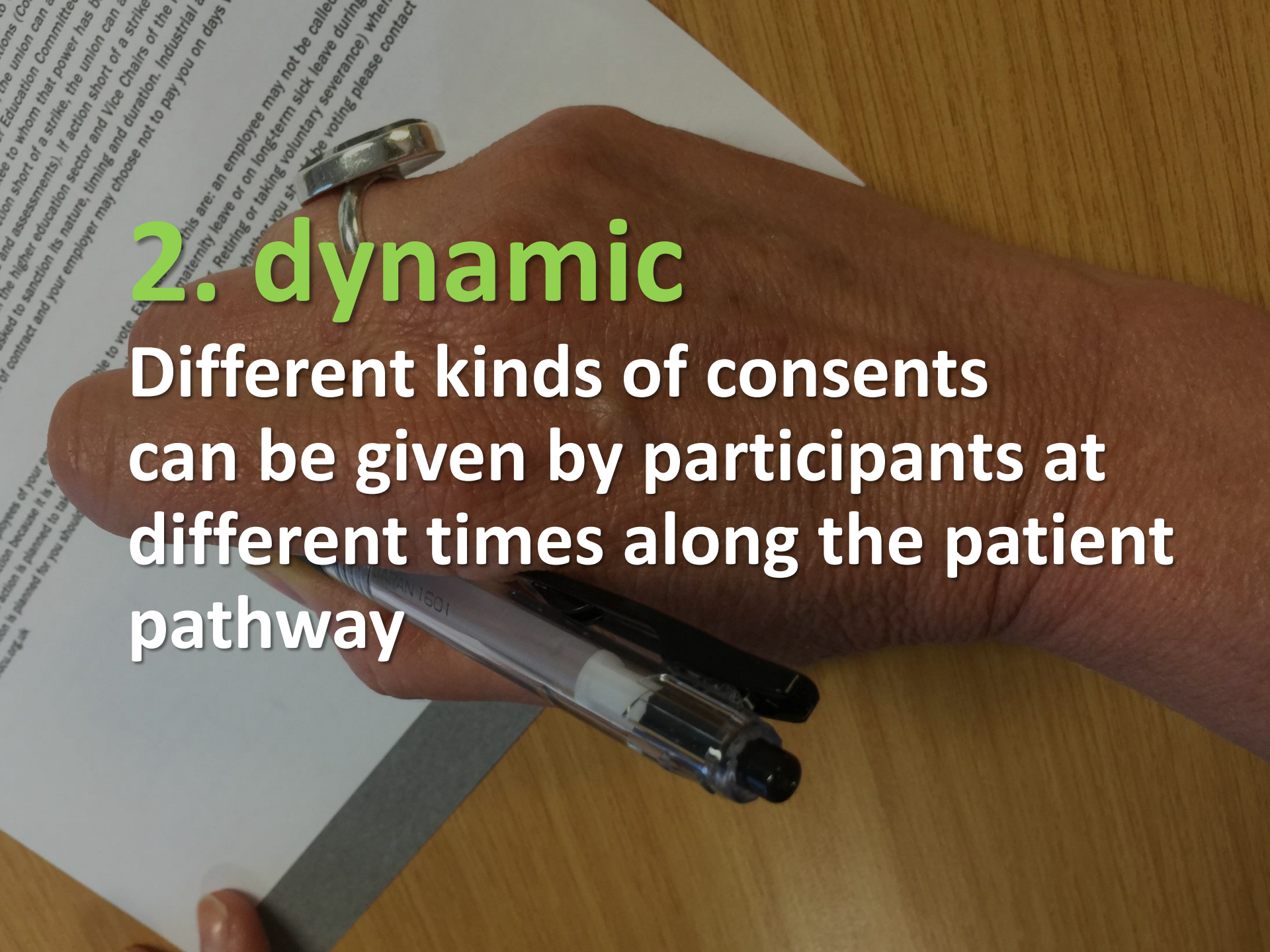
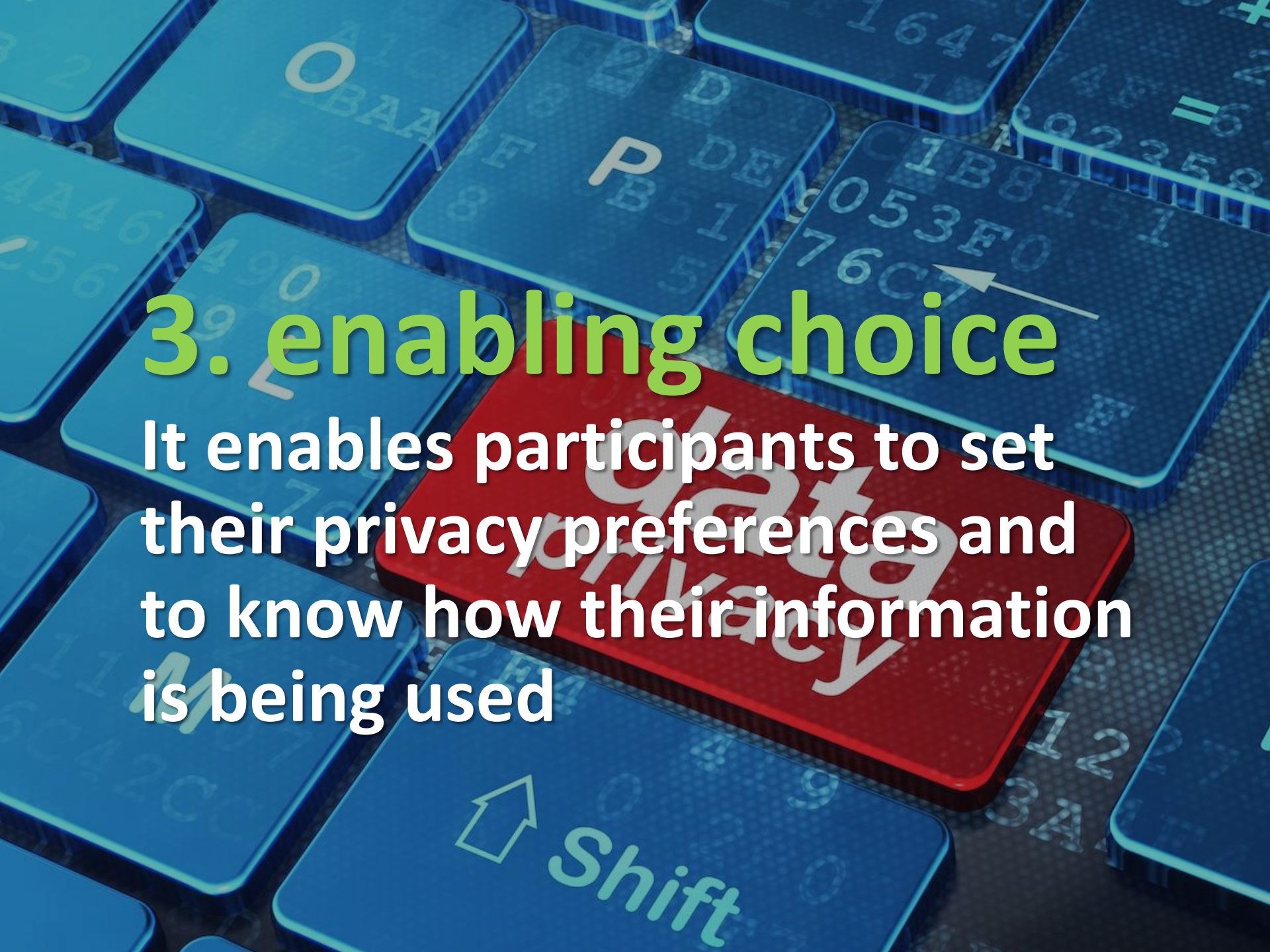
1.highest standards

It meets the highest international ethical and legal standards for consent in a world where data protection laws are in flux



2. dynamic

Different kinds of consents can be given by participants at different times along the patient pathway



3. enabling choice

It enables participants to set their privacy preferences and to know how their information is being used

4. tailored

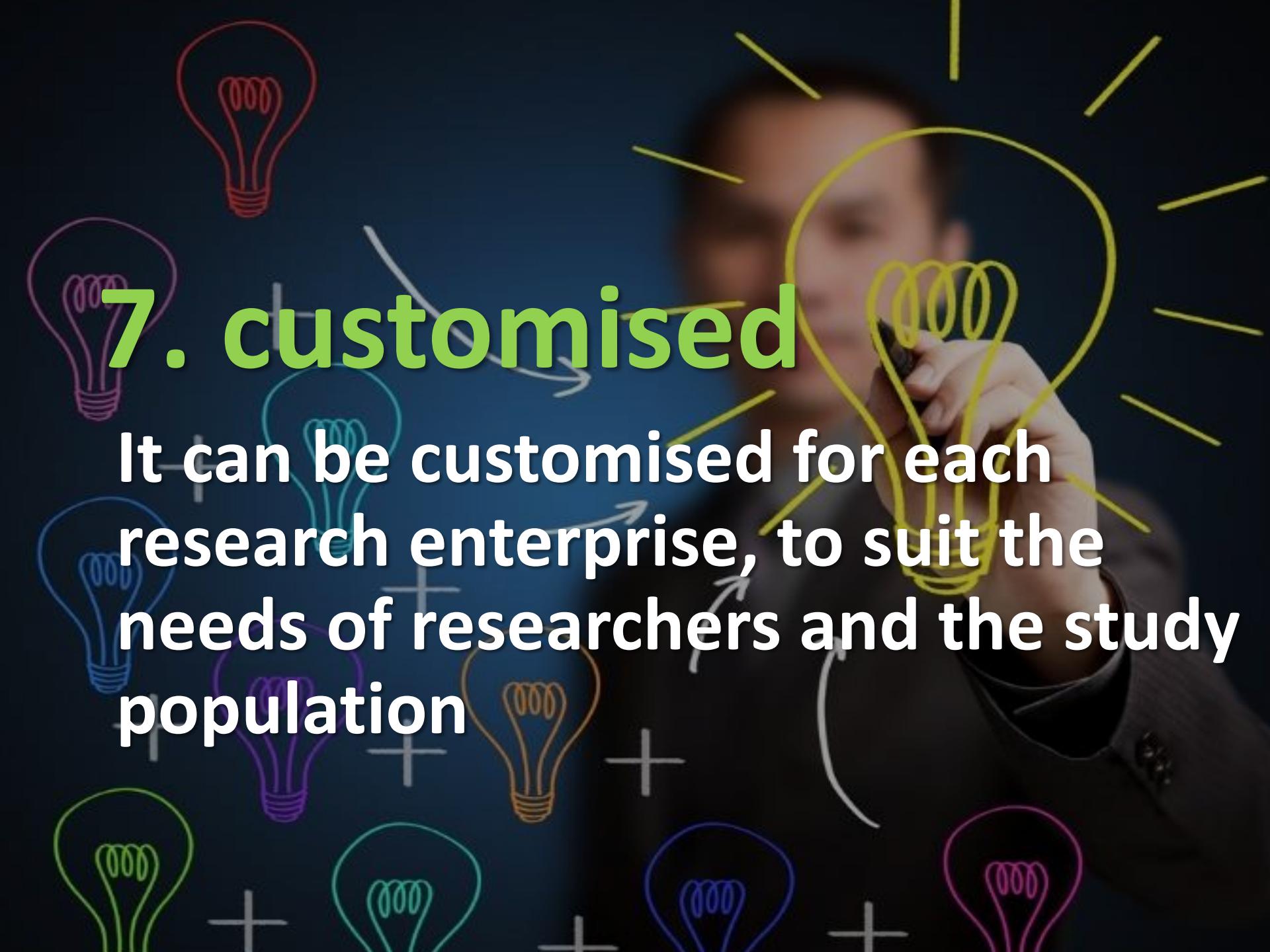
It can be tailored to participants needs so they can choose how, and when, they are contacted enabling activ involvement if desired

5. communication

It enables on-going communication and engagement throughout the lifetime of the research, so new consents and samples can be obtained

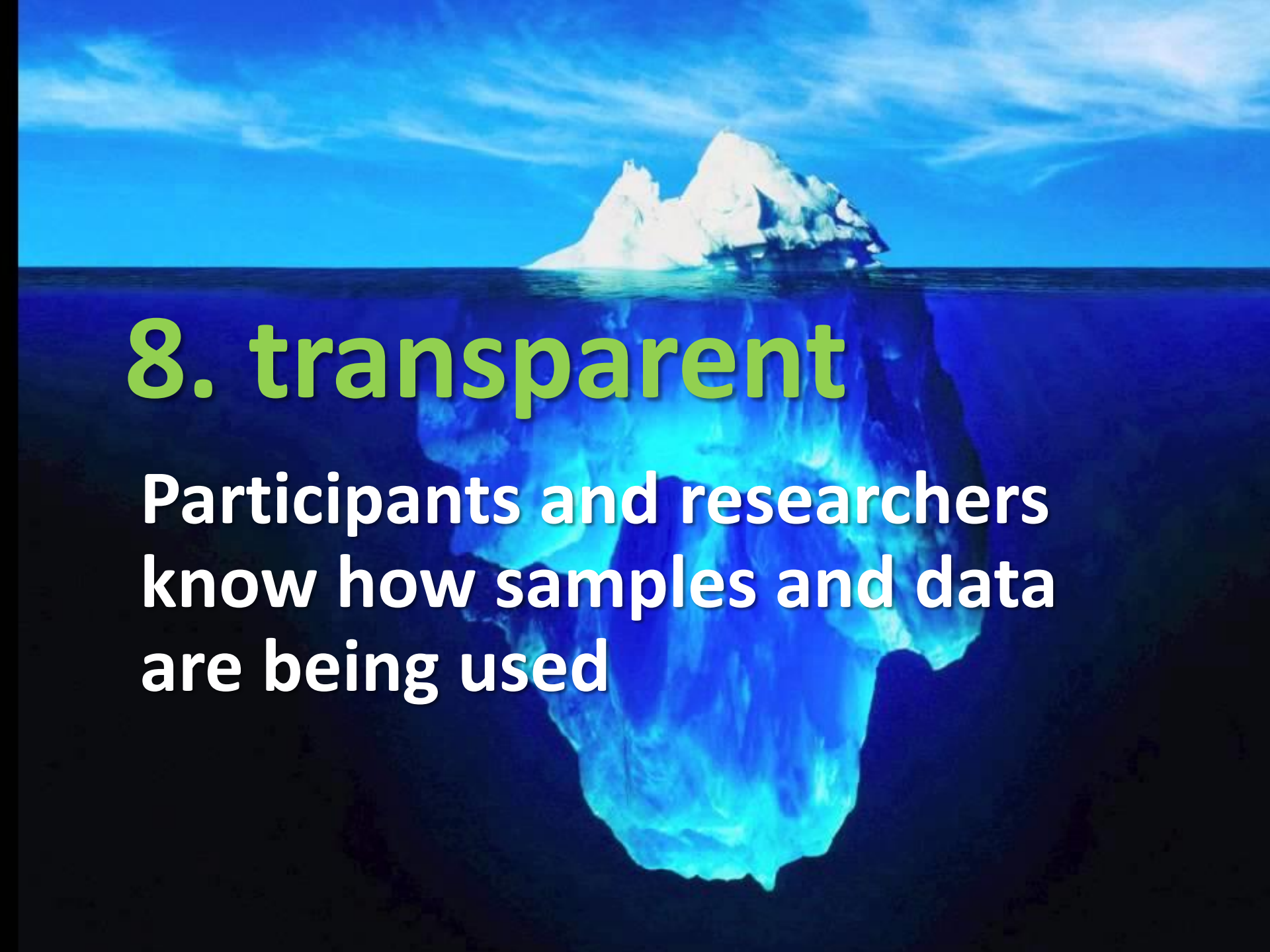
6. efficient

It simplifies and streamlines consent and recruitment processes, making them more responsive to changing circumstances



7. customised

It can be customised for each research enterprise, to suit the needs of researchers and the study population


8. transparent
Participants and researchers know how samples and data are being used

In conclusion

- Is one element on of a trustworthy governance system
- Addresses the inefficiencies of paper-based, physical consent interactions
- Provides the technical means to obtain a granular consent at various points along the translational pathway meeting different legal requirements
- Enables decisions made locally to be respected globally
- Provides a tool for ongoing communication and engagement
- Promotes translational research by bridging the divide between the clinic and research

Acknowledgements

- Team at HeLEX –Centre for Health, Law and Emerging Technologies (Melbourne and Oxford)
- Dr Kassim Javaid and the RUDY team
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- *Kaye etal* **Dynamic consent: a patient interface for twenty-first century research networks** *Eur Jour Hum Gene* (2015) **23,** 141–146;

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