# Regulatory and Ethics Breakout Summary

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# Access to Legacy Data + Research and the GDPR

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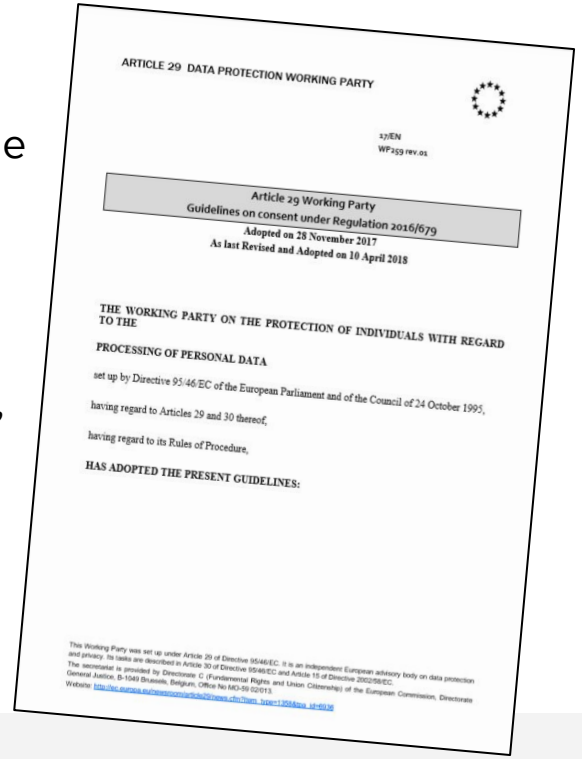
May, 2019

# Legal Bases for Data Processing (GDPR)

- Consent of the data subject
- Public interest
- Legitimate interests of the controller
- Data manifestly made public by the data subject
- Further processing for statistical or scientific research use (considered compatible with primary purpose of collection)

# EDPB-endorsed guidance of the A29WP

- Controllers processing data on the basis of consent “are not automatically required to completely refresh all existing consent relations with data subjects in preparation of the GDPR.”
- Fresh consent may be necessary if existing consents fall short of the GDPR’s standards, including:
  - Documentation demonstrating valid consent
  - Requirement of a “statement  or a clear affirmative action”
  - Mechanisms to easily withdraw consent
- But GDPR requirement to inform does not impair continued validity, under GDPR, of consent previously obtained under the Directive



ARTICLE 29 DATA PROTECTION WORKING PARTY

17/EN
WP259 rev.01

Article 29 Working Party
Guidelines on consent under Regulation 2016/679
Adopted on 28 November 2017
As last Revised and Adopted on 10 April 2018

THE WORKING PARTY ON THE PROTECTION OF INDIVIDUALS WITH REGARD TO THE

PROCESSING OF PERSONAL DATA

set up by Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995,

having regard to Articles 29 and 30 thereof,

having regard to its Rules of Procedure,

HAS ADOPTED THE PRESENT GUIDELINES:

This Working Party was set up under Article 29 of Directive 95/46/EC. It is an independent European advisory body on data protection and privacy. Its tasks are described in Article 30 of Directive 95/46/EC and Article 15 of Directive 2002/58/EC.
The secretariat is provided by Directorate C (Fundamental Rights and Union Citizenship) of the European Commission, Directorate General Justice, B-1049 Brussels, Belgium, Office No MO-59 02/013.
Website: http://ec.europa.eu/newsroom/article29/news.cfm?item_type=1358&tpa_id=6936

# ICGC-ARGO's Transition Tool

**Step 1**: Please answer the following questions[3]:

| **Is your data consented for:** | **Yes** | **No** |
|---|---|---|
| 1. Any approved future biomedical research? | | |
| 2. Deposit of open access fields datasets in open access databases? | | |
| 3. Deposit of controlled fields in controlled access databases? | | |
| 4. Linkage with other research datasets? | | |
| 5. International data sharing? | | |
| 6. Are there any restrictions to access by industry partners? | | |

ARGO Accelerating Research in Genomic Oncology
International Cancer Genome Consortium

**Step 2**: If the answers to all the above are **Yes,** your data can be used for ICGC-ARGO.
If any were **No,** please answer the following questions:

| | **Yes** | **No** |
|---|---|---|
| 1. Does your consent allow for re-contact of participants? | | |
| 2. Is it feasible for you to re-contact and re-consent your participants for inclusion in *ICGC-ARGO*? | | |

**Step 3**: If both answers to the above are **Yes,** please re-contact and re-consent.
If either or both are **No,** please answer the following:

| | **Yes** | **No** |
|---|---|---|
| 1. Is it possible for you to apply to an authorized local committee to obtain an ethics waiver of the re-consent requirement for participation in *ICGC-ARGO*? | | |

**Step 4**: If the answer to the above is **Yes,** please request a waiver per your local procedures.
If the answer is **No,** your data cannot be used for ICGC-ARGO.

# Legacy Data - Ethics Waiver

- If international data sharing is not foreseen in the consent, is **notification and opt-out**, or **re-consent** possible and practical? Otherwise:
- Conditions for a **waiver** from a research ethics committee:
  - Sharing of personal information is necessary,
  - Sharing has important social value,
  - Consent is impossible or impracticable,
  - Sharing does not contradict the known wishes of the individual,
  - Risk of adverse effect to participants is minimal,
  - Appropriate privacy safeguards are in place.

Sources: CIOMS, 2016; US Common Rule, 2017; Canada, Tri-Council Policy Statement, 2014 s 5.5A.

# Irish Health Research Regulation 2018

- Restrictions beyond those found in the GDPR
- Requires explicit consent for all new health research
- Requires pre-existing health research to obtain explicit consent by 30 April 2019
- Allows projects to apply for an exemption to this requirement, but this only applies to new research, not pre-existing health research which is ineligible for the exemption

# e-Consent,DynamicConsent

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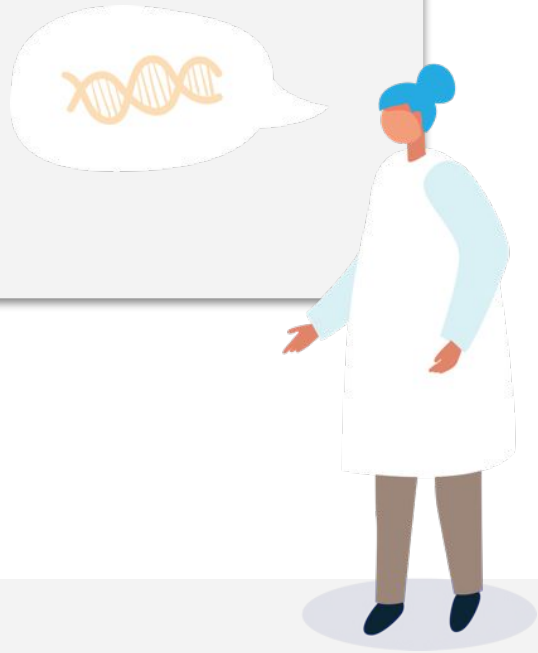
**Tiffany Boughtwood**
Australian Genomics
May, 2019



# Electronic Informed Consent ‘e-consent’

**Beyond** just an electronic representation of a participant’s consent documentation

+ enrich information materials
+ evaluation of understanding of the consent material
+ channel for participant communication / notification of study amendments
+ facilitate data management / reduce data entry

**Considerations**

Data protection, storage and archive

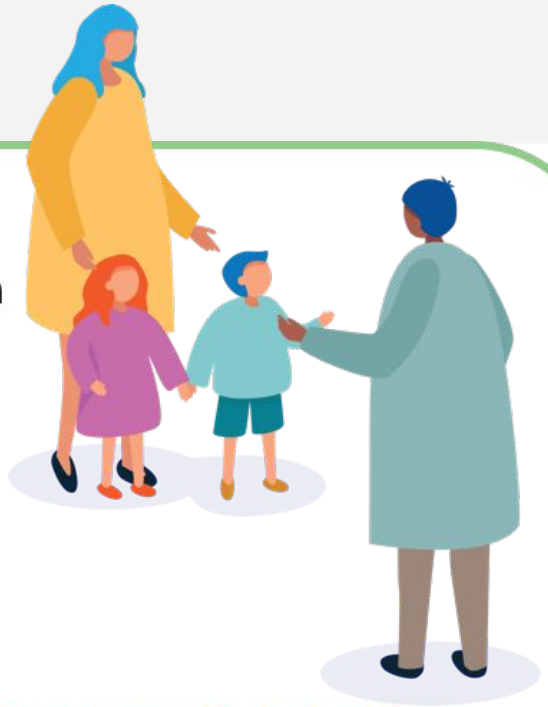
P to obtain consent remotely to include means of verification to determine identity

Ensure electronic signatures are legally valid within the jurisdiction

Management of mature minor consent – and transition to adulthood

Paper versions should always be available

# Dynamic consent



## The principle:

**Dynamic consent** is an emerging mechanism which enables study participants to provide consent and facilitates the ongoing management of clinical studies. It is a **"personalised, online consent and communication platform"**[1].

## The basics:

Consent preferences
Contact preferences

**…though the potential functionality is limitless**

[1]Kaye, J; Whitley, EA; Lund, D; Morrison, M; Teare, H; Melham, K (2015). "Dynamic consent: a patient interface for twenty-first century research networks". Eur. J. Hum. Genet. 23 (2): 141 6.

# Dynamic consent – aims and potential benefit

For **patients**, dynamic consent platforms aim to provide:

- more **appropriate, granular and flexible** consent options,
- access to **better study information**,
- opportunity to **increase scientific and medical literacy**, and
- two-way **communication** between participants and researchers, **building trust**.

For **research organisations**, dynamic consent facilitates:

- better electronic **consent records**,
- **retention of participants** in longitudinal studies,
- **clearer data sharing frameworks** for health information, and
- working toward addressing **ethical, legal & social issues** relevant to genomic studies.

# Dynamic consent – challenges

Factors **important to the user experience**[2]:

- Time involved in set up
- ID verification process
- Ease of navigation
- Likelihood of recommendation
- Preferences about online medical records

Populations enrolling are **less diverse** because it requires access to technology

**Reduces human contact** and face to face discussion in the consent process

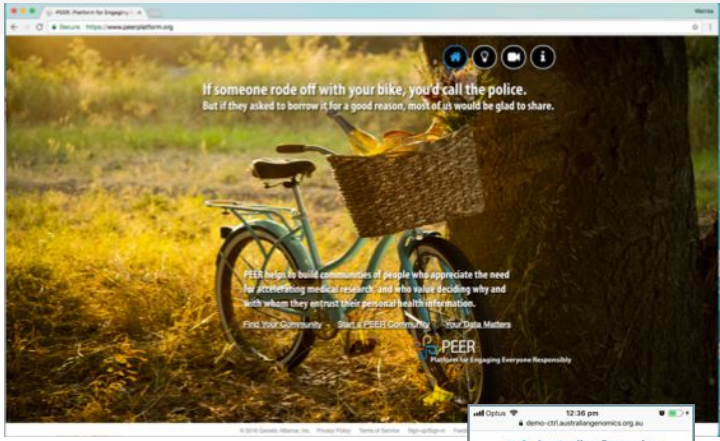
Participants may experience **'consent fatigue'**, a feeling of being over-burdened through ongoing contact

Individualising consent may lead to a **greater administrative burden**

[2]Thiel DB, Platt J, Platt T, King SB, Fisher N, Shelton R, et al. Testing an online, dynamic consent portal for large population biobank research. Public Health Genomics. 2015;18(1):26–39.

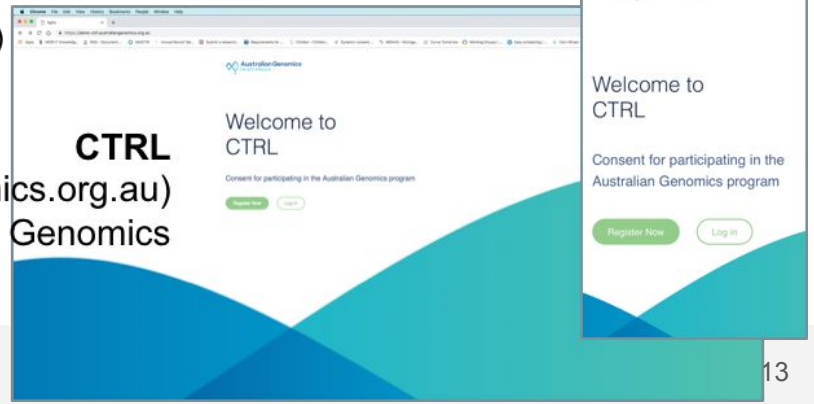
# Dynamic consent – examples of platforms


**RUDY**
(www.rudystudy.org)
Uni. Oxford




**PEER**
(www.peerplatform.org)
Genetic Alliance


**Biotrust**
(www.michigan.gov/mdhhs/)
Michigan DHHS




**CTRL**
(ctrl.australiangenomics.org.au)
Australian Genomics

# Research use of clinical (genomic) data

Experiences of
Genomics England/NHS and Australian Genomics

**Chris Patch and Clara Gaff**

"We estimate that over 60 million patients will have their genome sequenced in a healthcare context by 2025"

Birney, E., Vamathevan, J., & Goodhand, P. (2017). Genomics in healthcare: GA4GH looks to 2022. doi:10.1101/203554

# Why explore this?

**Initial need:** research consent which permits sharing of data

**Looming:** research use of (genomic) data created for the primary purpose of medical care

- Both Australian Genomics and Genomics England/NHS have experienced this shift, developing research participant consent and then designing clinical forms to address research use of genomic (and associated) data

- Aim: to stimulate discussion about the RE issues that arise and approaches taken in different countries to identify and better understand potential facilitators and barriers to the GA4GH mission of data sharing

# Evolving regulatory environments

## UK

- GDPR

## Australia

- Revisions to the NHMRC National Statement on Ethical Conduct in Human Research
- National Data Sharing and Release legislation

# Consent or not?

## NHS/Genomics England

A **new consent process** to record clinical and research choices in the form of a '**Record of Discussion**'

Addresses the need for transparency about data use and access within a national genomic data resource (National Data Guardian)

## Australian Genomics

A **consent form** for clinical testing which includes opt in/out for data sharing for research

Provides evidence that a consent process took place and prompts clinician discussion with patient

Accompanying information material for patients

# Examples of variation across countries

## NHS/Genomics England

Use in **germline and cancer testing** (where WGS commissioned)

Principle: National genomic data repository will be used to assist other people

> "I understand that the results of my test my have implications …for members of my family. I also understand that my results may be used to inform the health care of others. This would be done in away that I am not personally identified in this process"

## Australian Genomics

Designed for **germline use**

Builds on existing genetic consent

> "Where appropriate, results of this testing may be used for the healthcare of my family members.
>
> □ **Yes** □ **No"**

# Process

## England

NHS process

Partnership b/n NHSE and Genomics England

Engagement with clinicians, patients, participants, IM system developers,

Web-based task and finish group

Go live – Q3 this year. Integrated into clinical request workflow

## Australia

Australian Genomics process

Feeds into a new national government process

Draft developed after review of existing materials and development of recommendations.

Extensive open and targeted consultation (several rounds)

Currently being piloted with laboratories across 3 states

# Some considerations in operationalising

- Patient choices that can be recorded electronically (‘choice bundles’)
- Use of standards for manual entry into electronic systems
- Management of childhood to adult transition
- Withdrawal/alteration of choice
- How and where options selected will be recorded

# Data Access

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**Madeleine Murtagh**
*METADAC Chair*
*Newcastle University*

# Responsible, respectful, proportionate: graduated data access for complex, linked data - Overview

- Graduated data access; calibrated to potential data risks, sensitivity and/or ethical issues
  - Risks = privacy/disclosure, alienating participants, reputational damage to the study
  - Other ethical issues, e.g. RoR
- A mixed economy of data access governance
  - Tech mediated (potential) = Registered access; Light touch/administrative DAC;
  - Human mediated = Proportionate review; full DAC consideration
- Participant and public engagement
  - Participants involved in co-producing access policies and access decisions
  - Public communication
  - Impact = better decisions, more aligned with participant experiences, values and expectations

# Responsible, respectful and proportionate data access governance: an example of **graduated access for complex, linked data**

- METADAC - development funded by ESRC, Wellcome, MRC
  - Access model in development since 2010 (ACCC, pre-2014)
- Access for a growing number of UK longitudinal research studies
  - Deep phenotype data (social, economic, health, biomarkers, etc)
  - Successive waves over 20, 30, 60 years
  - Genomic data (genetic, epigenetic, exome, microbiome genetics)
- Graduated data access, calibrated for risk and sensitivity
- Calibrated to potential data risks, sensitivity and/or ethical issues
  - Privacy/disclosure
  - Alienating participants
  - Reputational damage to the study
  - Ethical issues, e.g. RoR

METADAC
www.metadac.ac.uk

# **Responsible**, respectful, **proportionate** data access: A mixed economy for complex, linked data

UK Data Archive

- Phenotype-only data - **Registered Access**
  - End user-licence
  - Special licence for higher risk data (e.g. small area geography) via study DAC

Sanger DAC/EGA

- Most genotype-only data – **Light touch/administrative DAC**
  - Checks researcher ID, project commensurate with consents, attestation to rules
  - Special licence for higher risk data (e.g. small area geography) via study DAC

METADAC

- Individual-level linked phenotype-genotype data, exome data - **human review**
  - **Proportionate** review (triage to sub-committee)
  - **Full DAC consideration** for sensitive, risky, controversial applications

INDIVIDUAL - CONSENT BASED

COLLECTIVE - CO-DECISION

# **Responsible**, **respectful**, proportionate data access

**Principles**

- Independence and interdisciplinarity
- Participant and public engagement

**How?**

- Study facing committee members
  - Participants of studies not governed under METADAC
  - Full voting members
  - Co-production of METADAC access policies, lead development of specific policies
- Public communication
  - Plain Language Summaries +++

COLLECTIVE - CO-DECISION

**What is the impact?**

- Better decisions, more aligned with participant experience
- Who knows better than participants, what will alienate participants?!

# International Context for Data Sharing

- GDPR (like it or not)
  - extraterritorial implication for international data sharing
- Legacy Data
  - as we move to clinical need, new approaches necessary
- Waiver
  - distinct from research ethics waiver
    - ?? no consent required if medical care

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