Does whole genome sequencing raise new challenges for RECs? – Legal Perspectives

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Does Whole Genome Sequencing present new challenges?

- Mostly it reframes existing issues, particularly about balancing autonomy and solidarity.
- However, some are brought into particularly acute focus.

Challenges? Practically, now.

- Direct to consumer marketing,
  - particularly in a social networking environment, when the data does not only concern the particular individual
  - Also with the blurring of research and medical use:
    - What will be available to the individual?
    - How will it be made available?

Challenges? Practically, now.

- Do traditional safeguards from ethics work?
- Anonymisation?
- Desirable?
- Possible?

- Separate medical use and socio-economic use (discrimination, +ve and –ve)

Challenges? Conceptually, now

- Have we sufficiently resolved the issues of commercialisation surrounding genetic information?
  - Who has a property claim to the information? (again, group nature of the data)
  - Will there be sufficient scrutiny of the informed consent contracts?

Challenges: Conceptually, future?

- Whole Genome Sequencing will increasingly become economically more attractive than multiple single tests

- This will yield enormous amounts of data that will be attractive not only to medical treatment, but also to research.
  - Can this amount of data be described as not excessive?
  - What is the relationship between treatment and research, and how will the interaction between researchers and medical professionals operate when the patient has increased as of right access to the data?

Our focus

- The collapsing distinction between data gathered for clinical and for research purposes

- The legal issues raised by the proposed data protection Regulation for research use of WGS originally gathered in a clinical context

A New Data Protection Landscape?

- Very much in the established line from 1980s, through 1995.
  - Similar *dramatis personae*
  - Separation of Duties and Rights
  - Legality of processing
  - Informing data subjects
  - Supervisory Authorities
  - Enforcement

Differences from 1995

- A Regulation not a Directive
- Best practice development by EC
- Specific definitions of genetic information
- Risk Assessment duties on Data Controllers
- Registration of risky processing (not all)
- Health and Research Routes more explicit
- Specific and Informed Consent

Regulation not Directive

- Directives have to be implemented by Member States
- Have some degree of discretion available
- 95/46/EC is not harmonised
- Regulations apply directly in Member State law
- Discretion available is centralised
- But, still local Supervisory Authorities
- Will the Regulation route survive?

Best Practice

- Throughout the Regulation, European Commission is empowered to identify and create best practice requirements
- Remains to be seen how these will be exercised (or if they will survive).
- Medical research community should push to be in the first round of these
- Collaboration with RECs

Specific definition of Genetic Information

- Directive 95/46/EC definition already very broad
- Clarity that genetic information is now clearly personal data
- But, will the definition effectively narrow the genetic information included?
- But, is tissue personal data, after *Marper*? This is not fully addressed in the Proposed Regulation

Risk Assessment

- Important development
- Exciting linkages to REC work for processing of data for medical research
- Data Controllers will have to make a specific risk assessment about the impact of the processing on the rights of the data subjects

- But, what will the expectations about the assessment be? EC best practice.

Registration of risky projects

- Currently all processing is registered
- Prioritising should strengthen the process
- (assuming that there will be spot checks on the risk assessments – but how will they be identified?)

Health and Research Routes more explicit

- Articles 81 (Health processing) and 83 (Research processing) make these routes more focussed
- For research, Article 6(g)&(h) are more important, arguably:
- Research is an explicit route to fair and lawful processing

Informed Consent

- Directive: Art. 7 – “Unambiguous” informed consent; Art. 8 – “Explicit” informed consent
- Cf. evidencing consent and the quality of consent
- Regulation: “freely given, specific, informed and explicit indication of his or her wishes by which the data subject either by a statement or a clear affirmative action signifies agreement”

The Data Protection Regulation

- Proposed successor to Data Protection Directive 95/46/EC
  - Establishes a number of conditions of ‘lawful processing’
  - These include according to Art 9(i)

    “processing is necessary for historical, statistical or scientific (…) purposes and subject to the safeguards contained within Article 83.”

Safeguards

- EC, under Art.83, may adopt delegated acts specifying criteria and requirements for research.

- REC approval *could* be specified as a requirement

- *In any case,* RECS role will otherwise be unaffected by Regulation

- *However ….*

Scope for Confusion: Meaning of Consent

- Regulation favours a particular kind of consent, that may be hard to satisfy in case of research using WGS:

> 'the data subject's consent' means any freely given specific, informed and explicit indication of his or her wishes by which the data subject, either by a statement or by a clear affirmative action, signifies agreement to personal data relating to them being processed;

- RECS are *not* bound to require *this kind of consent* – even if REC approval is an Art.83 condition

Need for clarity *by* RECs

- Proposed increase in institutional responsibility for ensuring data protection compliance
- Anticipated push away from consent as institutions advised not to rely on it to demonstrate lawful basis for processing
- If RECs require consent, then potential for researchers to be caught between institutional and REC demands
- RECs need to be clear
  A) What *they* mean by consent (in context of WGS)
  B) they are not requiring ‘consent’ as described by Regulation

Additional note on identification

- Sometimes approaching people for (even broad) consent requires a researcher holding more personal data than they need for the research

- Can imagine this being the case with WGS research, but Article 10:

> “If the data processed by a controller do not permit the controller to identify a natural person, the controller shall not be obliged to acquire additional information in order to identify the data subject for the sole purpose of complying with any provision of this Regulation.”

- Potential for tension if RECs require researchers to hold identifiable data that the Regulation suggests that “they shall not be obliged to acquire”

Summary: an opportunity/ need for closer working?

- Article 22(3) requirement upon institutions and suggestion of ‘external audit’ of activity

- Work together to ensure

  - It is understood (‘REC’) ‘consent’ can have a different meaning from that set down within Regulation

  - internal institutional pressures *away from consent* do not conflict with any REC pressure for consent

  - Pressure to contact does not conflict with requirement not to hold more information than is necessary.