The EU Framework Programme for Research and Innovation

HORIZON 2020

Ethics Review Data Sharing – Bridging Legal Environments

Dr Joana Namorado

Health Strategy Unit
DG Research and Innovation
European Commission
Overview

1. How is EU Research Policy designed?
2. Vision, legal basis, rules, procedures
3. Why this Ethics Review?
4. Breakdown of the Ethics Procedure
5. Data Privacy: a New Framework
6. Conclusion: Ethics – an advantage
Unromantic but essential

Ethics in Science and Health Research:
All the projects need to have a uniformly excellent ethics from beginning to end of the research.

Quality:
Research that demonstrates scientific, technical and managerial quality will have Ethics on an equal level.

_Demonstrates scientific purpose and technical ambition and foresight_
How is the EU policy implemented?

European Commission → Council of Ministers → European Parliament

FP Regulation

Calls for proposals → Work Programmes

Researchers

European Commission
Risk as legal hazard

Ex-post: some disadvantages
- Implies large budget provisions for lawsuits/litigations
- Internal review processes have NO VALUE in court
- Risk for researchers of being blocked by third parties – even at publication stage (cf. avian flu case)
- Advantage – no expense, might get away with it, but no deniability

Risk anticipation and mitigation

Ex-ante: advantages
- Unique process implemented by EU
- Identifies the issues, the risks
- Offers processes/solutions to mitigate them
- Protects the researcher, the project and the funding bodies

Disadvantage – perception of and expense
- Requires risk management procedures
- Minimizes adverse impact
- Large budget provisions for lawsuits/litigations
Results of the ex-post approach

According to the lawsuit, the University of Utah incurred $3.3 million in costs to remedy the security breach.

"full responsibility for a series of anomalies in data handling, analysis and management that have come under scrutiny in the past months."
Why *this* EU Ethics Review

- No funding for research forbidden in all MS and no funding in a MS where research is forbidden
- Support for initiatives that contribute to coordination & rationalisation of research with a responsible ethical approach
- Scientific evaluation and ethics review
- Approval on a case by case basis by Member States
The role of the European Commission in research (RTD)

1. As Policy maker
   • European Research Area
   • 3% of GDP spent on R&D

2. As Funding agency
   • EC manages 6% of total public R&D investment in the EU (through the multiannual Framework Programme)
   • Supporting research done by multi-national, multi-disciplinary teams in pre-defined thematic areas (e.g. Health)

3. As a Regulator
   • EC proposes legislative initiatives RTD –
   • Provides scientific evidence to Commission houses EGE (foresight)
   • Piloting revision of existing legislation
Ethics intensity low – simple management

- Project – one participant, few ethics issues – basic research
- Project – one participant, many issues – ERC, REA
- Project – multiple participants, few ethics issues
- Project – multiple participants, many ethics issues – RTD
- Project – multiple participants, many ethics issues, in many states – HEALTH

Ethics intensity High – Management of Risk
Main steps of the Ethics Review follow-up process

1. After scientific evaluation
2. Ethics Review conducted in Brussels by ethics experts
Ethics Process in Horizon 2020
Rules and legislative basis

**Specific FP (H2020)**
- H2020 Regulation: Article 19 "Ethical principles"
- Rules for Participation: Article 13 "Ethics Review"
- Inclusive practice
- Grant Agreement (GA): Article 34 "Ethics"

**Special focus hESC, Gene manipulation and Data**

**But also…..**
- Treaties (TEU, TFEU)
- Charter EU
- Rules for Participation: Article 13 "Ethics Review"
- Grant Agreement (GA): Article 34 "Ethics"
- Specific Regulations
- Specific Directives
- Decisions
- International Agreements and Conventions
- And
- The Staff Regulation
Setting the Stage for Ethics in Science: The basis

- Issues?
- Actions?
- Legal docs?
- Practical steps?
- Can we do better?

**The Particular case of ICT in HEALTHCARE**

- Data often electronic, Collected, stored, processed, in e-format
- Nature of Data – Polymorphic, patient, personal, contextual, pathology, etc
- Interpretation – What is sensitive and personal – IT is a whole PROFILE
- Use, re-use, save, merge, derive, re-merge, move, migrate
- Can we delete?
Data Protection Directive to Regulation?

- One rule for EU – "One stop shop"
- One only DPA for each subject
- National DPAs valid through the EU
- National DPAs outside the EU
- Consent explicit rather than implicit
- Easier access to own data
- A 'right to be forgotten'
- EU rules apply to PD abroad when service provider is active in the EU
- DPA authorities can fine violation of EU rules
- Penalties up to €1 million or 2% of global annual turnover
- The rules will apply to both domestic and cross-border transfers of data
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The Public trust as "consumers"

But hesitate to share as Citizens?

- Data quality, collection, storing, mining need à priori ethics for confidence
- Privacy data sharing policies at the centre of Research generates trust
- ER of projects - important for trust
- Collaboration doesn't equal complication
- Trust on Data protection directive now transferred to new Regulation
- Proof of compliance favours clarity
- Public cannot accept failure in this
Flexible Orchestration

All parts of ethics fit together seamlessly

All the projects have ethics from beginning to end of the research and the unknown is part of science

Quality:
Research demonstrates quality of Ethics on an equal level with science and budget

Demonstrates purpose, technical ambition and foresight
Sharing Data in EU – a paradigm?

• Big data for research and health care – the ethical way to go

• Personal data (private by default) in the EU Charter no way around it

• EU GDPR (May 2018) mirrors Data Protection Directive (95/46/EC)…but

• Data protection enforced by EU ethics review

• Generated TRUST within EU- respect for ownership

• Ethics compliance as condition for funding
Big Data – Challenge and Opportunity

- Ethics oversight for Big data in research – challenge because
  - processing of data
  - anonymization techniques
  - special conditions apply for transfer outside EU

- Protect good research and support the researchers

- Ethics from start
  - the use of new mining algorithms to
  - ensure ownership
  - Research cannot alter principles, standards and regulations

- Conditions a new context, opportunities

- But needs an imaginative solution
  - Ethics as honest broker?
Thank you

CDMA 02/178
B-1049 Brussels/Belgium
+32 2 29 85466
joana.namorado@ec.europa.eu
http://ec.europa.eu/research
Research and Innovation Challenge

- Health systems, information databases are diverse and fragmented
- Same for many health research databases
- Data formats, analysis, and transfer heterogeneity leads to incompatibilities
- Health data sharing is necessary for reliable data for research and health policies
Opportunity: Ethical use of data is possible

- Big-data researchers should have safe technical/methodological tools for:
  - Storage
  - Maintenance of quality data in repositories and databases requires the active management of data over its lifecycle: collection, cleaning, transformation (metadata), validation and preservation
  - Analysis for new solutions (big-analytical tools and computational methods to combine heterogeneous data making sense of it)
  - Usage/Share: making it usable & exploitable by a variety of actors.

But maintaining privacy by default

- Consequences of Privacy by Default not all joy

- Compliance with the European Legislation, means more European storage capacity structured in conformity.

- Ethics platform - An honest broker/gatekeeper and arbitrar of Fairness?