# Data protection regulation

**Viviane Reding in 2012:**



**”The Directive 95/46 EC have stood its test” !!**

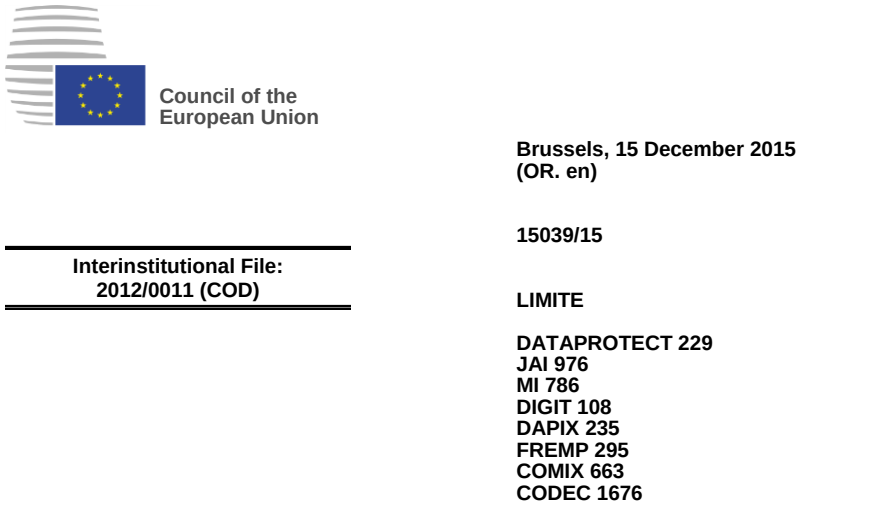
**Heterogeniety** – research obstacles – definition problems improved?

EP –”**informed consent**” vs EC & European Council “**derogations & pseudonymisation**”

**Public health research**: Can we monitor populations and link large data bases

# GDPR – General Data Protection Regulation

- Commission proposal 25. January 2012
- Political consideration until December 2015
- Final adoption 2. quarter 2016
- 2 year and 20 days implementation period (25/5 2018)



Council of the European Union

**Brussels, 15 December 2015**
**(OR. en)**

**15039/15**

**Interinstitutional File:**
**2012/0011 (COD)**

**LIMITE**

**DATAPROTECT 229**
**JAI 976**
**MI 786**
**DIGIT 108**
**DAPIX 235**
**FREMP 295**
**COMIX 663**
**CODEC 1676**

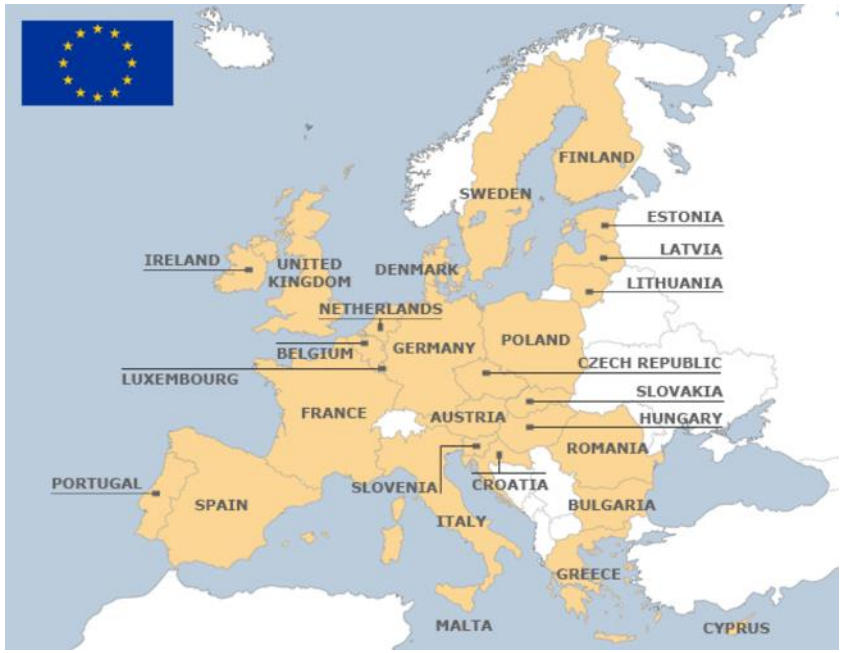
**NOTE**

| | |
|---|---|
| From: | Presidency |
| To: | Permanent Representatives Committee |
| No. prev. doc.: | 9565/15, 14936/15, 14901/15, 14902/15 |
| No. Cion doc.: | 5853/12 |
| Subject: | Proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) [first reading]<br>- Analysis of the final compromise text with a view to agreement |

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32016R0679

# Purpose

- Harmonisation of EU data protection legislation
- Improve individual rights and control over their own data
- Increase / maintain confidence in online services
- Update the existing Data Protection Directive of 1995 to a Regulation




*How will harmonisation impact public health and clinical research?*

# The GDPR - downsides

- The trialogue between the EC, EP and Council did not reach full harmonisation – in clauses related to scientific research.
- **Many research exemptions are left to Member States**
- Ambiguity bewteen:
  - Individual control
  - And concept of ”public interest”
- Research is not defined! – (and is not always in public interest)
- **Complex legislation**
- 99 articles and 173 recitals
- Recitals important for interpretation of articles

# Does one size fit all?

# What is Privacy?

- In the EU, human dignity is recognised as an absolute fundamental right.
- In this notion of dignity, privacy or the right to a private life, to be autonomous, in control of information about yourself, to be let alone, plays a pivotal role. Privacy is not only an individual right but also a social value.
- The right to privacy or private life is enshrined in the Universal Declaration of Human Rights (Article 12), the European Convention of Human Rights (Article 8) and the European Charter of Fundamental Rights (Article 7).
- Almost every country in the world recognises privacy in some way
- **Privacy is recognised as a universal human right while data protection is not – at least not yet.**

# What is Data Protection?

- Data protection is about protecting any information relating to an identified or identifiable natural (living) person including:
  - names, dates of birth, photographs, video footage, email addresses and telephone numbers.
  - Other information such as IP addresses and communications content - related to or provided by end-users of communications services - are also considered personal data.
- Aims to ensure the fair processing (collection, use, storage) of personal data by both the public and private sectors.

# Privacy, data protection and security

- In the EU, privacy and data protection are not absolute rights and can be limited under certain conditions according to the EU Charter of Fundamental Rights.
- The rights may need to be balanced against other EU values, human rights, or public and private interests (e.g. freedom of expression, freedom of press or freedom of access to information).

# GDPR recital citation

- (10)
  - ”ensure high level of protection of natural persons”
  - ”remove the obstacles to flows of personal data in EU”
  - ”Member States (MS) allowed to maintain or introduce national provisions in application of the rules of the Regulation”
  - MS ”margin of manuevre to specify rules for processing of special categories of personal data (sensitive data)”

# GDPR recital citation

- (15)
  - ”the protection of natural persons should be technological neutral”
  - ”files (and their coverpages) not structured according to specific critieria should not fall within the scope of this Regulation”
- (26)
  - ”Principles of data protection apply to any information on an identifiable natural person”
  - ”Pseudonymisation should be considered information on an identifiable natural person”
  - ”to be identifiable account should be taken of all means reasonable likely to be used –to identify the natural person directly or indirectly” –”taking cost, time and technology into consideration”

European Court of Justice 2016 – does not need to be zero

# GDPR recital citation

- (26 –cont)
  - ”Data protection should not apply to anonymous information – such a manner that the data subject is not or no longer identifiable”
  - The Regulation does not concern anonymous information, including for statistical or research purposes”
- (33)
  - ”Data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with ethical standards”
- (34) Genetic data should be defined as personal data
- (35)”Personal data on health include all data (past, current and future) pertaining to the health status of the data subject”

# General principles – recital (39)

- Lawfulness, fairness and transparency
- Purpose limitation (specified, explicit and legitimate purposes) *
- Data minimisation (adequate, relevant, limited to the necessary)
- Accuracy (kept up to date)
- Storage limitation (identification of data subjects for no longer than is necessary for the purposes) **
- Integrity and confidentiality (ensures appropriate security of the personal data) including preventing unauthorised access

* Scientific, historical, statistics is compatible with any purpose

** Scientific, historical, statistics can be stored longer

# GDPR recital citation

- (42) **”Processing based on consent – the controller should be able to demonstrate this”**
- (50) ”Processing personal data for purposes other than the initial- allowed if compatible with the intial purpose”
- (52) ”Derogation for special categories of data– health purposes, public health, managing health care, archiving, scientific or historical research or statistical purposes”
- (53) ”MS allowed to introduce further conditions, incl. limitations to processing of genetic, biometric and health data, not hampering the free data flow when it apply to cross border processing of such data”

# GDPR recital citation

- (61) The data subject should be given information on processing at the time of data collection or obtained form another source (within a reasonable period)
- (62) The above obligation is not imposed if the person already have information, if it is laid down in law or if information is impossible or involve a disproportionate effort
- **(82) To demonstate compliance with the Regulation records must be maintained on processing activties – and be available to the supervisory authority (DPA) on request**

# Recital citation

- (102 & 103) MS (national) and/or EC (EU in total) may decide that a third country, territory, or an international organisation offer adequate level of data protection. In such cases transfers of personal data ,may take place withtout the need for further authorisation.

- [at present DPA must accept a transfer and dictate terms to be specified in the DTA – safeguarding the level of protection and control of the personal data]

# Recital citation

- (156)
  - Processing personal data for archiving in public interest, scientific, historical or statistical purposes should be subject to appropriate safeguards
  - Further processing (of the above) is to be carried out when the controller has assessed that processing do not or do not longer permit identifaction of data subjects and appropriate safeguards exists (e.g. pseudonymisation)
  - MS are authorised, subject to safguards, derogations to processing, - data portability, archiving in public interest, scientific,historical or research purposes.
  - Propotionality and necessity principles apply, and processing for scientific purposes should comply with other relevant legislation e.g. clinical trials

# Recital citation

- (157)
  - Coupling information rom registries – researchers can obtain new knowledge of great value for medical conditions
- (158)
  - **The Regulation should not apply to deceased persons**
- (159 - 160)
  - **Where personal data are processed for scientific or historical research purposes this Regulation should also apply to that processing**

# Articles

- Article 6: Lawfullnes of processing (no change)
- Article 7: Conditions for consent (no change)
- Article 8: Child’s consent
- Article 9: Processing of special categories of personal data:
- 1.The processing of personal data, revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of **genetic data, biometric data** in order to uniquely identify a person or **data concerning health or sex life** and sexual orientation **shall be prohibited**.
- Paragraph 1 shall not apply if one of the following applies:

# Paragraph 1 shall not apply if one of the following applies: a-i

a. Explicit consent is given

i. processing is necessary for archiving purposes in the public interest, or scientific and historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

# Article 89 – derogations from other Articles

- Article 5:Principles to processing of personal data
  - (e) – no purpose limitation, no storage limitation
- Article 9:Processing of special categories of data
  - (i,j) Public health, research,scientific,historical,statistical
- Article 14:Information to data subjects on data obtained from other than the data subject.
  - -.5 (b) impossible, disproportionate.
- Article 15: Right of acces by data subject
- Article 16: Right to rectification
- Article 17: Right to be forgotten
  - 17.3 (d) – research, scientific,statistical (avoid bias)

# Article 89 – derogations from other Articles

- Article 18: Right to restriction of processing
- Article 19: Right to recieve notification on rectification/erasure
- Article 20: Right to data portability
- Article 21 – Right to object

# GDPR and  cancer registries

- **Legal basis** – need to be documented - the right to hold data
- **Notification** – observe use, not indicated at collection – and
- **Proportionality** – is it possible or needed to inform data subject
- **Processing types** – need full description and monitoring (Log)
- **Third parties** – DTA for documentation if personal data
- **Anonymous data** – minimise to needed – remove possibiliy for indirect or direct identifaction – full description on what is done by whom for what.
- **Security** – separate ID and data, Psuedonyminise, access control, limited access to personal data to those that need access – monitor - log

# GDPR and cancer registries – data controller/processor

- Controller – the entity deciding purpose and means of data processing.
- Processor – the entity that processes data on behalf of the controller
  - The processor need not a legal basis (article 6 or 9)
- **A controller processor agreement is required (article 28)**

# Cancer registries and Data Protection Impact Assessment (DPIA)

- DPIA needed when large amount of personal data are processed (article 35)
- DPIA is a self-assessment with the DPO taking the view of data subjects into account (article 35.9)

- If in doubt of the risks can be sufficiently averted the DPA should be consulted (article 36)

Beware confidentiality issues and data protection may impeed the possibility to function and to do research!