

# The European Data Protection Regulation and research

Sharing government administrative data: new  
research opportunities

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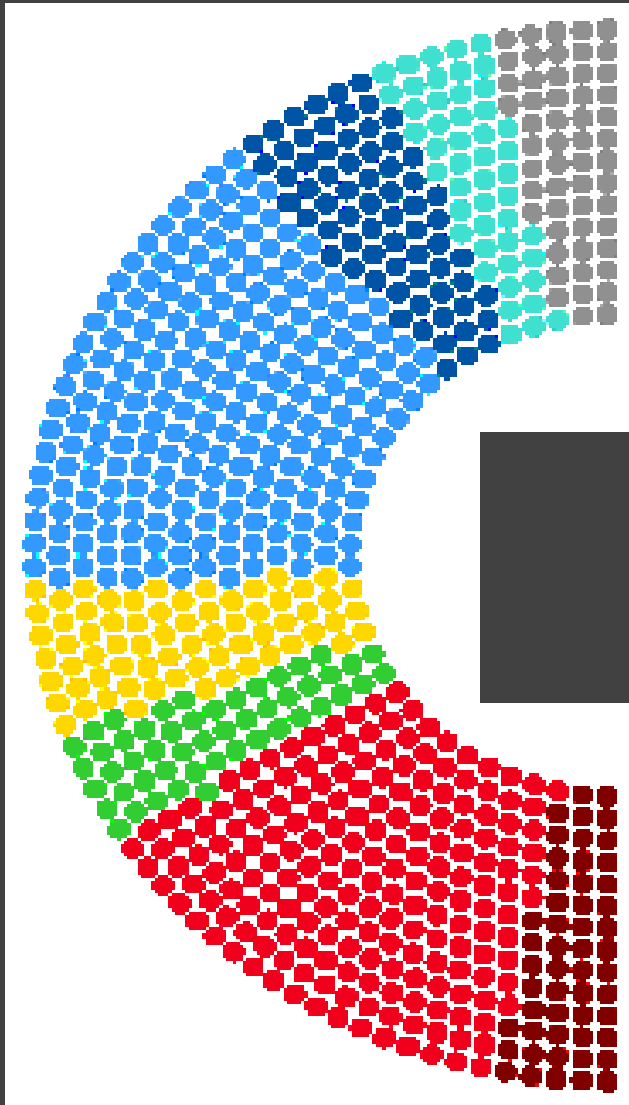
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# Background to the Regulation



- Proposal from Commission in January 2012
- Regulation = directly binding
- Broad scope
- Consent must be specific, explicit and informed
- Exemption from consent for the use of personal data in research

# The European Parliament's position



- Compromise amendments negotiated from over 3000 tabled
- Political context
- European Parliament adopted amendments in March 2014 in a 'block vote'
- Damaging research amendments
- Support for research in plenary debate

# Amendments: scientific research



- Narrows research exemption
  - > could not rely on exemption for identifiable data
- Removes concept of ‘further processing’
  - > could not rely on legal basis used for collection or initial use
- Brings pseudonymous data in scope of the Regulation
  - > rules would apply to more data than at present

# Amendments: data concerning health



- Introduces requirement for specific consent
  - Enables Member States to create an exemption from consent. But only:
    - for pseudonymous data;
    - in “high public interest”; and
    - where the research “cannot possibly be carried out otherwise”
- > Would prevent use of identifiable health data without specific consent
- > Would limit use of pseudonymous health data without specific consent

# The Council's position



- Council of Ministers still considering Commission's proposal
- Tentative agreement on one chapter of 11 so far
- Unclear when Council's position ('general approach') will be agreed
- More favourable position on research?


# Further information

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4(2) **'personal data'** means any information relating to an *identified or identifiable natural person* ('data subject'); *an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, unique identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social or gender identity of that person;*

4(2a) **'pseudonymous data'** means *personal data that cannot be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organisational measures to ensure non-attribution;*





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## Article 81

### Processing of personal data concerning health

*1b. Where the data subject's consent is required for the processing of medical data exclusively for public health purposes of scientific research, the consent may be given for one or more specific and similar researches. However, the data subject may withdraw the consent at any time.*

*1c. For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Directive 2001/20/EC shall apply.*



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## Article 81

### Processing of personal data concerning health

2. Processing of personal data concerning health which is necessary for historical, statistical or scientific research purposes, *such as patient registries set up for improving diagnoses and differentiating between similar types of diseases and preparing studies for therapies, is shall be permitted only with the consent of the data subject, and shall be* subject to the conditions and safeguards referred to in Article 83.



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## Article 81

### Processing of personal data concerning health

*2a. Member States law may provide for exceptions to the requirement of consent for research, as referred to in paragraph 2, with regard to research that serves a high public interests, if that research cannot possibly be carried out otherwise. The data in question shall be anonymised, or if that is not possible for the research purposes, pseudonymised under the highest technical standards, and all necessary measures shall be taken to prevent unwarranted re-identification of the data subjects. However, the data subject shall have the right to object at any time in accordance with Article 19.*



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## Article 83

### Processing for historical, statistical and scientific research purposes

1. *In accordance with the rules set out in this Regulation*, personal data may be processed for historical, statistical or scientific research purposes only if:

- (a) these purposes cannot be otherwise fulfilled by processing data which does not permit or not any longer permit the identification of the data subject;
- (b) data enabling the attribution of information to an identified or identifiable data subject is kept separately from the other information ***as long as these purposes can be fulfilled in this manner under the highest technical standards, and all necessary measures are taken to prevent unwarranted re-identification of the data subjects.***