

My Health Data - Your Research
Some preliminary thoughts on different values
in the General Data Protection Regulation

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My Background



Conflicting Values

The diagram consists of two large, white, arrow-shaped boxes pointing towards each other, set against a black background. The left arrow points right and contains the text 'Patient Autonomy'. The right arrow points left and contains the text 'Research Interest'. The two arrows meet at a central point, creating a visual tension between the two values.

Patient
Autonomy

Research
Interest

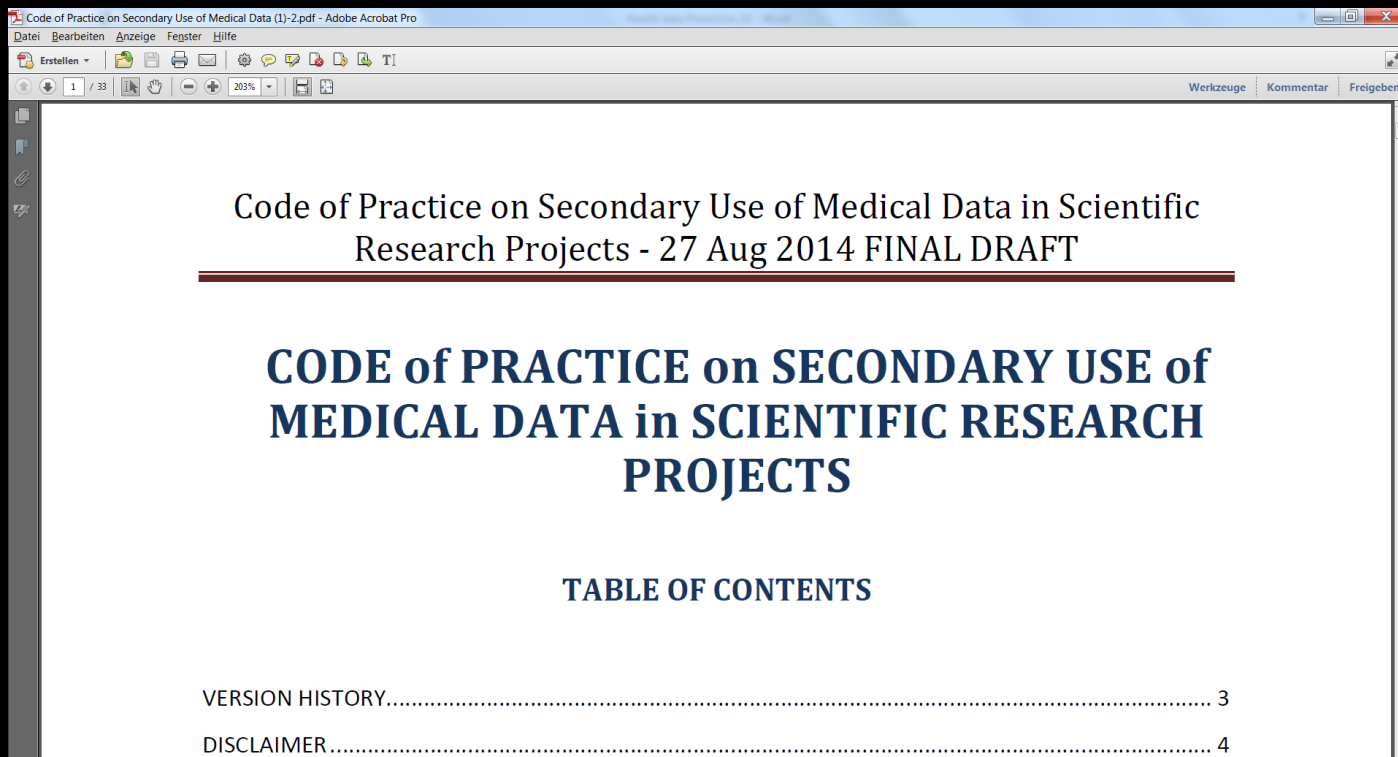
Lessons Learned

- Issues of data sharing are underestimated in the proposal phase and overestimated in the project phase
- Legal compliance with data sharing rules is a moving target
- Data Protection is a weapon of mass destruction
- Informed Consent is not a universal solution
- Anonymisation neither
- Everybody has an opinion (and is willing to blame the lawyer)

Existing legal framework

- Directive 95/46/EC
- 28 different member state laws
- 28 different interpretations of research exemption
- 28 different answers on a fundamental conflict of values
- 28 different answers on ‚personal‘ in personal data

Recent Development (Example)




„Recent“ Development: Upcoming legal framework

Regulation_Data Protection_Proposal_com_2012_11_en.pdf - Adobe Acrobat Pro

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Leseseichen

- 1. CONTEXT OF THE PROPOSAL
- 2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT
- 3. LEGAL ELEMENTS OF THE PROPOSAL
 - 3.1. Legal Basis
 - 3.2. Subsidiarity and proportionality
 - 3.3. Summary of fundamental rights issues
 - 3.4. Detailed explanation of the proposal
 - 3.4.1. CHAPTER I - GENERAL PROVISIONS
 - 3.4.2. CHAPTER II - PRINCIPLES
 - 3.4.3. CHAPTER III - RIGHTS OF THE DATA SUBJECT
 - 3.4.3.1. Section 1 – Transparency and modalities
 - 3.4.3.2. Section 2 – Information and access to

 EUROPEAN COMMISSION

Brussels, 25.1.2012
COM(2012) 11 final
2012/0011 (COD)

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)

- Parliament
 - Albrecht: 350 amendments
 - Other MEPs: 3133 amendments

Key articles

Art. 7

Art. 2 - Personal Data

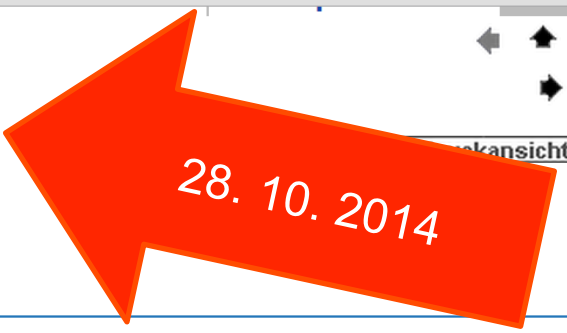
Health

Research

Siehe auch: [Urteil des VI. Zivilsenats vom 28.10.2014 - VI ZR 135/13 -](#)

Bundesgerichtshof

Mitteilung der Pressestelle



Nr. 152/2014

Vorlage an den EuGH in Sachen "Speicherung von dynamischen IP-Adressen"

Der Kläger verlangt von der beklagten Bundesrepublik Deutschland Unterlassung der Speicherung von dynamischen IP-Adressen. Dies sind Ziffernfolgen, die bei jeder Einwahl vernetzten Computern zugewiesen werden, um deren Kommunikation im Internet zu ermöglichen. Bei den meisten allgemein zugänglichen Internetportalen des Bundes werden alle Zugriffe in Protokolldateien festgehalten mit dem Ziel, Angriffe abzuwehren und die strafrechtliche Verfolgung von Angreifern zu ermöglichen. Dabei werden unter anderem der Name der abgerufenen Seite, der Zeitpunkt des Abrufs und die IP-Adresse des zugreifenden Rechners über das Ende des jeweiligen Nutzungsvorgangs hinaus gespeichert. Der Kläger rief in der Vergangenheit verschiedene solcher Internetseiten auf.

Mit seiner Klage begehrt er, die Beklagte zu verurteilen, es zu unterlassen, ihm zugewiesene IP-Adressen über das Ende des jeweiligen Nutzungsvorgangs hinaus zu speichern. Das Amtsgericht hat die Klage abgewiesen. Auf die Berufung des Klägers hat das Landgericht dem Kläger den Unterlassungsanspruch nur insoweit zuerkannt, als er Speicherungen von IP-Adressen in Verbindung mit dem Zeitpunkt des jeweiligen Nutzungsvorgangs betrifft und der Kläger während eines Nutzungsvorgangs seine Personalien angibt. Gegen dieses Urteil haben beide Parteien die vom Berufungsgericht zugelassene Revision eingelegt.

Der Bundesgerichtshof hat beschlossen, das Verfahren auszusetzen und dem Europäischen Gerichtshof zwei Fragen zur Auslegung der EG-Datenschutz-Richtlinie zur Vorabentscheidung vorzulegen.

1. Der Unterlassungsanspruch erstreckt sich auf die Speicherung von dynamischen IP-Adressen für die vorabentschieden...

Personal Data

DSGVO (LIBE)

- (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**;

95/46/EC

- (a) 'personal data' shall mean 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 identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity;

Recital 26 23

- (23) The principles of data protection should apply to any information concerning an identified or identifiable natural person. To determine whether a person is identifiable, account should be taken **of all the means reasonably likely to be used** either by the controller or by **any other person** to identify **or single out** the individual directly or indirectly. **To ascertain whether means are reasonable likely to be used to identify the individual, account should be taken of all objective factors, such as the costs of and the amount of time required for identification, taking into consideration both available technology at the time of the processing and technological development.** The principles of data protection should therefore not apply to anonymous data, which is information that does not relate to an identified or identifiable natural person. **This Regulation does therefore not concern the processing of such anonymous data, including for statistical and research purposes.**

all the means reasonably likely to be used

?

'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;

'encrypted data' means personal data, which through technological protection measures is rendered unintelligible to any person who is not authorised to access it;

separately and subject to technical and organisational measures to ensure non-attribution;

(2b) 'encrypted data' means personal data, which through technological protection measures is rendered unintelligible to any person who is not authorised to access it;

Art. 10 (LIBE)

Processing not allowing identification

1. If the data processed by a controller do not permit the controller or processor to directly or indirectly identify a natural person, or consist only of pseudonymous data, the **controller shall not process or acquire additional information in order to identify the data subject for the sole purpose of complying with any provision of this Regulation.**
2. Where the data controller is unable to comply with a provision of this Regulation because of paragraph 1, the controller shall not be obliged to comply with that particular provision of this Regulation. **Where as a consequence the data controller is unable to comply with a request of the data subject, it shall inform the data subject accordingly.**

- (37) The processing of personal data should equally be regarded as lawful where it is necessary to protect an interest which is essential for the data subject's life.

- (38) The legitimate interests of the controller, or in case of disclosure, by the third party to whom the data is disclosed, may provide a legal basis for processing, provided that they meet the reasonable expectations of the data subject based on his or her relationship with the controller and that the interests or the fundamental rights and freedoms of the data subject are not overriding. This would need careful assessment in particular where the data subject is a child, given that children deserve specific protection. Provided that the interests or the fundamental rights and freedoms of the data subject are not overriding, processing limited to pseudonymous data should be presumed to meet the reasonable expectations of the data subject based on his or her relationship with the controller. The data subject should have the right to object the processing free of charge. To ensure transparency, the controller should be obliged to explicitly inform the data subject

Provided that the interests or the fundamental rights and freedoms of the data subject are not overriding, processing limited to pseudonymous data should be presumed to meet the reasonable expectations of the data subject based on his or her relationship with the controller. The data subject should have the right to object the processing free of charge.

Profiling based solely on the processing of **pseudonymous data should be presumed not to significantly affect the interests, rights or freedoms of the data subject**. Where profiling, whether based on a single source of pseudonymous data or on the aggregation of pseudonymous data from different sources, permits the controller to attribute pseudonymous data to a specific data subject, the processed data should no longer be considered to be pseudonymous.

(58a) Profiling based solely on the processing of pseudonymous data should be presumed not to significantly affect the interests, rights or freedoms of the data subject. Where profiling, whether based on a single source of pseudonymous data or on the aggregation of pseudonymous data from different sources, permits the controller to attribute pseudonymous data to a specific data subject, the processed data should no longer be considered to be pseudonymous.

(59) Restrictions on specific principles and on the rights of information, rectification and erasure or on the right of access and to obtain data, the right to object, profiling, as well as on the communication of a personal data breach to a data subject and on certain related obligations of the controllers may be imposed by Union or Member State law, as far as necessary and proportionate in a democratic

Article 4
Definitions

For the purposes of this Regulation:

(1) (deleted)

(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,

'encrypted data' means personal data, which through technological protection measures is rendered unintelligible to any person who is not authorised to access it;

separately and subject to technical and organisational measures to ensure non-attribution;

(2b) 'encrypted data' means personal data, which through technological protection measures is rendered unintelligible to any person who is not authorised to access it;

Article 13a

Standardised information policies

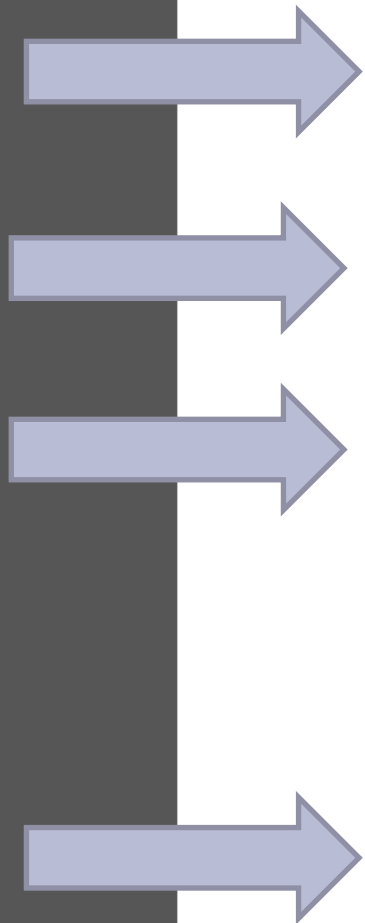
1. Where personal data relating to a data subject are collected, the controller shall **provide the data subject with the following particulars** before providing information pursuant to Article 14: [...]
 - (f) whether personal data are retained in encrypted form.

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Art. 13a

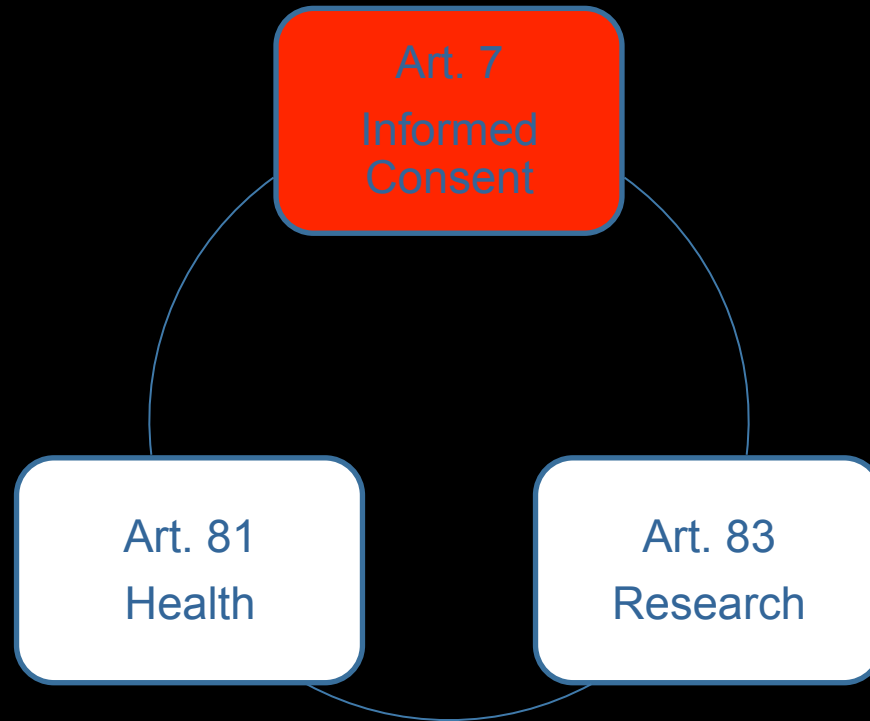
2. The particulars referred to in paragraph 1 shall be presented pursuant to Annex X in an aligned tabular format, using text and symbols, in the following three columns:

ICON	ESSENTIAL INFORMATION	FULFILLED
		
		
		
		
		
	No personal data are retained in unencrypted form	



Informed Consent ?

Key articles



7,500 Sold

Huffing
First Poste
React >
Read m

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Like
170
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By placing an order via this Web site on the first day of the fourth month of the year 2010 Anno Domini, you agree to grant Us a non transferable option to claim, for now and for ever more, your immortal soul. Should We wish to exercise this option, you agree to surrender your immortal soul, and any claim you may have on it, within 5 (five) working days of receiving written notification from gamesation.co.uk or one of its duly authorized minions.

terms and conditions. The clause, as by GameStation, reads,

By placing an order via this Web site on the first day of the fourth month of the year 2010 Anno Domini, you agree to grant Us a non transferable option to claim, for now and for ever more, your immortal soul. Should We wish to exercise this option, you agree to surrender your immortal soul, and any claim you may have on it, within 5

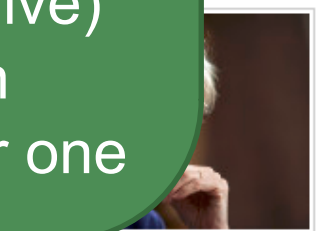
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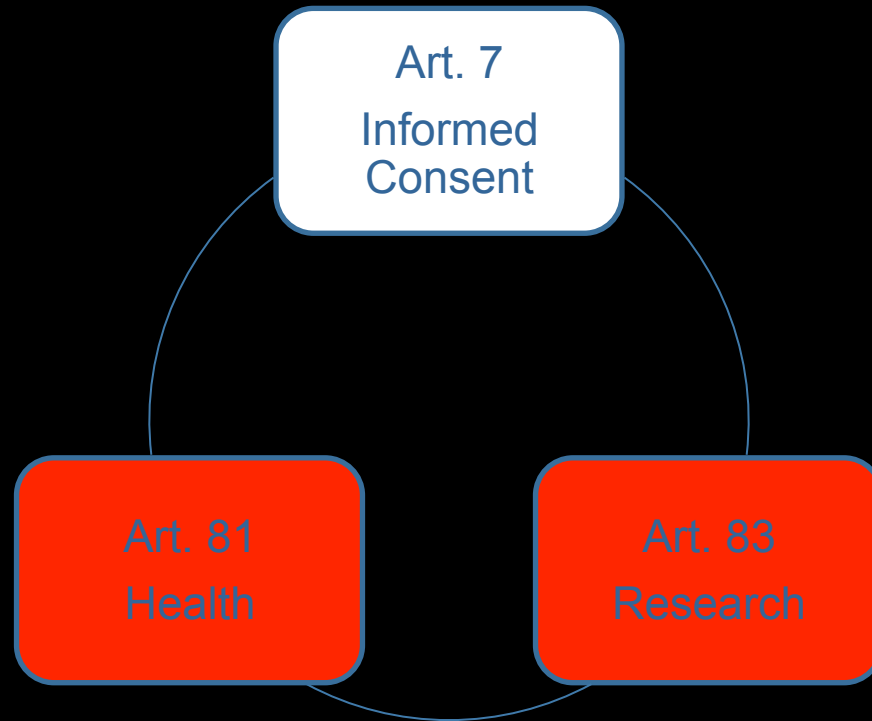
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- + Clinical Trials Regulation

Key articles



Commission's Draft

- Art. 83
 - Personal data may be **processed** (without consent) if
 - (1) the research purpose can't be achieved by using anonymous data and
 - (2) the data is properly pseudonymised and
 - (3) the matching table is kept separately from the data
 - Personal data may be **published** (without consent) only if
 - it is provided that it
 - *“is necessary to present research findings or to facilitate research*
 - *insofar as the interests or the fundamental rights or freedoms of the data subject **do not override these interests**”*

Albrecht's Draft

- Art. 81 par 2a
- “**Member States law** may provide for exceptions to the requirement of consent for research, [...] with regard to research that serves **an exceptionally high public interests** [sic!], **if that research cannot possibly be carried out otherwise.** [...] Such processing shall be subject to **prior authorisation** of the competent supervisory authority, in accordance with Article 34(1).

Parliament's Version

- Art. 81 par 2 “*Processing of personal data concerning health which is necessary for [...] scientific research purposes 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.*”
- Consent may be given for one or more specific and **similar researches** (art. 81 par 1b)
- **Member states** may provide for exceptions to this consent requirement, but only “*with regard to research that serves a high public interest, if that research cannot possibly be carried out otherwise.*”


Outcome

- 28 Member States
- Everything unclear such as
 - Which requirements research needs to meet to serve a high public interest?
 - How to decide whether the research could not have been carried out otherwise?
- Increased (personal) liability risks
- Electronic Consent still not supported

Questions

- One regulation fits all?
- Personal Data?
- Clinical Trials Regulation?
- Patient Autonomy
 - E-consent
 - Patient-Portal?
 - E-Health
 - Data Security?

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Designing a menu for your genes

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