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GDPR AND CLINICAL TRIALS

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Note: This presentation is not and should not be relied upon as legal advice

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2 Minutes About GDPR Background and this Presentation

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Personal Data Is:

1. Or-Hof Corp.
2. office@or-hof.com
3. Dan@or-hof.com
4. Dan@gmail.com

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Personal Data (GDPR) Is:

any information relating to an

identified or identifiable

natural person (‘data subject’);

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Personal Data (GDPR) Is:

- name, ID, location, online identifier;
- one or more factors specific to the -

physical, physiological, genetic, mental, economic, cultural or social identity of a natural person;

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The Single-Out Question

Can we single-out a specific individual that the data-set refers to?

If we reasonably can – privacy laws apply

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So… Personal Data Is:

1. Or-Hof Corp. [False]
2. office@or-hof.com [False]
3. Dan@or-hof.com [Probably]
4. Dan@gmail.com [Probably]

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Why does the GDPR Matters to us?

1. We care about individuals' privacy
2. As of next year, GDPR becomes a law in IL, US and other countries
3. Because we process data about Europeans
4. 20,000,000

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Why does the GDPR Matters to us?

EU Entities – processing of [ANY] personal data …

regardless of whether the processing takes place in the EU or not.

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Why does the GDPR Matters to us?

Non-EU Entities -

1. Offering goods or services to data subjects in the EU

   [Website in German, Prices in €, Targeted Marketing]

2. Monitoring human behavior which takes place in the EU

   [Profiling, behavior-based predictive analytics]

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Why does the GDPR Matters to us?

Indirect Applicability -

Process data for those who need to be GDPR compliant.

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Why does the GDPR Matters to us?

1. We care about individuals' privacy [Of course we do]
2. As of next year, GDPR becomes a law in IL, US and other countries [False]
3. Because we process data about Europeans [Partial]
4. 20,000,000 [YES!!]

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‘Processing’ of Personal Data means –

1. Data analysis
2. Cloud storage
3. Back-up
4. Destruction

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‘Processing’ (GDPR) means -

- any operation / set of operations
- performed on personal data / sets of personal data

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‘Processing’ of Personal Data means –

1. Data analysis [Correct]
2. Cloud storage [Correct]
3. Back-up [Correct]
4. Destruction [Correct]

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Controller or Processor?

1. Sponsor
2. Contract/Clinical Research Organization
3. Electronic Data Capture service provider

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A ‘data controller’ -

“determines the purposes and means of the processing of personal data”

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A ‘data processor’ -

Anyone appointed by Controller to process personal data

on behalf of the controller

(appointed by the Sponsor to work with the clinical trial).

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Controller or Processor?

1. Sponsor [Controller]
2. CRO [Processor or joint controller (CRO being delegated a full clinical development plan)]
3. EDC [Processor]

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For Marketing Purposes - We are -

1. A Processor
2. A Controller

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For Marketing Purposes - We are -

1. A Processor [False]
2. A Controller [Correct]

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Consent must be -

1. Explicit and informed
2. Explicit, freely given, specific, informed and unambiguous
3. freely given and whole heartedly
4. freely given, specific, informed, unambiguous and in good-faith

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Consent must be -

1. Explicit and informed [Partial]
2. Explicit, freely given, specific, informed and unambiguous [Correct]
3. freely given and whole heartedly [False]
4. freely given, specific, informed, unambiguous and in good-faith [False]

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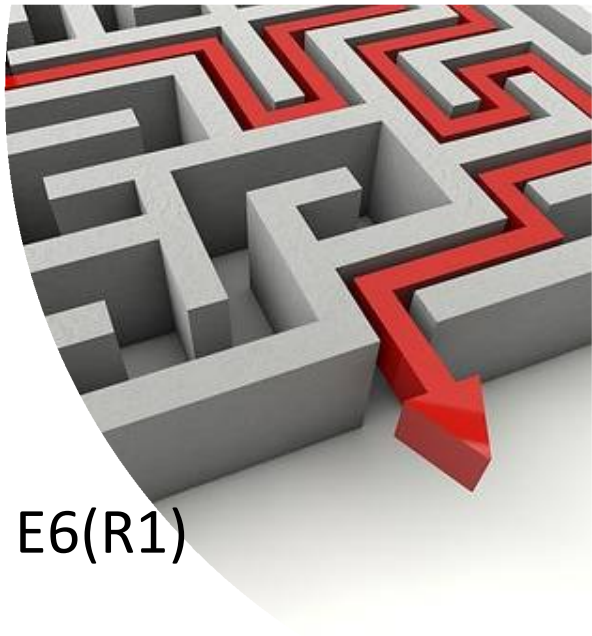

Consent in Clinical Trials -

Section 4.8 to GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R1)

[INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE]

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Consent – State Specific

GDPR Art. 9(4) –

Member States may maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.

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What Must I do with the Data?

1. Encrypt it
2. Pseudonymize it
3. Minimize it
4. Delete it

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Data Protection by Design -

1. Encryption [a de-facto must]
2. Pseudonymization [Where applicable]
3. Minimization [a must]
4. Deletion / anonymization [data retention policy]

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If a person sends us a ‘right to be forgotten’ notice, we -

1. Tell her/him to get lost
2. Tell her/him that the RTBF is not relevant to us
3. Locate data related to her/him and delete it
4. Tell her/him that we can keep the data

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If a person sends us a ‘right to be forgotten’ notice, we -

“The controller shall facilitate the exercise of data subject rights”

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We may keep the data which is necessary for -

- Archiving purposes in the public interest, scientific or historical research purposes
- Defending legal claims

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If a person sends us a ‘right to be forgotten’ notice, we -

1. Tell her/him to get lost [Bad idea]
2. Tell her/him that the RTBF is not relevant to us [Partial]
3. Locate data related to her/him and delete it [Partial]
4. Tell her/him that we can keep the data [Partial]

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If I email a file with personal data to the wrong customer, I -

1. Panic
2. Report it immediately to the right customer.
3. Report it immediately to my supervisor.
4. Recall the message, and if it doesn't help, call the 'wrong customer' and ask to delete the message.

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Data Breach

If I email a file with personal data to the wrong customer, I -

1. Panic [Only if you have to]
2. Report it immediately to the right customer [False]
3. Report it immediately to my supervisor [Correct]
4. Recall the message, and if it doesn't help, call the 'wrong customer' and ask to delete the message. [False]

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Bottom Line

1. Mapping and Assessment
2. Gap Analysis
3. Compliance Implementation

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Thank You

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