ERDERA
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Consent/assent for processing personal data

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RESEARCH WITH DATA



To support
research

To support
innovation

To support
better decisions

DATA











Research with personal data?

Personal data processing mind map
by answering the following questions:

What is personal data?
What examples of personal data can you think of?

What is processing?
Are there specific conditions for processing?

What is sensitive data ?
Think to some examples

Do you need to assent to use your personal data?

PERSONAL DATA - ART.4 GDPR



any information relating a person that allow, directly or indirectly, to identify that person

- *Name, first name…*
- *reference to an identification number (e.g. social security number)*
- *one or more factors specific to his physical, physiological, mental, economic, cultural or social identity (e.g. birthday, home address, school number, email, IP address, mobile positioning data, patient records…)*

SENSITIVE personal data relevant for research

MORE STRICLTLY REGULATED



- **'Health data' :** personal data related to physical or mental health […] **which reveal information about his or health status"**

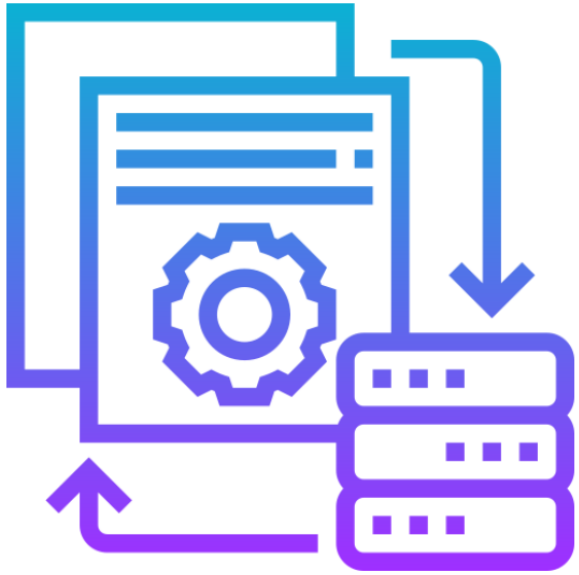
- **'Genetic data' :** personal data relating to the inherited or acquired genetic characteristics of a natural person **which give unique information about the physiology or the health of that person…**

- **'Biometric data' :** personal data … **which allow or confirm the unique identification of that person** (e.g. facial images or fingerprints)

PROCESSING OF PERSONAL DATA ART.4 GDPR

PROCESSING
any operation or set of operations which is performed on personal data or on sets of personal data, if or not by automated means, such as

- ***collection***
- *recording*
- *organisation, structuring*
- ***storage**, adaptation or alteration*
- ***consultation, use***
- *retrieva,*
- ***disclosure by transmission***
- ***dissemination** or making available*
- *alignment or **combination***
- ***erasure or destruction***



Data Protection Principles under GDPR

- **Lawfulness, fairness, and transparency**: Any processing of personal data should be lawful, fair and transparent. (information easily accessible and easy to understand with a clear and plain language)

- **Purpose Limitation**: Personal data should only be collected for specified, explicit, and legitimate purposes, determined at the time of the collection, (not further processed in a manner that is incompatible with those purposes)

- **Data Minimisation**: Processing of personal data must be adequate, relevant, and limited to what is necessary in relation to the purposes for which they are processed.

Data Protection Principles under GDPR

- **Accuracy**: personal data are accurate and, where necessary, kept up to date.
- **Storage Limitation**: time limits should be established for erasure or for a periodic review to ensure that the personal data are not kept longer than necessary
- **Integrity and Confidentiality**: Personal data should be processed in a manner that ensures appropriate security and confidentiality of the personal data.
- **Accountability**: compliance with GDPR principles should be demonstrated

CONSENT FOR PROCESSING SENSITIVE PERSONAL DATA



Consent remains cornerstone as main legal basis for the processing of personal data

Important clarifications on the **characteristics of valid consent** in general

(Article 7)

- *"For **consent** to be **informed**, the **data subject should be aware** at least of the identity of the Controller and **the purposes** for which the personal data are intended"* Recital 42
- It requires an **affirmative action**: silence or inactivity should not constitute consent.
- "The data subject has given **explicit consent** to the processing of personal data…**concerning health"** (Article 9)

Authorisation from parents (legal representatives) information/assent from children

Information before consent for processing sensitive personal data



Patients, parents and children are entitled to receive information about the processing of their own personal data (even where consent is given by a parent on their behalf to the processing of their personal data)

Information to the data subject shall be

- **concise, transparent, intelligible and easily accessible form,**
- **using clear and plain language,**

in particular for any information addressed specifically to a child

Summary of relevant children rights and principles to be applied in the processing of personal data



- ✓ Children have to **receive information, according to their age and degree of maturity**
- ✓ **Children have the same rights as adults over their personal data** (rights to access their personal data, request rectification, object to processing and have their personal data erased).
- ✓ **Modalities should be provided for facilitating the exercise of the data subject/child's rights** (e.g. access to, rectification or erasure of personal data…)
- ✓ **Children should be recontacted to express their own consent** to authorise the processing of their personal data **once reached the legal majority** according to national law.
- ✓ **Transfers to third non-European countries if an appropriate level of protection of the data subjects** is guaranteed (according to GDPR)

DIFFERENT CONSENT AND ASSENT FORMS TO PARTICIPATE IN RESEARCH AND FOR DATA PROCESSING

INFORMATION + CONSENT /ASSENT FORMS FOR RESEARCH



FROM PARENTS CONSENT TO CHILDREN ASSENT

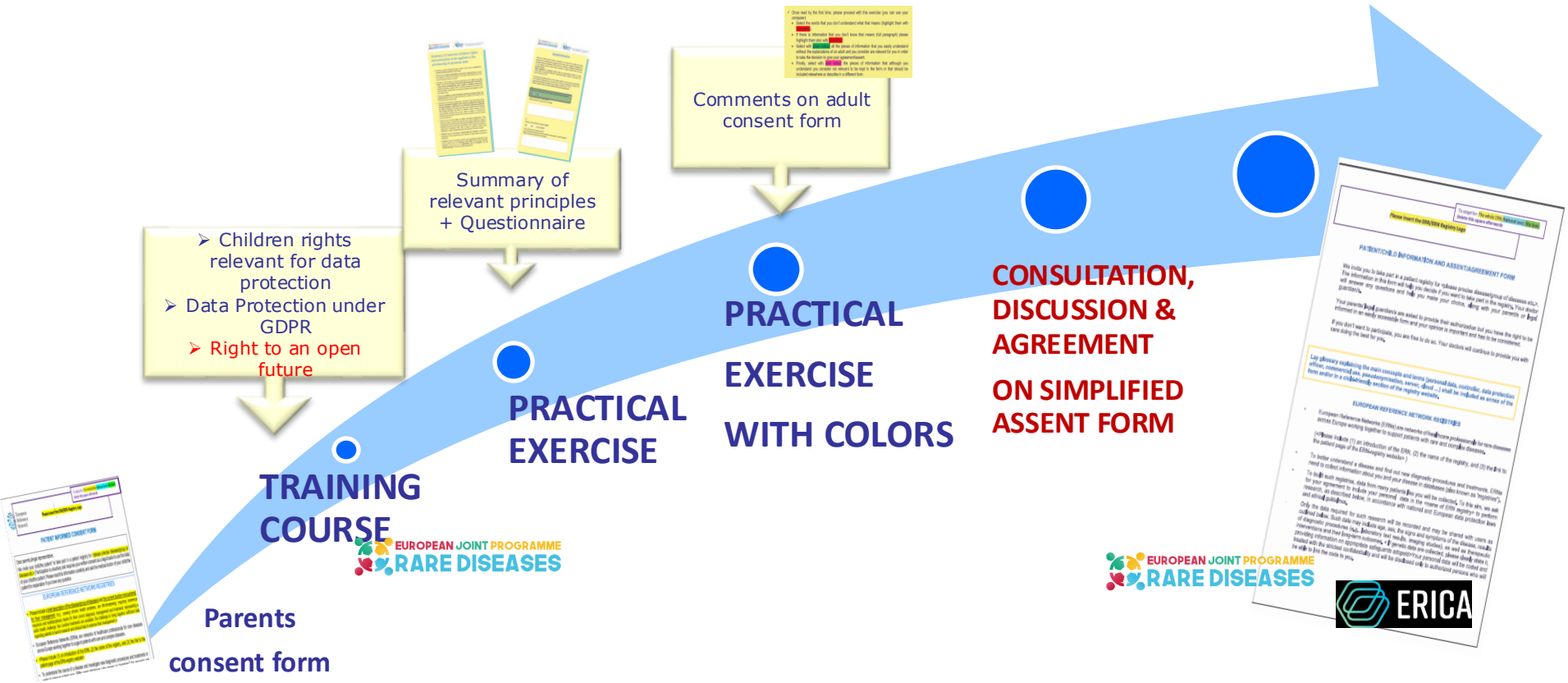
INFORMATION + CONSENT /ASSENT FORMS FOR DATA PROCESSING



TO BE WITHDRAWN AT ANY TIME

Age tailored assent form (12-18) for processing and sharing personal data within European Reference Networks (ERNs) for rare diseases

METHODOLOGY





AGREED CONCLUSIONS

paediatric assent form is to be considered as a **part of a more comprehensive strategy** to increase children awareness of patient registries activities and role to foster their participation and engagement

Lay glossary explaining the main concepts and terms (personal data, controller, data protection officer, commercial use, pseudonymisation, server, cloud …) shall be included as annex of the form and/or in a child-friendly section of the registry website.

Interactive elements and explanatory diagrams such as flowcharts, animations or images should be included to explain what is a registry, how the data is collected and studied, and explicitate the flow of personal data foreseen in each registry.

According to the children right to an open future, children have to be protected against being engaged in certain irreversible choices. Thus, decisions regarding commercial use shall be avoided as much as possible and postponed until the child acquires the legal majority and can decide by his/herself. In anycase an opinion from an ethics committee shall be required on a case by case basis.

Additional and more comprehensive child-friendly materials (images, videos, leaflets…) informing about appropriate safeguards and data protection policies adopted shall be included in the website of a registry.

Lay summaries with the results of studies carried out with the data of children participating in the registry should be developed.

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OUTCOMES

- ✓ **co-designing assent forms including children feedback** and use their advices on methodology and concerns to be addressed
- ✓ **Giving children the chance to agree to the main purposes of the registry while providing them with the choice about other data processing activities** (e.g., the reuse of data for research projects with commercial sponsors or the possibility to be re-contacted to participate in other research projects, the transfer of data to non-EU countries…)
- ✓ **Reinforcing the concept of "granularity,"** as stated in the GDPR and to create personalized "consent profiles" based on patients' preferences on their data use



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TO FOSTER RESEARCH AND PUBLIC TRUST





Adequate model of governance of research with data should be promoted
in accordance with children/future generation's rights
WITH PARTICIPATORY METHODOLOGY

European Rare Diseases Research Alliance

2nd Training for Young Advocate RD





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