Guidance on GDPR Compliance in Humans Subjects Research

This guidance pertains to collecting data from research participants in the EU, or receiving data from institutions or organizations in the EU. This guidance is not comprehensive of all GDPR policies for data processing, but provides highlights relevant for researchers and research participants.

1. What Is the GDPR?

The General Data Protection Regulation (GDPR) of the European Union (EU) regulates the use, access, and processing of data collected from residents of the EU. The GDPR provides a high standard of data protection, which must be considered during the conduct of human subjects research, involving participants who are in the EU, in addition to those requirements of 45 CFR 46 (OHRP), 21 CFR 56 (FDA), HIPAA, FERPA, and any other applicable regulation or standard.

If Investigators recruit research participants who are EU residents or are otherwise protected by the provisions of GDPR, Investigators are expected to be aware of any requirements for data protection, management, and informed consent than those already required by 45 CFR 46. The following guidance is a summary of key information about GDPR, and is not comprehensive of all requirements for researchers processing data subject to the policy.

2. What Are the Basic Ethical Principles of the GDPR?

The basic ethical assumptions of the GDPR are similar to those of the Belmont Report:

- Principle of Autonomy: GDPR "*protects fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data*." (Art.1(2)), and "*Natural persons should have control of their own personal data*." (Rec.7)
- Principle of Beneficence: "*The right to the protection of personal data is not an absolute right; it must be considered in relation to its function in society and be balanced against other fundamental rights, in accordance with the principle of proportionality*." (Rec.4)
- Principle of Justice: "*The processing of personal data should be designed to serve mankind" and cognizant of "cultural, religious and linguistic diversity*." (Rec.4)

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3. When Does GDPR Apply to Researchers and Research Participants?

Type	Source	Description	GDPR Application
Personal Data	Rec.23	Personal data of data subjects who are in the EU, even if the controller, processer, or monitor of the data is not established in the EU. A "data subject" is not limited to an EU citizen or resident, but any natural person who is in the EU at the time of processing their personal data.	Applies
Pseudonymous Data	Rec.26	Data that have undergone pseudonymisation, which are still considered identifiable, unless it is not "reasonably likely" that a natural person could remain identifiable in the data set. Data deidentified by the HIPAA standards or coded by OHRP standards may still be considered identifiable under GDPR.	Applies
Registries and Scientific Research	Rec.157	Data processed for scientific research purposes.	Applies
Historical Research	Rec.160	Data processed for historical research purposes, unless the natural person is deceased.	Applies
Statistical Purposes	Rec.162	Data processed for statistical purposes, which are the operation of collection and the processing of personal data necessary for statistical surveys or for the production of statistical results.	Applies
Anonymous Data	Rec.26	Anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable, including for statistical or research purposes.	Exempt
Secondary Processing	Art.5(1)(b), Art.6(4), Rec.50	Data processed for a purpose other than that for which the personal data have been collected, not based on the data subject's consent, when the controller ascertains the processing is compatible with the purpose for which the personal data are initially collected. Further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation').	Exempt

4. What are the Key Definitions in GDPR?

- Identifiable Natural Person: An identifiable natural 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, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. (Art.4(1), Rec.26)
- Personal Data: Any information relating to an identified or identifiable natural person ('data subject'). (Art.4(1)) Health, Genetic, and Biometric information are considered Personal Data. (Rec.34,35)
- Sensitive Personal Data: Data relating to racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health, genetic, and biometric. Sensitive personal data may only be processed in non-prohibited uses and require "specific protection." (Art.8(1), Rec.51)
- Pseudonymisation: The processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person. (Art.4)
- Research: Includes activities related to "technological development and demonstration, fundamental research, applied research and privately funded research." (Rec.159)
- Controller: The natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data. (Art.4)
- Processor: A natural or legal person, public authority, agency or other body that processes personal data on behalf of the controller. (Art.4)

5. What Rights do Data Subjects Have under GDPR?

Data subjects, who are research participants in the context of a research protocol or activity, have the following general rights:

GDPR Right	
Right to Access	To confirm that data are being processed, and be provided information about the nature of that processing.
Right to Rectification	To rectify inaccurate personal data, or complete incomplete data.
Right to be Forgotten	To obtain from the controller the erasure of all personal data, without undue delay. When data have been made public by the controller, this erasure shall take into account the practicability of the request.
Restriction of Processing	To restrict how data are processed.

Data Portability	To receive personal data from a controller, in a useable format.
Right to Objection	To object to processing of personal data relating to his or her particular situation, unless the controller demonstrates compelling, legitimate grounds for the processing.

6. What Special Protections do Minors Have under GDPR?

For any child below 16, the holder of parental responsibility over the child must provide consent for any processing of personal data. For any child over 16, processing of personal data shall be lawful, excepting where prohibited without consent by the GDPR. The controller shall make a reasonable effort to verify affirmative provision of parental consent, taking into consideration available technology.

7. Are LU Consent Form Templates Compliant with GDPR Requirements?

The LU Consent Form templates are GDPR Compliant in the following elements. The following requirements apply where personal data are collected from the data subject. The same requirements apply where personal data have not been obtained from the data subject, with the provision that this consent information be provided within a reasonable period after obtaining the data (at the latest within one month), at the latest time of first communication with the data subject, or at the latest when the personal data are first disclosed to another recipient:

45 CFR 46	**45 CFR 46 (2019 Element)**	**GDPR Ref.**	**GDPR Standard**	**LU Consent Element**
116(a)(1)-(4)	Shall obtain legally effective informed consent.	Rec.32	Consent must be clear and affirmative, freely given.	*Voluntary Participation Notice*
116(a)(1)-(4)	Shall obtain legally effective informed consent.	Art.7	Consent must be clearly distinguished from other services or decisions.	*Why is this research being conducted?*
116(b)(8)	Subject may discontinue participation at any time.	Art.7	Right to withdraw consent at any time.	*How do I withdraw from this study?*
116(b)(7)	Whom to contact for answers to pertinent questions.	Art.13(1)(a)	Identity and contact details of the controller.	*Who can I contact with questions or concerns?*
116(b)(7)	Whom to contact for answers to pertinent questions.	Art.13(1)(b)	Contact details of the data protection officer, where applicable.	*Who can I contact with questions or concerns?*
116(b)(1)	Explanation of the purposes of the research.	Art.13(1)(c)	Purposes of the processing for which the personal data are intended.	*Why is this research being conducted?*
116(b)(9)		Art.13(1)(d)	The legitimate interests pursued by the controller or third party, when applicable.	*Will my data be used for future research?*

116(b)(9)		Art.13(1)(e)	Recipients or categories of recipients of personal data, when applicable.	*Will my data be used for future research?*
116(b)(9)	Research involving collection of identifiable information or biospecimens.	Art.13(1)(f)	Description of transfer to third country under an adequacy decision, when applicable.	*Will my data be used for future research?*
116(b)(1)	Explanation of the purposes of the research.	Art.13(2)(a)	Period for which data are stored, or criteria to determine period.	*GDPR Template Language*
116(b)(7)	Whom to contact for answers to pertinent questions.	Art.13(2)(b)	Right to request access to, rectification of, or erasure of, or restriction of use of personal data.	*GDPR Template Language*
116(b)(8)	Subject may discontinue participation at any time.	Art.13(2)(c)	Right to withdraw at any time without affecting lawfulness of any processing prior to that withdrawal, when applicable.	*How do I withdraw from this study?*
116(b)(7)	Whom to contact for answers to pertinent questions.	Art.13(2)(d)	Right to lodge a complaint with a supervisory authority.	*Who can I contact with questions or concerns?*
		Art.13(2)(e)	Whether provision of data is a statutory or contractual requirement.	*GDPR Template Language*
116(b)(9)	Research involving collection of identifiable information or biospecimens.	Art.13(3)(a)	Information on any further processing for purposes other than that for which the personal data were collected	*Will my data be used for future research?*