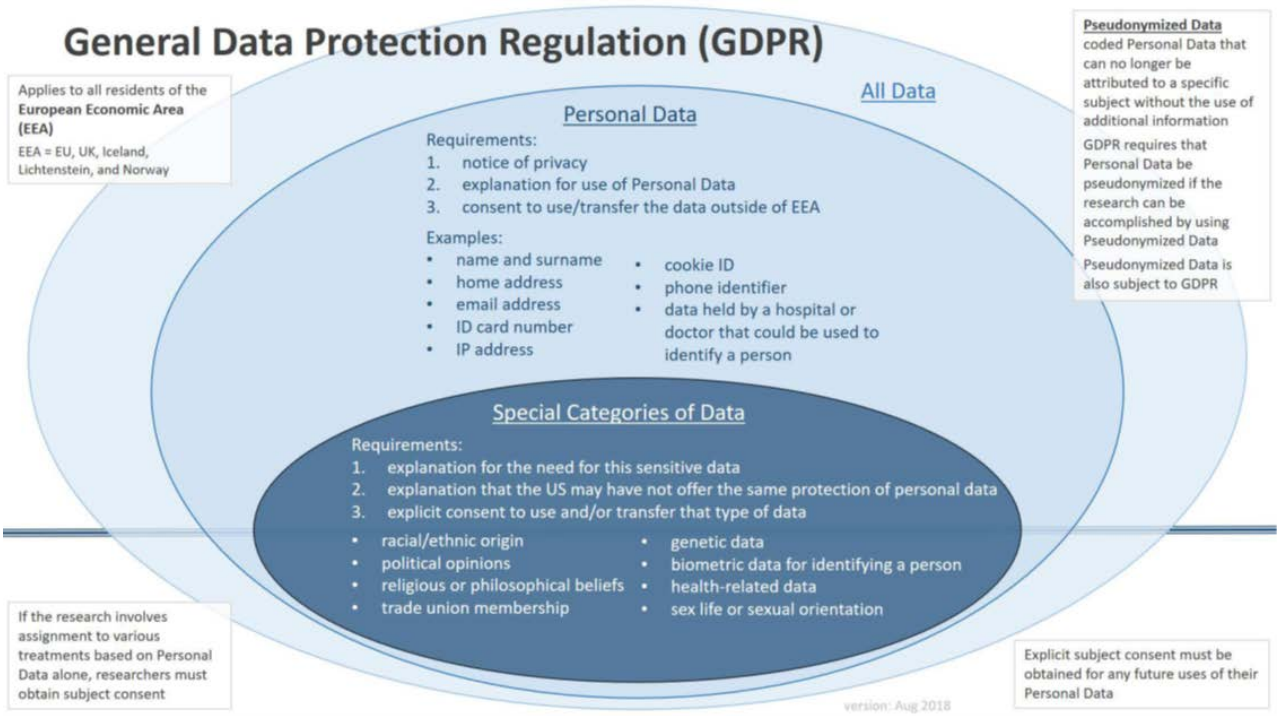
Title: European Union General Data Protection Regulation
Date of Last Revision: 11/08/18
Audience: Researchers

EU GDPR Guidance – When is Notice or Consent Required



GDPR requires that where Personal Data of a Data Subject in the EEA is collected, used, or accessed for research purposes, the researcher must provide the Data Subject specific information in a **notice** of privacy and, and under certain circumstances, must also obtain the **explicit consent** of the Data Subject for certain Processing activities.

NOTICE REQUIREMENTS

When Personal Data of an individual in the EEA is collected, used, or accessed for research purposes, GDPR requires that individuals be informed of the following information:

- The specific types of Personal Data collected and processed;
- The reasons, or purposes, for using the individual's Personal Data (i.e., using the Personal Data in order to conduct the research study);
- The expected duration for retaining Personal Data;
- The types of entities or individuals who will have access to or receive the Personal Data;
- A description of the individual's rights under GDPR (which should also include language that informs the Data Subject that their Personal Data will be protected under GDPR and how withdrawal of their consent to participate in the study will affect UC's subsequent use of their Personal Data);

- Notice that his or her Personal Data will be available in the United States (or other countries outside the EEA), and a description of how UC will protect the personal data;
- If Personal Data is being used to make decisions about the person or to create a profile, relevant information (this is discussed in more detail below); and
- Contact information for UC and the local privacy officer.

This information must be provided to Data Subjects located in the EEA in any research study that involves collecting or using their Personal Data.

If the Personal Data of an individual located in the EEA is used in research, where the Personal Data is provided to UC by a third party, individuals also must be informed of:

- The source of the data; and
- A description of the categories of personal data.

CONSENT REQUIREMENTS

In addition to giving research subjects notice of the information required above, GDPR also requires that Data Subjects provide consent to certain Processing activities. GDPR stipulates that consent must be freely given, specific, informed and an unambiguous indication that the Data Subject has consented to the particular Processing of Personal Data.

Consent is required where:

1. Special Categories of Data, discussed below, are collected and processed;
2. Personal Data will be transferred to the United States, or even accessed in the United States; or
3. Personal Data is used to assign a research subject to receive, or not receive, a certain treatment in a study;

Special Categories of Personal Data

Certain types of Personal Data require additional protection under GDPR. Generally, when research involves Special Categories of Personal Data, the individual must explicitly consent to the use of this data for a given purpose. GDPR explicitly identifies the types of Personal Data that constitute Special Categories of Personal Data, which are:

- Racial or ethnic origin;
- Political opinions;
- Religious or philosophical beliefs;
- Trade union membership;
- Genetic data;
- Biometric data for the purpose of uniquely identifying a natural person;
- Health-related data; and
- Sex life or sexual orientation.

If any Special Categories of Personal Data of an individual in the EEA is collected, used, or accessed for research purposes, the researcher must obtain explicit consent for the use of that sensitive data from the Data Subject. This can be accomplished by ensuring that the Data Subject is informed of the use of the specific Special Category of data, the purpose of the use (i.e., to conduct the research study, which is summarized for the Data Subject), and requiring that the Data Subject consent to participation in the research study.

Personal Data Transfers to the United States

When researchers collect Personal Data from individuals in the EEA and intend to access the data in the United States, or transfer the data to the United States, generally, the researcher must obtain the explicit consent of the Data Subject. *Thus, in most, if not all scenarios in which a researcher is collecting Personal Data, consent to transfer the data to the U.S. will be required.*

In addition to obtaining consent of the individual, GDPR requires that the Data Subject also be informed that the United States does not protect Personal Data in the same manner as Personal Data may be protected in the EEA.

If a researcher is not collecting the Personal Data, but is instead receiving or using Personal Data collected or obtained from a researcher or institution in the EEA, the UCI Contracts Officer will included standard contractual clauses approved by the European Commission in any underlying agreements such as a data use agreement between UCI and the EEA researcher or institution providing the Personal Data. Although individuals do not need to consent to the transfer, they must still be informed that their Personal Data is protected, and they have the right to obtain a copy of the UCI's Statement of Privacy related to UC's research uses of data that includes such language.

Personal Data to Assign Subjects to Different Treatments

GDPR gives Data Subjects the right not to be subject to a decision based solely on the automated processing of their Personal Data, where there is a legal or similarly significant effect on the person. A decision is based solely on automated processing when there is no meaningful human involvement in the decision. A decision that affects the healthcare a person receives can be considered one that has a significant effect on an individual. For example, assigning clinical trial subjects to receive an intervention or placebo based solely upon each subject's diagnostic data, where the assignment is done without any meaningful input from a physician or the research team, could be regulated by GDPR.

However, GDPR does allow solely automated processing that could significantly affect a Data Subject where the Data Subject explicitly consents to the activity. *Thus, where the research involves assignment to various treatments based upon Personal Data alone, the researcher must obtain the explicit consent of the Data Subject. Where the decision will use special categories of Personal Data, the Data Subject must also explicitly consent to the uses of such data for this purpose.*

Finally, the Data Subject must also be informed of how the decision is made (i.e., the logic involved), the potential consequences of the decision, the right to obtain human involvement in the decision, and to challenge the decision, if the research allows.