



Human Research Protection Program (HRPP)

The General Data Protection Regulation (GDPR) & Human Subjects

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I. What is the GDPR?

The General Data Protection (GDPR) is a European law that went into effect on May 25, 2018 and establishes protections for privacy and security of “personal data” about individuals in European Economic Area (“EEA”)-based operations and certain non-EEA organizations that process personal data of individuals in the EEA. The EEA consists of:

Austria	Belgium	Bulgaria	Croatia	Republic of Cyprus
Czech Republic	Denmark	Estonia	Finland	France
Germany	Greece	Hungary	Iceland	Ireland
Italy	Latvia	Lichtenstein	Lithuania	Luxembourg
Malta	Netherlands	Norway	Poland	Portugal
Romania	Slovakia	Slovenia	Spain	Sweden
United Kingdom				

II. What is “personal data”?

Under the GDPR, “**personal data**” refers to any information that relates to an identified or identifiable natural person (i.e. an individual, not a company or other legal entity), otherwise known as a “data subject”.

Examples of “personal data” include: a person’s name, email address, government-issued identification, or other unique identifier such as an IP address or cookie number, and personal characteristics, including photographs.

- **Special categories of personal data:**

The GDPR highlights some “special categories” of personal data which merit a higher level of protection due to their sensitive nature and risk for greater privacy harm.

This includes: information about a data subject's health, genetics, race or ethnic origin, biometrics for identification purposes, sex life or sexual orientation, political opinions, religious or philosophical beliefs, or trade union membership.

- **GDPR and Coded Data:**

Importantly, the GDPR considers “pseudonymized data” (e.g., coded data) to be “personal data” even where one lacks access to the key-code/crosswalk required to link data to an individual data subject. This is inconsistent with U.S. regulations protecting human subjects and, therefore, important for researchers to understand.

- **GDPR and Anonymized Data**

The GDPR *does not apply* to data that have been anonymized. Under the GDPR, in order for data to be anonymized, there can be **no key-code in existence to re-identify the data**. For example, if Brown serves as the sponsor of a research study with a site located in the EEA and receives only coded data from the EEA site, such data from the EEA site remain “personal data.” This holds true even when Brown researchers have no access to the key-code/crosswalk required to link data to an individual data subject.

III. What activities are subject to the GDPR?

Activities involving identifiable information if personal data is being collected from one or more research participants *physically located* in the EEA at the time of data collection. Of note, the participant **does not need to be an EEA resident**.

Activities involving the transfer of personal data collected under the GDPR from an EEA country to a non-EEA country (like the U.S.).

Activities involving collection of identifiable personal data from individuals who are *physically located within the U.S.* at the time of data collection -- *even if the participant is an EEA citizen* -- are not subject to the GDPR.

IV. How do I ensure that my study complies with the GDPR?

- Collect only the absolute minimum personal/demographic data needed to complete the study. If your study can be completed using only de-identified data, then we strongly advise you to take this approach.
- Many online survey sites collect personal information, including IP addresses, by default. Ensure that you set up your study to receive **only** the information you are seeking. To the extent possible, verify that any third-party website or app being used for data collection is GDPR-compliant.
- Use an active (“opt-in”) informed consent. Under the GDPR, consent must be freely given, specific, informed, unambiguous, and explicit. A description of the data processing and transfer activities to be performed, if applicable, must be included in the informed consent document. Following an informed consent description, a “Click next to proceed to the survey” button or equivalent is sufficient for “active” consent for online data collection.
- Ensure that your consent form is in compliance with GDPR requirements (see below).
- For activities in which identifiable data is collected, you must have an executable plan to remove data in the event a participant requests to have his/her data removed.

V. How is the consent documentation and process affected by GDPR?

The good news is that many of the consent requirements under the GDPR are consistent with those

that you already implement as part of standard consent processes and documentation.

Below are the GDPR requirements:

1. Consent records, including time and date of consent, must be maintained for each subject. In the case of verbal, online, or any other type of undocumented consent, the Principal Investigator is responsible for maintaining a consent log indicating each subject (either by name or study ID number) and the date and time that consent was provided.
2. Consent must be explicit. If the consent form or consent script serves multiple purposes (e.g. a consent form that is also the recruitment email), then the request for consent must be clearly distinguishable.
3. Each subject has a right to withdraw consent at any time. Each subject must be informed of this right prior to giving consent. Withdrawal of consent must be as easy as giving consent.
4. Consent must be an affirmative action. This means that opt-out procedures are not permitted.
5. Consent information must be provided in clear and plain language in an intelligible and easily accessible format.
6. Consent must be freely-given. Individuals in a position of authority cannot obtain consent, nor can consent be coerced. This means that faculty members or teachers cannot obtain consent from their own students.
7. Consent forms must contain the following information:
 - The identity of the Principal Investigator
 - The purpose of data collection
 - The types of data collected, including listing of special categories:
 - racial or ethnic origin
 - political opinions
 - religious or philosophical beliefs
 - trade union membership
 - processing of genetic data
 - biometric data for the purpose of unique identification
 - health data
 - sex life and/or sexual orientation information
 - The right to withdraw from the research and the mechanism for withdrawal
 - Who will have access to the data
 - Information regarding automated processing of data for decision-making about the individual, including profiling
 - Information regarding data security, including storage and transfer of data
 - How long data will be stored (this can be indefinite)
 - Whether and under what conditions data may be used for future research, either related or unrelated to the purpose of the current study

In the event of a data breach, notify the Office of Research Integrity, Human Research Protection Program immediately so that appropriate steps can be taken by the University.