European Union (EU) General Data Protection Regulation (GDPR) Informed Consent and Notice Requirements

The European Union General Data Protection Regulation (EU GDPR) broadly applies to data about people who reside in the European Union countries plus Norway, Iceland and Lichtenstein. The EU GDPR limits when and how personal data can be collected, stored, processed and used. It also provides individuals with certain rights related to their personal data, including notice or consent, rights of access, and in some cases, requests for deletion. [For the complete list of affected countries and more information see: EU GDPR FAQs]

Under the EU GDPR, **personal data is defined as any information relating to an identified or identifiable natural person.** An identifiable natural person is an actual person (not a corporation or other business entity) who can be identified, directly or indirectly, by reference to:

- Any identifiers, such as name, ID, location data, online identifier; or
- Factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person.

GDPR Informed Consent or Notice Requirements

The EU GDPR requirements are to be implemented in addition to **the Regulatory Consent Requirements listed above.**

The EU GDPR requires a lawful basis for collecting and processing personal data. In research, that lawful basis is consent. In order to be compliant with the EU GDPR, **the following requirements must be adopted into the consent procedures and consent form:**

- 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 they provided consent.
- 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 within the document.
- 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.
- Consent must be an affirmative action. This means that opt-out procedures or pre-checked boxes indicating consent are **not** permitted.
- Consent information must be provided in **clear and plain** language in an **intelligible and easily accessible format**. Consent forms using excessive jargon or that do not have separate sections with section headings will be returned for revision.
- 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.
- 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 purposes of unique identification;
    - Health data; and/or
    - Sex life or sexual orientation information;

- The right to withdraw from the research and the mechanism for withdrawal (this may mean keeping the link indefinitely);
- 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.

What if consent is withdrawn?

Upon the withdrawal of consent at any time, the controller should delete or anonymize the personal data straight away and its use of the data for the research study should stop.

However, if the data needs to be retained after consent is withdrawn, the informed consent form must specify as such and indicate at the outset that, even if consent is withdrawn, the entity will retain the data for another identified lawful basis. However, this does not mean that the controller can swap from consent to another lawful basis. When data is processed for multiple purposes, the controller must be clear at the outset about which purpose applies to each element of data and which lawful basis is being relied upon.