Use of Personal Data from the European Union

The General Data Protection Regulation (GDPR) establishes protections for the privacy and security of personal data (Personal Data) about individuals in the European Economic Area (EEA) (the European Union (EU) member states, plus Norway, Iceland, Liechtenstein and Switzerland). It is important for Baylor University (BU) researchers conducting human subjects research to know what responsibilities they have regarding individuals in the EEA while collecting or handling their data. The GDPR potentially affects the research activities of universities in the United States if the research involves Personal Data about individuals located in those countries regardless of the individuals' citizenship status, but generally will not affect Personal Data collected from EU citizens while residing in or visiting the U.S. It establishes a complex privacy regime that differs in key respects from the HIPAA Privacy Rule and the Common Rule.

Personal & Sensitive Data

Any research project which uses the Personal Data of an individual that is collected in the EEA must abide by the requirements of the GDPR. **Personal Data** is defined as "any information that relates to an identified or identifiable natural individual" who is in the EEA, regardless of the individual's EU citizenship status. An individual is identified or identifiable if the individual 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." For example, the identifiers listed in the IRB application would generally render an individual identifiable for purposes of GDPR as well as HIPAA.

If Personal Data is also Sensitive Data, it requires "special protection," meaning that you must obtain explicit consent (i.e., signed) to collect or use it. **Sensitive Data** is data concerning "one's health, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, sexual orientation, biometric data, or data concerning a natural person's sex life."

If you have data which has been rendered anonymous in such a way that the individual is not identifiable, it is no longer considered Personal Data. For data to be truly anonymized under the GDPR, the anonymization must be "irreversible." Coded data (or "pseudonymized" data) is not considered anonymous even if the researcher has entered into an agreement to not have access to the key code.

Informed Consent & Data Collection

There are specific elements related to data privacy which must be provided to an individual when their Personal Data is being collected, used, or accessed. If Sensitive Data is being collected, used, or accessed, you must use the full informed consent process, with translation as appropriate. Additionally, you must ensure that you are collecting only the minimum necessary information for your defined purpose.

Some of the GDPR required elements for data privacy are already included in typical consent forms. The Office of Research Compliance will evaluate your consent form for any additional required GDPR elements and revise accordingly.

According to the GDPR, personal data can only be collected and processed for "a well-defined purpose." This may complicate our ability to approve research involving future use of data, deception or incomplete disclosure; however, GDPR working groups are planning on future guidance.

Data Storage & Maintenance

Once you possess Personal Data subject to GDPR, these individuals are entitled to certain rights regarding how the data is handled. This means that you must store their information in a way that permits them to take advantage of the following rights

- The right to request information about the handling of the participant's data. *Note*: It is acceptable to add a limitation that, for scientific integrity, access to some of the data may not be allowed until the study ends.
- The right to withdraw consent at any time, including the right to withdraw from study participation, follow-up or further handling of data. *Note*: It is acceptable to add a limitation that data already processed is legally covered by the original consent, but no further data will be collected.
- The right to file a complaint with a data protection authority.
- The right to know the recipients or categories of recipients of the personal data, if any, and the identity of the people who may have access to the data.
- The right to request correction of data if it is inaccurate or incomplete, and to restrict use while it is being corrected.
- The right to request deletion of the participant's data if the data are no longer needed, or there is no other legal requirement for their use. *Note*: FDA regulations require retention of the participant data for specified periods of time. It is acceptable to delete all identifiers from the data (i.e., anonymize the data) and keep it separate from the data set for purposes of scientific and data integrity.
- The right to request transfer of data to the participant or others in a commonly used format.

Examples of when GDPR will apply to research at Baylor

- A BU researcher travels to an EEA country and collects identifiable Personal Data from individuals in that country.
- A BU researcher collaborates with a researcher located in an EEA country and the EEA researcher sends identifiable Personal Data to the BU researcher.
- An individual in the US enrolls in a BU research project which requires him/her to wear a device that collects health information. The US individual travels to an EEA country while in the study and continues to wear the device. All Personal Data collected and transferred to the US while the participant is in the EEA country is subject to the GDPR.
- A BU faculty member accompanying students abroad in an EEA country or teaching in a study abroad program in an EEA country collects identifiable Personal Data about the BU students and/or the local students.