

General Data Protection Regulation GDPR Consent Form Language

As described elsewhere in this informed consent form, during the study, data pertaining to your participation in the study will be generated and recorded. In addition, we will collect from you your personal data and sensitive personal data, including health-related data. We refer to all such data as “Your Study Data,” which will be specifically regulated in the EU/EEA under the General Data Protection Regulation (the “GDPR”). Your Study Data may be processed or used for the following purposes, which we refer to, collectively, as “Data Processing”:

- to carry out the study;
- to confirm the accuracy of the study;
- to monitor that the study complies with applicable laws as well as best practices developed by the research community;
- to make required reports to domestic and foreign regulatory agencies and government officials who have a duty to monitor and oversee studies like this one; and,
- to comply with legal and regulatory requirements, including requirements that data from this study, without information that could directly identify you, be made available to other researchers not affiliated with the study sponsor or with the study team. It is possible, for example, that as part of efforts to make research data more widely available to researchers, regulatory authorities in some countries may require that Your Study Data, without information that could directly identify you, be made publicly available on the internet or in other ways.

The following entities and organizations may engage in Data Processing of Your Study Data:

- the study team, including other people who, and organizations that, assist the study team:
 - o Ranak Trivedi, PhD (PI)
- the study sponsor: Stanford University
- the ethics committee or institutional review board that approved this study; and
- domestic and foreign regulatory agencies and government officials who have a duty to monitor or oversee studies like this one.

We may conduct the study in the United States or in other countries where the laws do not protect your privacy to the same extent as the laws in your country of residence. In addition, we may disclose Your Study Data for Data Processing to entities and individuals located in the United States or in other countries where the laws do not protect your privacy to the same extent as the laws in your country of residence. However, all reasonable steps will be taken to protect your privacy in accordance with the applicable data protection laws.

Stanford University takes part in the EU-U.S. Privacy Shield Framework. According to European Commission Implementing Decision (EU) 2016/1250, the EU-U.S. Privacy

Shield provides an adequate level of protection for Your Study Data. (See, <https://www.privacyshield.gov/list>)

The GDPR gives you certain rights with regard to Your Study Data. You have the right to request access to, or rectification or erasure of, Your Study Data. You also have the right to object to or restrict our Data Processing of Your Study Data. Finally, you have a right to request that we move, copy or transfer Your Study Data to another organization. In order to make any such requests, please contact Ranak Trivedi, PhD at ranakt@stanford.edu.

There is no limit on the length of time we will keep Your Study Data for this research because it may be analyzed for many years. We will also retain your Study Data to comply with our legal and regulatory requirements. We will keep it as long as it is useful, unless you decide you no longer want to take part. You are allowing access to this information indefinitely as long as you do not withdraw your consent.

You may withdraw your consent at any time. If you withdraw your consent, this will not affect the lawfulness or our collecting, use and sharing of Your Study Data up to the point in time that you withdraw your consent. Even if you withdraw your consent, we may still use Your Study Data that has been anonymized so that the data no longer identifies you. In addition, we may use and share Your Study Data that has been pseudonymized (by removal of your name and certain other identifiers so that the data does not directly identify you) as permitted by applicable law for purposes of: (a) public health (e.g., ensuring high standards quality and safety of health care and/or of medicinal products or medical devices), (b) scientific or historical research or statistical analysis as permitted by applicable European Union or European Union Member State laws and (c) archiving in the public interest. Further, we will maintain Your Study Data in fully identifiable form if required by law.

You consent to the collection, use and transfer of Your Study Data, which includes health and other sensitive personal data, for the purpose of carrying out the research study and know that you can withdraw your consent at any time, and we will stop processing your personal data, except as described above.