**General Data Protection Regulation GDPR Consent Form Language**

**[Instructional Text: If Stanford is involved in a study that takes place in the EU/EEA, involves a Stanford establishment in the EU/EEA, or otherwise involves individuals in the EU/EEA, please include the following language in all applicable consent forms:]**

*We will collect your personal data for this study, including data related to your health and/or other sensitive personal data as described in this consent form. We refer to this data as “Your Study Data.” Any Study Data from this research that is conducted in the European Union/European Economic Area (EU/EEA) will be collected, stored, used, and shared (processed) as required by the EU/EEA law known as the General Data Protection Regulation (“GDPR”). Your Study Data may be processed for the following reasons (purposes):*

**[Instructional Text: As applicable, add to the below list of data processing purposes to ensure that this informed consent includes all potential purposes for collecting and processing the data.]**

* *to carry out and confirm the accuracy of the study;*
* *to help us monitor and ensure that the study is following research best practices;*
* *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 follow applicable laws and regulations, 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 the study team.  For example, 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, to make research data more widely available to other researchers.*

*The following persons and organizations may process Your Study Data for the purposes listed above:*

**[Instructional Text: Revise the below list of recipients to identify the specific categories of natural persons and organizations that receive study data as part of the study team, or otherwise.]**

* *the study team, including other people who, and organizations that, assist the study team:*
  + *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*
  + *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*
  + *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_;*
* the study sponsor: [insert name of study sponsor]
* device/drug manufacturer: [insert name of manufacturer]
* *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 and other countries where the laws do not protect your privacy to the same extent as the laws in the country where you live (reside). Your Study Data may be transferred to these countries for the purposes described above. We will take reasonable steps to protect your privacy, consistent with applicable laws. For example, where appropriate, we enter into data transfer agreements with standard contractual clauses approved by European authorities that provide certain terms and conditions on how Your Data can be used and shared. These data transfer agreements help ensure Your Study Data is adequately protected.*

**Instructional Text: Data Subject Rights and Data Retention Language:**

*The GDPR gives you certain rights with regard to Your Study Data, including the right to: (1) request access to, correct, or erase Your Study Data, (2) object to or restrict our processing of Your Study Data, and (3) request that we move, copy or transfer Your Study Data to another organization. To make any such requests, please contact the Principal Investigator at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.*

*You may also withdraw your consent at any time.  If you withdraw your consent or request Your Study Data be erased, we can still legally collect, use and share Your Study Data up to the point in time that you withdraw your consent or request your data be erased. Even if you withdraw your consent, we may still use Your Study Data that has been anonymized by removing any data that identifies you. We may also use and share Your Study Data that has been pseudonymized by removing your name and certain other identifiers so that the data does not directly identify you, where permitted by law. Your anonymized or pseudonymized data may be used for purposes of: (a) public health (e.g., ensuring the high quality and safety of health care and/or of medical drugs or devices), (b) scientific or historical research or statistical analysis as allowed by the EU or EU Member State laws, and (c) saving or storing for important reasons of public interest. We will keep Your Study Data in identifiable form if required by law.*

*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 keep your Study Data to follow our legal and regulatory requirements. We will keep it as long as it isuseful, 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.*

**[Instructional Text Signature Block Text: Explicit consent of the transfer of health information outside of the EU/EEA is required. You can obtain this consent by adding the following text to the language near the signature block.]**

*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.*