General Data Protections Regulation (GDPR)

Addendum to the Informed Consent Document for Research Subjects

who are located in the European Union for

[Insert Name of Study]

As described in the informed consent document for the research study named above (the “Study”), personal data pertaining to your participation in the Study will be generated and recorded. The personal data includes an element of, or all of, the following; your personal health-related data, biometric data, genetic data, racial or ethnic data, data concerning your sex life or sexual orientation, and philosophical beliefs. We refer to all such data as your “Study Data.”

In addition to being regulated by applicable U.S. laws, if you are located in the European Economic Area during your participation in the Study, your Study Data will also be subject to the protections of the European Union’s General Data Protection Regulation (the “GDPR”).

Your Study Data will be processed, or used, for the purpose of conducting the Study described in this informed consent. In addition, your Study Data will be anonymized data and pseudo-anonymized in order for us to [track overall performance of the Study and for potential future research]. When your Study Data is pseudo-anonymized, the data set will omit your name, home address and other identifiers that directly identify you and be coded with a unique numeric identifier. [The key linking you to the code will not be shared outside the research team unless you consent below to future research conducted outside of this research project.]

International Transfer of Your Study Data

We may conduct the Study and future research in the United States or in other countries where the laws do not protect your privacy to the same extent as the laws in the European Economic Area. In addition, we may disclose your Study Data in order to conduct the Study or future research 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 the European Economic Area. In either case, we will comply with the privacy and data protection laws that apply to you if you are located in the European Economic Area.

***Instructions: Insert the following if the investigator is receiving the data from another researcher or institution in the EEA:*** We have entered into a data transfer agreement with [discloser], which includes standard contractual clauses approved by the European Commission and ensures an adequate protection for your Study Data. You may obtain a copy of the standard contractual clauses by contacting the Principal Investigator [or alternate contact, and include name and e-mail address.]

Recipients of Your Study Data

The following entities and organizations may process your Study Data for purposes of conducting the Study (together, “Recipients”):

* Those individuals associated with this research project as research personnel;
* [If funded;The sponsor or the Contract Research Organization for the study;]
* The University of Arizona (UA) and the UA Institutional Review Board
* Domestic and foreign regulatory agencies and government officials who have a duty to monitor or oversee studies like the Study described in the informed consent form.

***Future Use:******the following must be included:*** A statement that identifiers might be removed from the private information or biospecimens, and that after such removal, the information or biospecimens may be used for future research studies without additional informed consent. [Explain what research may be conducted with these data/specimens]. **Or;** a **s**tatement that the identifiable information or biospecimen, even if identifiers are removed, will not be used or distributed for future research.

Your Rights

If you are located in the European Economic Area during your participation in the Study, the GDPR gives you certain rights with regard to your Study Data. You have the right to request access to, rectification, or erasure of, your Study Data. You also have the right to object to or restrict our use 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 the research team at [insert phone number of PI and alternate contact if there is one]. Please be aware that these rights over your Study Data may be limited if we are unable to identify you from your Study Data alone because, for example, your Study Data has been anonymized or pseudo-anonymized.

Data Retention

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 keep it as long as it is useful, unless you decide you no longer want to take part. You are allowing access to your Study Data indefinitely as long as you do not withdraw your consent.

***Instructions:******If you process personal data without human intervention as part of the study, then include following automated processing language:***

Automated Processing

I understand that by participating in this Study, the research team will enroll me in one arm of the Study (i.e., receiving the investigational drug) instead of another (i.e., receiving a placebo in the control group) based solely on automated processing, including profiling, of my diagnostic and other personal data. This Study requires that we assign people to receive certain treatments based solely upon their diagnostic and other information. If you do not wish to be subject to this automated processing, we will not be able to enroll you in the Study.

*Instructions: If you will be including future research of specimens the following must be included to alert the potential participant of the extent of the future research:*

Consent to Future Research and Donation of Specimens

In addition to your consent to Moffitt’s processing of your Study Data for the Study described in this informed consent form, we request your consent to allow us and/or another person to process your Study Data [and/or a request for your donation of your tissue/blood (“Specimens”)] for other future research.

Please read each sentence in the chart below and put your initials in the “Yes” box to the right of the sentence if you consent to the additional data processing for the research purpose described in the sentence. Put your initials in the “No” box if you do not consent to the data processing to the right. If you have any questions about our request for consent [and/or your donation of Specimens], please talk to [the researchers]. If you choose not to consent to processing of your Study Data for future research [and/or donate your Specimens], any leftover tissue or blood that is not needed for diagnosis will be disposed of [and/or no additional normal tissue or blood will be removed for research purposes].

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| --- | --- | --- |
|  | **Yes** | **No** |
| You may keep my Study Data [and Specimens] for future research, that may not be specified at this point.  My Study Data [and Specimens] will be stored with an identification number that can be used by researchers to identify me in cases where identification is permitted by applicable law and in a way that [does/does not] directly identify me. [Insert if this applies to your project; However, I understand that it is theoretically possible to use genetic information from other sources to identify me.] |  |  |
| You may share my Study Data [and Specimens] with other researchers. My Study Data [and Specimens] will be stored with an identification number that can be used by researchers and other entities to identify me in cases where identification is permitted by applicable law and in a way that [does/does not] directly identify me. [Insert if this applies to your project; However, I understand that it is theoretically possible to use genetic information from other sources to identify me.] |  |  |
| [If you will sell the data collected, include the following statement.]You may share my Study Data with other entities (including for-profit companies) for a profit. My Study Data [and Specimens] will be stored with an identification number that can be used by researchers and other entities to identify me in cases where identification is permitted by applicable law and in a way that [does/does not] directly identify me. [Insert if this applies to your project; However, I understand that it is theoretically possible to use genetic information from other sources to identify me.] |  |  |

Withdrawing Your Consent

You may withdraw your consent at any time. If you withdraw your consent, this will not affect the lawfulness of 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 and may use your Study Data that identifies you (i) where we are required by law to maintain your identifiable personal data and (ii) as required to comply with regulatory requirements applicable to the conduct of the Study.

Questions Regarding Use of Your Study Data

[PI Name] is the data controller responsible for the use of your Study Data. If you have any questions regarding the use of your personal data, please contact the Principal Investigator at the number outlined in the informed consent form.