**TC IRB General Data Protection Regulation (GDPR)**

**Consent Notice Template**

**Instructions: This notice is required when the research collects or creates Personal Data[[[1]](#footnote-1)](#Article4) from subjects located in the EU (European Union) or EEA (European Economic Area). If the research is obtaining “Sensitive Data[[[2]](#footnote-2)](#Article9),” explicit consent is required. Delete all instructional text (in blue) before including this information as part of the consent form, under the PROTECTION OF YOUR CONFIDENTIALITY section. The below information should be distinct from the rest of the consent form language.**

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**GDPR Notice for Collection and Use of Research Data**

This research will collect data about you that can identify you, referred to as research data. The General Data Protection Regulation (“GDPR”) requires researchers to provide this Notice to you when we collect and use research data about people who are in a country that belongs to the European Union (EU) or in the European Economic Area (EEA).

We will obtain and create research data directly from you or from **(insert the data sources, including repositories, collaborators, publicly available sources, etc.)** so we can properly conduct this research. As we conduct research procedures with your research data, new data may be created.

We will collect and use the following types of data for this research:

**(Delete any categories of information that you will not collect or create)**

* Contact Information
* Health information
* Your racial or ethnic origin
* Your political opinions
* Your religious or philosophical beliefs
* Your sexual orientation or beliefs
* Genetic data
* Information about your response to the research procedures

**(Insert the categories of any additional data that you will collect)**

**(Include, if applicable, otherwise delete)** We will enter data about you and your health into a computer, and a computer program will help the research team decide if you meet the requirements to be in this research.

**(Include, if applicable, otherwise delete)** The research protocol requires us to enter data about you and your health into a computer. A computer program will be used to assign you to one of the following specific research treatments: **(list research treatments)**. If you sign this consent form, you are consenting to the use of this automated process to determine the treatment you receive. **(Describe any other procedures that use an automated process to make decisions about the subject)**

Please initial one of the boxes below to indicate whether you consent to the use of the automated processes described above.

* I consent to the use of the automated process described above \_\_\_\_\_\_\_\_\_
* I do not consent to the use of the automated process described above \_\_\_\_\_\_\_

This research will keep your data for **(insert the time the data will be maintained by the research)** after this research ends.

The following categories of individuals may receive data collected or created about you: **(Delete any category that is not applicable)**

* Members of the research team so they properly conduct the research
* Teachers College staff will oversee the research to see if it is conducted correctly and to protect your safety and rights
* The research Sponsor who will monitor the research and analyze the data
* Agents of the Sponsor who will assist the sponsor with data monitoring and analysis
* Representatives of the U.S. Office of Human Research Protections (OHRP) who oversee the research
* Other researchers, so they can perform procedures required by this research
* Other researchers, including researchers in other countries, so they can conduct additional research on **(condition)** and other unrelated diseases and problems

**(List the additional categories of individuals who may receive access to Personal Data and describe the reason for the disclosure.)**

**(Include, if applicable, otherwise delete)** We will transfer your research data to our research site in the United States. The United States does not have the same laws to protect your research data as States in the EU/EEA. However, the research team is committed to protecting the confidentiality of your research data. Additional information about the protections we will use is included in the main consent document.

The GDPR gives you rights relating to your research data, including the right to:

* Access, correct, or withdraw your research data; however, the research team may need to keep research data as long as it is necessary to achieve the purpose of this research
* Restrict the types of activities the research team can do with your research data
* Object to using your research data for specific types of activities
* Withdraw your consent to use your research data for the purposes outlined in the consent form and in this document (Please understand that you may withdraw your consent to use new research data, but research data already collected will continue to be used as outlined in the consent document and this Notice)

The Teachers College Information Technology (TCIT), on behalf of Teachers College, is responsible for the use of your research data for this research. You can contact the Teachers College Information Technology (TCIT) by phone at 212-678-3300 or by email at privacy@tc.columbia.edu if you have:

* Questions about this notice.
* Complaints about the use of your research data.
* If you want to make a request relating to the rights listed above.

***[If the data will be used for sponsored research or research authored by another research institution, where a non-TC researcher or non-TC institution is determining the data to be collected and scope of research, and TC is acting at the direction of the non-TC researcher or non-TC institution]: [name and contact information of sponsor/institution; sponsor/institution’s Data Protection Officer (DPO) and Representative, if any, and their contact information; if no DPO or Representative, provide name and contact information of sponsor/institution privacy official.]***

1. [***Article 4 of the GDPR***](https://gdpr-info.eu/art-4-gdpr/)***states “'personal data'*** *means* ***any information relating to an identified or identifiable natural person ('****data subject****')”***  [↑](#footnote-ref-1)
2. ***According to***[***Article 9 of the GDPR***](https://gdpr-info.eu/art-9-gdpr/)***applies additional conditions for processing Personal Data about racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person’s sex life or sexual orientation is prohibited unless additional requirements are met such as informed consent from the data subject.*** [↑](#footnote-ref-2)