

## Sample GDPR Privacy Notice and Consent

**Study Institution/Data Controller:** The Trustees of Columbia University on behalf of the Columbia University Irving Medical Center’s [department or institute]; 154 Haven Avenue, 2nd Floor, New York, NY 10032 (“Columbia”);

**Contact Person:** Jane Doe, Principal Investigator at Columbia, Phone Number: 555-555-5555; Email Address: [jdoe@columbia.edu](mailto:jdoe@columbia.edu)

Your Study Data, as defined below, is regulated in the European Economic Area under the EU General Data Protection Regulation (the “GDPR”). Columbia acts as the Data Controller with respect to Your Study Data.

### Research Study Data

When you participate in Columbia’s ABC Study (the “Study”), Columbia will generate and record data about your participation in the Study. In addition, we will collect and create sensitive personal data, including [health-related data (e.g., information relating to the type of tumor you have, XYZ; your heart rate following treatment ABC); biometric data (e.g., your iris recognition, your DNA); genetic data (e.g., specific phenotypic or variant data); racial or ethnic data; data concerning your sex life or sexual orientation; political opinions or philosophical beliefs, and/or trade union membership] and other personal data as part of the Study (collectively, Your Study Data). Your Study Data may include your first and last name, date of birth, contact information, medical record number, and medical history; your blood sample or saliva sample; and your photos.

### Purpose of the Research Study

Your Study Data may be processed or used for the following purposes:

- To determine whether you meet the eligibility criteria for the Study;
- To invite you to participate in the Study;
- To carry out the Study and other purposes for which you indicated your consent in this form;
- To confirm the accuracy of the Study;
- To monitor whether the Study complies with applicable laws as well as best practices developed by the research community;

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- To make required reports to United States (U.S.), domestic, and other foreign regulatory agencies and government officials who have a duty to monitor and oversee research studies like this Study;
- To comply with legal and regulatory requirements, including any requirements to share Your Data with U.S., domestic, or other foreign regulatory agencies and government officials who have a duty to monitor and oversee research studies like this Study; and
- To conduct research studies in the future that are related or unrelated to the subject matter of this Study.

### **Recipients of Your Study Data**

The following individuals and organizations may process Your Study Data in connection with the Study:

- Columbia, as the study sponsor;
- The Principal Investigator and the study team who conduct the Study at the Study Institution, as well as the organizations that support the study team;
- The ethics committee or institutional review board that approved the Study; and
- U.S., domestic, and other foreign regulatory agencies and government officials who have a duty to monitor or oversee studies like this one, including, but not limited to, the FDA and the U.S. Office for Human Research Protections.

Depending on the future research uses of Your Study Data you consent to in this form, Your Study Data may also be disclosed to researchers not affiliated with the study sponsor or with the study team.

### **Study Data to be transferred to other countries outside the EEA**

Columbia may use and disclose Your Study Data for processing for the purposes stated in this form 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 the country in which you are located. However, Columbia and the study team will take reasonable steps to protect your privacy in accordance with the applicable data protection laws.

[Transfers from EEA Research Subjects Directly to Columbia:] By consenting to Columbia's use of Your Study Data in connection with this study and/or future research, you agree that that Your Personal Data will be transferred to Columbia's location in the United States and to other

countries outside of the EEA as necessary to carry out the study and/or future research. [Transfers from EEA Institutions to Columbia:] Columbia has entered into a data transfer agreement with [EEA researcher/institution], 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 Contact Person listed above.

The recipients of Your Study Data identified above: (i) take part in the EU-U.S. Privacy Shield Framework; (ii) have or will enter into a data transfer or other agreement with us that ensures, or will ensure, an adequate protection of Your Study Data; or (iii) must have access to Your Study Data in order for us to conduct the study, such as a regulatory agency as required by laws applicable to the conduct of the study. (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.) If you reside in the European Economic Area during your participation in the study, in the event we disclose Your Study Data to other recipients, we will only do so with your consent.

### **GDPR Rights Respecting Your Study Data**

If you reside in the European Economic Area during your participation in the study, the GDPR gives you certain rights with respect 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 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 the Contact Person identified above.

Columbia will delete Your Study Data when it is no longer needed for the study or other research purposes [or when you withdraw consent you provide below in this Consent Form]. However, we will retain Your Study Data when necessary to comply with our legal and regulatory requirements.

You may withdraw any consent you provide on this form 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 or maintain Your Study Data that identifies you to comply with our legal and regulatory requirements.

<i>You permit Columbia to collect and use Your Study Data for the purpose of carrying out the study described in this form.</i>	<i>Yes</i> <input type="checkbox"/>	<i>No</i> <input type="checkbox"/>
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<i>Members of Columbia's study research team may contact you directly to obtain additional information, including new or additional biological samples, in connection with the study described in this form.</i>	<b>Yes</b> <input type="checkbox"/>	<b>No</b> <input type="checkbox"/>

<i>You permit Columbia to use Your Study Data for possible future research by Columbia's medical staff, faculty, or other Columbia-affiliated investigators to learn about [specify subject matter of future research] that is approved by Columbia's Institutional Review Board or another appropriate research ethics committee.</i>	<b>Yes</b> <input type="checkbox"/>	<b>No</b> <input type="checkbox"/>
<i>You permit Columbia to share Your Study Data with any third-party academic or not-for-profit institution or commercial entity for possible future research related to [specify subject matter of future research] that is performed with approval by an institutional review board or other appropriate research ethics committee.</i>	<b>Yes</b> <input type="checkbox"/>	<b>No</b> <input type="checkbox"/>

So long as Your Study Data remains identifiable, you are free to withdraw the use of Your Study Data kept for future research. If you decide to withdraw Your Study Data from such use, you should notify the Contact Person immediately. If you withdraw your consent to future research, this will not affect the lawfulness or our use and sharing of Your Study Data up to the point in time that you withdraw your consent. Even if you withdraw your consent to future research, we may still use Your Study Data that does not identify you for future research, except that for where we are required by law to maintain your identifiable personal data.

<i>You permit Columbia to enroll you 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 your diagnostic and other personal data.</i>	<b>Yes</b> <input type="checkbox"/>	<b>No</b> <input type="checkbox"/>
<i>You understand that if you do not consent, we will not be able to enroll you in the study, because this study requires that we assign people to</i>		

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<i>receive certain treatments based solely on their diagnostic and other information.</i>		
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**Name of study participant (print):** \_\_\_\_\_

**Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_