**Consent Template: GDPR**

To provide the information necessary under the European Union General Data Protection Regulation 2016/679 (“EUGDPR”), this document must be used along with the general consent form when collecting personal data for the purposes of research from citizens of the European Union. **To reduce the potential for IRB revision requests and delayed study approval, please use our template.**

The contents of the consent template have been organized to facilitate comprehension. **Consent documents should be written in plain language, generally at an 8th-grade reading level.** The reading level can be higher if the planned participant population tends to have a higher literacy rate than the general population. For more information on plain language, go to <http://www.plainlanguage.gov/>.

Please note the following:

1. Text in [brackets] represents information about your study that you must add.
2. A forward slash (/) indicates that you must select an option specific to your study (e.g., “will/will not” or “I/we”) and remove the remaining option(s).
3. Additional instructions or sample text are provided in boxes.
4. Before you submit your consent document to the IRB, delete this cover page, all brackets, and the boxes. You’ll also need to remove any extra spaces created when the boxes were removed.
5. Please follow the **instructions in blue** below, revising or providing the information in **red**. You will need to remove the instructions as you go, including these instructions. The font color of your completed document should be **black**.
6. The finished document should reflect what you will give to prospective participants.
7. If your study will involve multiple types of participants requiring different consent forms, save each file using a file name specific to each consent document, clearly identifying the type of consent and the intended audience (e.g., parental consent, survey consent, etc.).

For more information on the EUGDPR, go to <https://gdpr-info.eu/>

**General Data Protection Regulation (GDPR) Consent**

*To Be Signed By Individual Providing Personal Data*

**Controller Information**

Provide the name of the principal investigator (PI) along with contact information below.

For the purposes of this research study, the principal investigator (PI), [Your Name], is the controller of your personal data. You may contact [Your Name] by phone and email at [phone number and email].

**Uses of Personal Data**

In one to two sentences and in plain language, please list the purpose of your study as it relates to personal data use.

Your personal data will be used for the purpose of research. Specifically, the research seeks to [study purpose].

**Categories of Personal Data**

Below, please provide the specific data fields you intend to use for the research study. “Special categories" of personal data require a higher level of protection due to their sensitive nature and consequent risk for greater privacy harm.  This includes information about a data subject's **health, genetics, race or ethnic origin, biometrics for identification purposes, sex life or sexual orientation, political opinions, religious or philosophical beliefs, or trade union membership.**  Although criminal convictions and records are not considered "special categories" of personal data, this information is subject to amplified protections under the GDPR.

The categories of personal data you are being asked to allow the principal investigator to use are [Retain the options that are applicable to your research and remove those that are not.] [your name, address, email address, telephone number] and [Include a description of any other personal data you will collect, including any special categories as defined in the GDPR.] [\_\_\_].

**Confidentiality of Personal Data & Provisions for Data-Sharing**

Please complete the following paragraph:

The records of this study will be kept private. Research records will be stored securely, and only the researcher[s] will have access to the records. [Include the following sentence if the possibility of sharing the data exists. If this is not the case, you may delete it.] The principal investigator may share your personal data with third parties, including [List all other parties that will receive participants’ personal data.] [\_\_\_].

Include the following paragraph if you reside within the United States. If you reside within the EU, you may remove the paragraph.

[Your personal data will be transferred out of the European Union to the principal investigator located in the United States. By signing this consent form, you acknowledge and understand that your personal data will be transferred out of the European Union to the principal investigator in the United States and that the United States does not protect personal data in the same manner as it may be protected in the European Union. By signing this consent form and checking “gives consent” below, you consent to this transfer of your personal data.]

**Provisions for Data Storage & Your Rights**

Please retain and do not alter the following paragraph:

Your personal data will be stored in accordance with the record retention requirements applicable to research activities and Health and Human Services (HHS) regulations in the United States. Under the EUGDPR, you have the right to request access to, rectify, erase, and restrict the processing of your personal data. You also have the right to revoke this consent to use your personal data. If you feel the principal investigator has violated the EUGDPR, you have the right to file a complaint with the appropriate EU supervisory authority.

**Your Consent**

Select/revise the appropriate options in red below to ensure that this form is completed and returned to you. If you plan to collect electronic signatures, please be sure to capture the fields listed below.

Please [sign/electronically sign], check the desired box, date, and return this form to the principal investigator.

I consent to [Insert your name as the PI.] [researcher’s name] using my personal data for the purposes described in this notice and understand that I can withdraw my consent at any time using the contact information provided above in this notice.

\_\_\_ Gives consent

\_\_\_ Does not give consent

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Printed Name of Individual Providing Consent

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Address of Individual Providing Consent

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Signature of Individual Providing Consent Date