DPA 2018 Privacy Notice & Consent Addendum

INSTRUCTIONS: If the study proposes to conduct research involving residents of the European Economic Area, please complete the following data processing disclosure in addition to the main consent document. This consent form provides information for potential research participants to understand how the processing of their personal data will be conducted for the purpose of this research project. For participants who are residents of mainland China or Russia, contact the Health Information Privacy Compliance Office at privacy@umn.edu. For other international residents, refer to the International Data Privacy Consent Addendum. All instructions are in red font. Please delete the instructions before submitting the form to the IRB for review.

**Title of Research Study:**[insert title of research study here]

**STU#:** [insert study number]

**Principal Investigator:**[insert name of principal investigator]

**Supported By:**[List all monetary and non-monetary support for this research. If not externally funded, state your school or department]

You can find information related to the purpose of the research project, how it will be conducted and by whom from the primary consent form for this research project, which you should receive as a separate document (the “**Primary Consent Form**”). This document describes how your data will be collected, processed, and stored as a part of that research project.

We (the research team and the University of Minnesota) are conducting the processing of personal data related to this research project on the basis of your consent. Please sign at the bottom to indicate that you have read and understood how your personal data will be processed, your related rights, and that you consent to the collection, processing, and storage of your data as described below.

# Personal Data Collected

Fill out the categories of data you will use for the research project, aiming to be as detailed as possible. In particular, please be sure to describe any “sensitive personal data”, which is defined under [UK Data Protection Act 2018 (DPA 2018)](https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted)  as data related to an individual’s:

1. personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs;
2. trade-union membership;
3. genetic data;
4. biometric data processed solely to identify a human being;
5. health-related data;
6. data concerning a person’s sex life or sexual orientation. The categories of data bulleted below are just examples and should be replaced depending on the project.

We will collect or generate personal data about you in connection with your participation in this research project, including:

|  |
| --- |
| ● *Your first and last name, date of birth, contact information, medical record number, and medical history;*  ● *Information you submit to us, including as part of research project forms, surveys, or questionnaires;*  ● *Genetic data (in particular, …………………..)*  ● *Data related to health (in particular, blood type, heart rate, ……….. )*  ● *Behavioral data (in particular, ……………………..)* |

Only include this if you obtain personal data from other sources than what you observe directly and what the subject is providing to you. Otherwise, delete this paragraph:

We will also obtain personal data related to you from third party sources, as follows:

|  |
| --- |
| ● *Data related to your social interactions from your social media accounts;*  ● *Data related to your school performance from your student file;*  ● *Data gathered automatically from your use of [list any websites or apps used to collect site / app usage data from participants]* |

Include if this is the practice, otherwise delete this sentence:

As a safeguard to protect your privacy, we pseudonymize (key-code) your personal data. *[Optionally, include information of who has access to the key-coded data and who has access to the key, as well as the circumstances when re-identification can occur]*.

# Use of Your Personal Data

Using data to extend research is considered a “compatible use” and this language applies. If data potentially may be used for other, non-research purposes, re-consent would be required.

We will use your personal data primarily for the purposes of this research project, including the purposes described in the Primary Consent Form. If the results of this research indicate that further studies might be beneficial, we may process your personal data for the purpose of extending our research in other fields or areas.

We will also use your personal data to the extent necessary to comply with legal and regulatory requirements, including any requirements to share your personal data with regulatory agencies and government officials who have a duty to monitor and oversee research studies like this research project.

# Retaining Your Personal Data

We will retain your personal data for as long as necessary to fulfill the purposes and uses described in this form, including for purposes of satisfying any legal, accounting, or reporting requirements. We may also keep your records if legally required or to fulfill another legitimate interest.

If the retention period depends on specific factors, please use the following language to describe those factors.

The period of time for which we retain your personal data will depend, in part, on [include the factors that influence this period of time].

# Recipients of Your Personal Data

Include information about all entities that have access to the personal data, including service providers that are contracted for handling data or any other service on your behalf (ex: cloud service providers). Please indicate the name of the service provider. Highlighted bullet points should be edited or removed, as applicable to the study. If organizations and individuals are described in the Primary Consent form, keep that bullet point. The bullet regarding receipt by third parties should be maintained.

We will share your personal data with the following recipients:

|  |
| --- |
| * *…the Supervisory Body for X (US based)………* * *…Processors that act on our behalf: a cloud service provider, an image processor…….* * Organizations and individuals described in the Primary Consent Form as participating in the conduct or support of the research project or receiving data or results from the research project; * Third parties, including public authorities, for those situations where we have a legal obligation to do so, such as where we are required to share your personal data with regulatory agencies and government officials who have a duty to monitor and oversee research studies like this research project. |

# Privacy Regulations

The University of Minnesota is an institution based in the United States, and your personal data will be transferred to the United States, which has not sought nor obtained an adequacy decision from the European Commission. This means that there may be risks to your personal data in this jurisdiction. However, we will take all reasonable steps to protect your privacy in accordance with applicable data protection laws.

The research team is committed to protecting the confidentiality of your personal data. We comply with the University’s policies and procedures regarding the privacy and security of your personal data, in accordance with applicable state and federal law. More information is available here: [UMN Health Information Privacy & Compliance Office](https://healthprivacy.umn.edu/).

By signing this consent form, you acknowledge and consent to the collection, use, and disclosure of data about you to conduct this study in the ways described above. You also acknowledge and consent to the transfer of your personal data and other information to, and the processing of such data and information in, the United States.

# Your Rights

Under the [UK Data Protection Act 2018 (DPA 2018)](https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted)  and its implementing laws at the national level, if you reside in the United Kingdom during your participation in this study, you have the following rights, with the conditions and limitations set out in Chapter III of the DPA:

(1) A data subject is entitled to obtain from the controller—

(a) confirmation as to whether or not personal data concerning him or her is being processed, and

(b) where that is the case, access to the personal data and the information set out in subsection (2).

(2) That information is—

(a) the purposes of and legal basis for the processing;

(b) the categories of personal data concerned;

(c) the recipients or categories of recipients to whom the personal data has been disclosed (including recipients or categories of recipients in third countries or international organisations);

(d) the period for which it is envisaged that the personal data will be stored or, where that is not possible, the criteria used to determine that period;

(e) the existence of the data subject’s rights to request from the controller—

i. rectification of personal data (section 46), and

ii. erasure of personal data or the restriction of its processing (section 47);

(f) the existence of the data subject’s right to lodge a complaint with the

Commissioner and the contact details of the Commissioner;

(g) communication of the personal data undergoing processing and of any available information as to its origin.

When you withdraw your consent, we will not collect additional information related to you. We may also erase the personal data we already collected. If you withdraw your consent, this will not affect the lawfulness or our collecting, use, and sharing of your personal 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 personal data to comply with our legal and regulatory requirements.

To exercise your rights, please use the contact information below to submit a request. When you submit a request, please indicate your name, the name of this project, your reasons for making the request, if necessary, and other details you think will be useful for us to comply with your request.

# Additional Information

If you have any concerns about how your personal data is being handled, please contact us using the information below. If you are not satisfied with our reply and how we protect your personal data, you can contact the data protection authority in your home country or in another relevant jurisdiction for this processing activity, pursuant to the conditions of DPA 2028.

Contact Information

If you have further questions or concerns regarding your data privacy and want to talk to someone besides the research team, you may alternatively contact the Institutional Review Board or the Health Information Privacy Compliance Office at UMN.

* Institutional Review Board: (612) 626-5654 or [irb@umn.edu](mailto:irb@umn.edu)
* Health Information Privacy Compliance Office: (612) 624-7447 or [privacy@umn.edu](mailto:privacy@umn.edu).

# Research Participant Consent

By my signature below, I consent to the collection, processing, and storage of my data as described in this form.

*[There are three sets of signature options listed below. Use the signature block appropriate for your study. Delete those that do not apply. This form must be signed by the participant or the participant’s legally authorized representative prior to participating in the research.]*

**Signature Block for Capable Adult:**

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

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Signature of Participant Date

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Printed Name of Participant

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Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent

**Signature Block for Witness:**

**WITNESS STATEMENT:**

The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is illiterate

☐ The participant is visually impaired

☐ The participant is physically unable to sign the consent form. Please describe:

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☐ Other *(please specify)*:

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**For the Consent of Non-English Speaking Participants when an Interpreter is Used:**

A**s** someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

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Signature of Interpreter Date

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Printed Name of Interpreter

**OR:**

**Statement from a Non-Interpreter:**

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

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Signature of Individual Date

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Printed Name of Individual

**Signature Block for Adult Unable to Consent:**

Your signature documents your permission for the named participant to take part in this research.

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Printed Name of Participant

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Signature of Legally Authorized Representative Date

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Printed Name of Legally Authorized Representative Date

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Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent Date