Please delete or modify all information in red and modify the header. Text should be black when the document is complete. Remember that information in the consent should match what is described in your protocol.

**Model GDPR Informed Consent Addendum**

Study: {Insert Protocol Title and IRB-SBS #}

In the Consent Form for this study you are told about how personal information about you will be collected and handled as part of your participation in the study. We would like to give you additional information due to the European General Data Protection Regulation (GDPR). This affects the handling and control of your personal information in this study.

**1. Information about the Study Sponsor and the Institution carrying out this study:**

The Sponsor of this study is: {Insert Sponsor name and address; if no sponsor, delete this line and delete “the Study Sponsor and” from the header line}. The institution carrying out the study and collecting your personal information is: University of Virginia, PO BOX 400400, Charlottesville, VA, 22904-4400.

{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. For the option that doesn’t apply, delete the option and the text below the option.}

Option 1:

We will not share your personal data with any third party. We will only disclose the personal data to authorities for those situations where we will receive a lawful order to do so.

Option 2:

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…….

● Public authorities, for those situations where we will receive a lawful order to do so.

**2. Personal data use**

{Choose one of the two options which best applies to your study and delete the other option.}

{Option 1:}

We will only use your personal data for the purposes of this research project.

{Option 2:}

We will use your personal data primarily for the purposes of this research project. If the results of this research will indicate that further studies are beneficial for {include topic/field/area of study/benefit for society}, we may process your personal data for the purpose of extending our research in the field/area of {include specific area/field}. You will be informed before the further compatible processing takes place.

**3. Special categories of personal information:**

Please be aware that the personal information about you that will be collected in the study includes special categories of personal data, namely information about:

{This information needs to be specific to the study. Delete any of the below that will not be collected. For items that will be collected, you will need to state specifically what information will be collected. This section needs to match the checklist in the protocol’s International Research Data Source question.)

* Demographics: Name, Age, Birthdate (for example, if there are others, list them here)
* Contact information: email, phone number, address, IP address
* Information about a Subject's Health
* Racial or Ethnic Origin
* Political Opinions
* Religious or Philosophical Beliefs
* Trade Union Membership
* Sexual Orientation
* Data concerning a person's sex life
* Biometric Data
* Genetic Data
* Criminal Activity

{Only include the next paragraph 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 obtain additional personal data related to you from third party sources, as follows:

● Data related to your social interactions from your Facebook account;

● Data related to your school performance from your student file;

● ………..

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

As a safeguard to protect your privacy, we will link your personal data with a code and remove your identifying information. {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.}

**4. Your privacy rights**

For your personal information collected by the study you have the following data privacy rights:

* To request information about the handling of your data. However, to protect the scientific integrity of the study, you may not be able to receive access to some of the data before the study ends.
* To request correction of data about you if it is incorrect or incomplete. During the assessment of this request, you have the right to restrict the processing of data about you.
* To request transfer of data about you to you or someone else in a commonly used format.
* To file a complaint with a data protection authority.
* To withdraw your consent at any time without giving a reason. You can withdraw your consent for study treatment and/or further follow up, without withdrawing consent for handling your data. You may also withdraw consent to the handling of your data, as described in the Consent Form. Then you will no longer be in the study, but the researchers will still use the data about you that was collected before you withdrew. After you withdraw, no further data will be collected from you.
* Along with your withdrawal, you have the right to request the deletion of data about you if your data are no longer needed or there is no other legal requirement for their use.

**5. Transfer of data to other countries**

\*\*text from Beth Hodgson\*\*

Your information may be transferred to or handled in countries other than the country where it was originally collected. Those countries may not have the same data protection laws as the country in which you initially provided the information. When we transfer your personal information to countries whose data protection level has not been confirmed as adequate by the European Commission, we will provide appropriate safeguards for the transfer of personal information as required by law.

\*\*text from Michigan consent template\*\*

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 under this jurisdiction. However, we adopt and implement sufficient safeguards to protect your personal data, as described in this form. We transfer your data on the basis of your explicit consent, under Article 49 GDPR.

If you have any concerns about how your personal data is being handled, use the address below to contact us. If you will not be 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 Article 77 GDPR.

**If you wish to pursue any of your data privacy rights, please contact:**

{Insert Study Team Contact information}

or

IRB-SBS

Telephone: (434) 924-5999

Email: irbsbshelp@virginia.edu

Website: https://research.virginia.edu/irb-sbs

Website for Research Participants: https://research.virginia.edu/research-participants

UVA IRB-SBS # Include Protocol Number HERE!

**6. Retention of personal information**

Your information will be stored for at least [insert years] after the end of the study, or longer if needed for legal requirements.

**7. Signature**

Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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