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 and/or application.

**Model GDPR Informed Consent Addendum**

**(Version 2-16-22)**

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:**

*If applicable:* 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 (Choose option below)**

A. 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.

B. 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

University of Virginia

Institutional Review Board for Health Sciences Research (IRB-HSR)

Telephone: (434)-924-2620

Email: irbhsradmin@virginia.edu

Website: <https://research.virginia.edu/irb-hsr>

Website for Research Participants: <https://research.med.virginia.edu/clinicalresearch/participate-in-a-trial/>

UVA IRB-HSR # 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. Signatures**

**What does your signature mean?**

Before you sign this form, please ask questions about any part of this addendum that is not clear to you. Your signature below means that you have received this information and all your questions have been answered.

You will receive a copy of this document after you have signed it.

**Consent From Adult**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PARTICIPANT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PARTICIPANT (PRINT) |  | \_\_\_\_\_\_\_  DATE |  |  |

**To be completed by participant if 18 years of age or older.**

**If an interpreter is involved in the consent process because the potential subject does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the Short Form or full consent written in the language they can understand.**

**Person Obtaining Consent**

By signing below, you confirm that you have fully explained this study to the potential subject, allowed them time to read the addendum or have the addendum read to them, and have answered all their questions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING CONSENT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING CONSENT (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

***If no children are enrolling, or if verbal assent from the child was previously approved by the IRB, delete the section “Assent from Child” below:***

**Assent from Child**

***Consent from the parent/guardian MUST be obtained before approaching the child for their assent.***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARTICIPANT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PARTICIPANT (PRINT) |  | \_\_\_\_\_\_\_  DATE |  |  |
| **To be completed for any child aged 7 to <18.** | | | | | | |

**Person Obtaining Assent of the Child**

***Consent from the parent/guardian MUST be obtained before approaching the child for their assent.***

By signing below, you confirm that the study has been explained to the child (less than 18 years of age), all questions have been answered and the child has voluntarily agreed to participate.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING ASSENT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PERSON OBTAINING ASSENT (PRINT) |  | \_\_\_\_\_\_\_  DATE |

**Parental/ Guardian Permission**

By signing below, you confirm you have the legal authority to sign for this child.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (PRINT NAME) |  | \_\_\_\_\_\_ DATE |  |  |
| ***Second parent/guardian signature section to be added if there is risk but no benefit to the participant.*** | | | | | | |
|  |  |  |  |  |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (PRINT NAME) |  | \_\_\_\_\_\_ DATE |  |  |

**If you are unable to obtain parental permission from both parents, explain why not:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Person Obtaining Parental/Guardian Permission**

By signing below, you confirm that you have fully explained this study to the parent/guardian, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING PARENTAL PERMISSION (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING PARENTAL PERMISSION (PRINT NAME) |  | \_\_\_\_\_\_\_\_ DATE |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Surrogate Consent for Adult Participant**

In the event the adult participant is unable to give informed consent for participation in this study:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PERSON GIVING CONSENT FOR PARTICIPANT DATE

(Signature/ Printed)

RELATIONSHIP TO PARTICIPANT: *Check one of the options below*

\_\_\_\_\_Agent under an Advance Directive that authorizes participation in research

\_\_\_\_\_Court-appointed Guardian

\_\_\_\_\_Spouse (unless divorce action has been filed)

\_\_\_\_\_Next of kin

**If an interpreter is involved in the consent process because the surrogate does not speak English well or at all, the surrogate should NOT sign on the line above – leave this line blank. Instead, the surrogate should sign the IRB approved, fully translated consent form or the Short Form written in the language they can understand.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Person Obtaining Consent of the Surrogate**

By signing below, you confirm that you have fully explained this study to the potential subject’s surrogate, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING CONSENT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING CONSENT (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Person Obtaining Assent of the Adult Subject**

The subject is unable to give assent due to the following reason: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**OR**

By signing below, you confirm that the study has been explained to the adult subject, all questions have been answered and the adult subject has not demonstrated resistance or dissent by word or gesture to enroll in the study. You also confirm that if the subject demonstrates resistance or dissent at any point in the study that they will not be subjected to any additional study interventions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING ASSENT (SIGNATURE) |  | PERSON OBTAINING ASSENT (PRINT) |  | \_\_\_\_\_\_\_  DATE |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Consent of the Subject to Continue to Be in the Study**

Your legal representative gave his/her permission for you to be in this research study. This is because you were not able to make your own decision due to your illness. Your condition is now better. You are being asked to decide whether to continue to be in this study. The decision is up to you. Before you sign this form, please ask questions about any part of this study that is not clear to you. When you sign below, you are saying you understand the information we gave you about the study and in this form.

**If you sign this form, it means that you agree to continue being in the study.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

PARTICIPANT PARTICIPANT DATE

(SIGNATURE) (PRINT)

**If an interpreter is involved in the consent process because the subject does not speak English well or at all, the subject should NOT sign on the line above – leave this line blank. Instead, the subject should sign the IRB approved, fully translated consent form or the Short Form written in the language they can understand.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Person Obtaining Consent of the Subject to Continue to Be in the Study**

By signing below, you confirm that you have fully explained this study to the subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

PERSON OBTAINING PERSON OBTAINING DATE

CONSENT (SIGNATURE) CONSENT (PRINT)

**Signature of Impartial Witness**

**If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.**

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study.   I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

**Please indicate with check box the identified individual(s):**

Subject

Parent(s)/Guardian of the subject

Subject’s surrogate

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ IMPARTIAL WITNESS (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ IMPARTIAL WITNESS (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

**Interpreter**

*If the study is explained to a potential subject in a language other than English, the signature of the interpreter is required, and signatures are required on separate forms depending on the language spoken by each individual. See table below for additional information.*

|  |  |
| --- | --- |
| ***INDIVIDUAL*** | ***SIGN*** |
| *Subject/Surrogate* | *Translated Short Form  OR translated Full Consent* |
| *Interpreter* | *EITHER*   * *Translated Short Form AND English Version of Full Consent* * *Translated Full Consent* |
| *Person Obtaining Consent* | *English Version of Full Consent* |
| *Parent/Guardian* | *Applicable form in language they understand (sign one of the following)*   * *English Version of Full Consent,* * *Translated Full Consent* * *Translated Short Form* |

**The study was explained to the following individuals in a language other than English.**

*Check all that apply.*

Subject

Parent(s)/Guardian of the subject

Adult subject’s surrogate

**Interpreter**

By signing below you confirm that the study has been fully explained in a language the person understood and that all of their questions have been answered.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  INTERPRETER (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ INTERPRETER (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

*If an interpreter was used via an outside phone service such as Cyracom, enter the interpreters ID# on the signature line above and document in the consenting process note that an outside interpreter via phone service was used to obtain consent/assent.*