**RESEARCH PARTICIPANT INFORMATION SHEET**

**STUDY TITLE:** [Insert the official title of the study, as it is given in the IRB application]

**VCU INVESTIGATOR:** [Insert the full name and title of the VCU Investigator]

*TEMPLATE INSTRUCTIONS:*

* Instructions and comments are indicated in blue boxes, and [yellow highlighting].
* Delete the instructions and comments after reading and following.
* Example text should be edited to be appropriate for your study.
* Use lay language at an 8th grade reading level.
* If it is necessary to use technical terms, a lay definition of the term must be provided.
* Define all acronyms at first use.
* Page numbers must be included in the format “Page \_\_ out of \_\_\_\_”.
* If the study enrolls only children, replace “you” with “your child”

INSTRUCTIONS: Per [WPP VIII-1](https://research.vcu.edu/human_research/irb_wpp/VIII-1.htm), at a minimum, the investigator conducting exempt research is expected to provide the following information to a prospective participant:

1. A description of the project as research,
2. An explanation of research procedures,
3. A statement that participation is voluntary, and
4. The name and contact information of the researcher

Additional consent information may be included from the Biomedical or Social-Behavioral Consent Templates to inform research participants more fully about the study.

You/your child are invited to participate in a research study about [briefly describe the study’s purpose]. Your/Your child’s participation is voluntary.

[Example 1:] Your child will be asked to participate in either individual reading time or group reading time during your regular reading class for the next \_\_\_ months. The researchers will also collect information about [describe general topics] from your child’s school records. [Describe all of the things that participants will be asked to do during the study].

[Example 2:] In this study, you will be asked to do the following things:

1. Visit [location] \_\_ times for study visits
2. Play a money game on a computer while the researchers video record your behavior
3. Take surveys and answer questions about [describe the topics and kinds of questions that will be asked]
4. Participate in an interview or focus group about [describe the topics and kinds of questions that will be asked]

INSTRUCTIONS: Insert the following text only if

 1) The research qualifies for exempt category 3 (benign behavioral interventions)

 AND

 2) Will involve deception (withholding information or misleading participants)

**45 CFR 46.104(d)(3)(iii):** “If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.”

Studies not submitted under exempt category 3 should delete the following text:

During this study, you will be unaware of or misled regarding the nature or purpose of the research. By participating, you are agreeing to this deception.

INSTRUCTIONS: If your study involves any of the following, insert the applicable template language provided on the next page.

If you have any questions, concerns, or complaints about this study now or in the future, please contact [insert name, phone number, and VCU email address of lead contact person for the study].

**Additional Template Language that May Be Applicable to Your Study**

**Certificate of Confidentiality**

**\*\*This sub-section is required for all studies funded in whole or in part by the NIH, that were commenced or ongoing, on or after December 13, 2016. It is also required for all non NIH-funded studies that will voluntarily seek a Certificate of Confidentiality (note: all human subject research qualifies for a CoC). Modifications are not recommended.**

To help us protect your privacy, we have obtained [or insert: will apply for] a Certificate of Confidentiality from the National Institutes of Health. If this certificate is obtained, it will offer the protections described here. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

[If you intend to make voluntary disclosure about things such as child abuse, intent to hurt self or others, or other voluntary disclosures, insert:] The researchers may share information about you or your participation in the research project without your consent if: [State here the conditions under which voluntary disclosure would be made, such as child or elder abuse or neglect, or harm to self or others.]

**\*\*The following paragraph is required for all clinical trials and for studies that will voluntarily post on the ClinicalTrials.gov website. It may not be modified.**

For more information about CT.gov requirements, see <https://cctr.vcu.edu/support/consultation/clinical-trials-gov/>

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.clinicaltrials.gov/), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

**WILL I BE PAID TO PARTICIPATE IN THE STUDY?**

INSTRUCTIONS: Include in this section a description of any planned compensation that will be given to participants. Use straightforward language and include the amount paid per visit.

**\*\*This is an optional section. It only applies to studies that plan to compensate participants and may be modified as appropriate.**

[Example:] You will be paid $\_\_\_\_\_ in cash/by check/by gift card for each study visit, and if you complete all scheduled study visits, you will have received a total of $\_\_\_\_. If you withdraw before the end of the study, you will be paid $\_\_\_\_\_ per completed study visit.

[Include if paying money to participants:] Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

[Include if appropriate] Please be aware that the investigative team and the University may receive money for the conduct of this study.

[Example:] You will receive 1.5 SONA credits if you finish the study. If you withdraw before the end of the study, you will receive 0.25 credits for every 15 minutes that you participated.

**HOW WILL MY EDUCATIONAL RECORDS BE USED AND SHARED DURING THE STUDY?**

INSTRUCTIONS: Access to educational records is regulated by the Family Educational Rights and Privacy Act (FERPA), which stipulates generally that schools must have written permission from the parent or eligible student in order to release any information from a student’s education record. For more information about FERPA requirements, contact [VCU Records and Registration](https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/).

For research uses of education records, there are several options for how data can be accessed (see [WPP XVII-17](https://research.vcu.edu/human_research/irb_wpp/XVII-17.htm)). **If you have further questions about your options, then you should consult with VCU Records and Registration to determine which is best for your study.**

If the “written, signed consent” option will be used, then the consent form must specify:

* The records to be released
* Reasons for the release
* Parties to whom records may be released
* Notice that, upon parental or adult student request, the school will provide him/her with a copy of the records disclosed
* Notice that, upon parental request, the school will provide the student with a copy of the records disclosed

**The following language is required if the study involves obtaining education record information under the FERPA “written, signed consent” option. It may be modified as appropriate.**

As part of this research, we will ask you to share identifiable information from your educational records, which is protected by the Family Educational Rights and Privacy Act (FERPA). The following types of information will be used for the conduct of this research: [list the specific types of educational records/information to be released (e.g. test grades, GPA, homework, writing samples, etc.)]. This educational information will be released to the Principal Investigator and the research staff [if information may be released to other persons or groups, list them here]. Upon request, the school will provide you with a copy of the records disclosed.

INSTRUCTIONS: For research uses of education records, there are several options for how data can be accessed under FERPA (see [WPP XVII-17](https://research.vcu.edu/human_research/irb_wpp/XVII-17.htm)). **If you have further questions about your options, then you should consult with VCU Records and Registration to determine which is best for your study.**

**The following language is required if the study involves obtaining identifiable education record information under the FERPA “written signed consent” option. It may not be modified.**

FERPA Statement:

Under the Family Educational Rights and Privacy Act (FERPA) of 1974, updated January 2009, I understand that my educational records cannot be released without my written permission. I authorize the release of my academic records from Virginia Commonwealth University for the purpose of this study. I understand that I have the right to rescind this release agreement of my academic records at any time.

**Signature Block for Enrolling Adult Participants**

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

Adult Participant Name (Printed)

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

Adult Participant’s Signature Date

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

Name of Person Conducting Consent Discussion (Printed)

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

Signature of Person Conducting Consent Discussion Date

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

Principal Investigator Signature (if different from above) Date

**HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?**

INSTRUCTIONS: This section includes all of the required elements of valid HIPAA Authorization. Include this section if the study will use Protected Health Information (PHI) associated with or derived from a healthcare service event (e.g. treatment, payment, operations, medical records, etc.) as either secondary data or direct report from participants.

**\*\*This is an optional section that applies only to studies accessing, using, or maintaining PHI AND if the study’s HIPAA pathway is “Signed Authorization Combined with Consent.” Remove this section if a separate HIPAA Authorization form will be used. Modifications are not recommended.**

VCU researchers can ensure all of the HIPAA authorization requirements are being met by utilizing this template language as directed. **If you choose not to include all of the required elements, you must request a Partial Waiver of Some Elements of Authorization and list the elements that you want to waive.**

Researchers also have the option to draft their own authorization language. If drafting your own language, this section is required to include 8 elements in order for the authorization to be valid (elements listed at [WPP XII-3](https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/)). A Partial Waiver should be requested for any omitted elements.

As part of this research study, we will ask you permit us to access existing information from your healthcare records. [Insert if applicable: New health information will also be added to your healthcare records from study-related tests, procedures, visits, and/or questionnaires.] This type of information is considered “Protected Health Information” that is protected by federal law.

**What type of health information will be used or shared with others during this research?**

[Double click on the boxes to insert a check mark. Or, you may delete the table and provide a list in paragraph form:]

The following types of information may be used for the conduct of this research:

|  |  |  |
| --- | --- | --- |
| [ ]  Complete health record | [ ]  Diagnosis & treatment codes | [ ]  Discharge summary |
| [ ]  History and physical exam | [ ]  Consultation reports | [ ]  Progress notes |
| [ ]  Laboratory test results | [ ]  Medical imaging reports | [ ]  Imaging films/scans/pictures |
| [ ]  Photographs, videotapes | [ ]  Complete billing record | [ ]  Itemized bill |
| [ ]  Information about drug or alcohol abuse | [ ]  Information about Hepatitis B or C tests |
| [ ]  Information about mental health  | [ ]  Information about sexually transmitted diseases |
| [ ]  Other physical or mental health information (specify):       |

**Who will use or share protected health information about me?**

VCU and [VCU Health / VCU Dental Care] are required by law to protect your identifiable health information. By consenting to this study, you authorize [inset either: VCU/VCU Health or VCU/VCU Dental Care] to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

|  |  |
| --- | --- |
| * Principal Investigator and Research Staff
 | * Study Sponsor [delete if none]
 |
| * Health Care Providers at VCU Health / VCU Dental Care
 | * Data Coordinators [delete if none]
 |
| * Institutional Review Boards
 | * Research Collaborators [delete if none]
 |
| * Government/Health Agencies
 | * Data Safety Monitoring Boards [delete if none]
 |
| * Others as Required by Law
 |  |

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

**When will this authorization (permission) to use my protected health information expire?**

[Insert ONE of the following options:]

[Option 1:] This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

[Option 2:] This research study involves a Data Registry or Sample Repository and the authorization will expired [specify other expiration time point].

[Option 3:] This authorization will expire when [specify other expiration time point].

**Statement of Privacy Rights**

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at [insert VCU PI’s full name and mailing address].

**Signature Block for Enrolling Adult Participants**

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Adult Participant Name (Printed)

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Adult Participant’s Signature Date

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

Name of Person Conducting Consent Discussion (Printed)

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

Signature of Person Conducting Consent Discussion Date

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

Principal Investigator Signature (if different from above) Date

**OPTIONAL STORAGE FOR FUTURE RESEARCH STUDIES**

INSTRUCTIONS: Include in this section a description of what data or samples will be stored for future unspecified research in a registry or repository, either at VCU or at another institution (e.g. sponsor’s registry or biobank, collaborator’s registry, etc.).

The following information is considered key information that participants should be told in this section so that they can make an informed decision about participating in the registry/repository:

* The purpose of creating or contributing to a registry/repository
* What data/samples will be stored, where, and by whom
* The potential secondary uses of the data/samples
* Risks of re-identification and potential loss of confidentiality
* Whether/how participants can withdraw their data/specimens from the registry.

Additional information about the registry/repository, such as benefits, ownership of the data, costs, etc. should also be added if/when it is relevant to the subject’s decision about participation.

**\*\*This is an optional section that applies only to studies that plan to create or contribute to a research registry or repository and may be modified as appropriate.**

**Data Submission to an NIH-Designated Controlled-Access Database or Repository**

For NIH-funded research, investigators are frequently expected to obtain unrestricted consent for future uses and sharing of data and/or samples, particularly genomic and phenotypic data. Template language may be available at the funding institute or center’s website.

Unrestricted consent:

Participants can be asked to agree to storage of their samples and/or data and to the use of their samples/data in any future unspecified research on any topic ("general research use"). Unrestricted consent maximizes the utility of collected samples and/or data.

Specific consent:

Sometimes, it may be appropriate to seek consent for more narrowly defined research uses of participant samples and data. This consent approach may increase participation of people who have concerns about privacy or do not want their samples and data used for research on certain topics.

To advance science, it is helpful for researchers to share information. They do this by putting data or samples into one or more scientific databases (called registries or repositories), where it is stored along with information from other studies. Researchers can then study the information in other ways and combine information from many studies to learn even more about health and disease.

[Example – general VCU registry/repository] As part of this study, we would like to keep the information and/or samples that you provide, along with your [describe the identifiers that will be part of the registry (name, phone, email, etc.)] in a registry/repository to be available for other research studies in the future. Your information and samples would be stored at [VCU] by [full name of investigator who will oversee the registry] and could be used for other research studies about any topic [If future research will be limited to specific types of studies/diseases, indicate here; otherwise leave open-ended]. Your data/samples will be protected, but there is always a possibility that information could be accessed by individuals without authorization. There is no limit on the length of time we will store your information/samples.

[Example - Unrestricted consent for sharing] Your samples, genomic data and/or health information will be stored indefinitely by \_\_\_\_ in one or more scientific databases at \_\_\_\_, and shared with other researchers. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from. This information will not be labeled with your name or other information that could be used to easily identify you. However, it is possible that the information, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen.

[Example – Contribution to a controlled access NIH genetic database:] Your individual genomic data and health information will be put in a controlled-access database at the National Institutes of Health. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. However, it is possible that the information from your genome, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen. Researchers approved to access information in the database will agree not to attempt to identify you.

[Insert for all studies with registries:] In the future, if you decide that you don’t want to be part of this registry, you can request that your information/samples be removed and destroyed by contacting [name of investigator who should be contacted (e.g. the PI at VCU)]. However, information that has already been shared with other researchers will continue to be used.

**Include the following paragraph if the registry involves children. It may be modified to reflect this study’s plan for re-consenting children in the registry who reach the age of majority.**

[Example:] When your child reaches age 18, we will try to contact them to ask whether they want to continue to participate in this research registry. If we cannot find your child, we will remove all identifying information, and continue to use their samples, genomic data and health information in research. [Or describe your plan for recontacting the child to obtain consent]

**Permission to Store Data and/or Samples for Future Research Studies**

*Please circle your answer:* I agree that my data and/or samples may be stored and used for future research as described above.

 YES NO